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Section 1: IEAV QUALITY PROGRAM DESCRIPTION AND QUALITY ASSURANCE RESPONSIBILITIES

Program Description

The Independent Environmental Assessment and Verification Program (IEAV) of Oak Ridge Associated Universities (ORAU) provides technical assistance and training through a contract with the U.S. Department of Energy (DOE), the U.S. Nuclear Regulatory Commission (NRC) and with other government agencies under interagency agreements. The IEAV staff is managed through the organization of 5 groups: Survey Projects, Professional Training Programs (PTP), Radiochemistry Laboratory, Atmospheric Turbulence and Diffusion Division (ATDD), and Administrative Support. The **Survey Projects** group conducts independent verification at sites 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 characterization surveys, environmental assessments, program appraisals and document reviews, and consulting on environment-related topics. The Survey Projects group also provides a full range of health physics support in decommissioning reviews, dose modeling, radiation protection program audits, instrument evaluations, dosimetry, and related technical evaluations. **Professional Training Programs** provides laboratory-based, hands-on radiological training courses in health physics, medical health physics, and environmental monitoring. The **Laboratory** performs radiochemical analysis of samples in support of the Survey Projects work and also serves as the primary Nuclear Regulatory Commission radiochemical laboratory. The **Administrative Support** group provides services such as coordinating travel arrangements, purchasing supplies, document processing, and serving as liaison to other ORAU support groups. IEAV provides support to the National Oceanic and Atmospheric Administration (NOAA) **Atmospheric Turbulence and Diffusion Division**. Specific quality requirements for work performed by ORAU ATDD staff are defined by NOAA project requirements and are not addressed in this document. Performance of activities is managed according to procedures designed to assure validity of developed data and technical information to provide quality training courses. IEAV operations are conducted within the ORAU Integrated Safety Management (ISM) Program. The ISM Program endorses the following guiding principles:

- ✓ Line management responsibility for safety
- ✓ Clear roles and responsibilities
- ✓ Competence commensurate with responsibilities
- ✓ Balanced priorities
- ✓ Identification of safety standards and requirements
- ✓ Hazard controls tailored to work being performed
- ✓ Operations authorization
- ✓ Worker involvement

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 IEAV. This manual describes administrative systems, as well as specific quality control procedures, which apply to all functional groups in IEAV.

The methodology for performance of work processes and the associated Integrated Safety Management requirements are presented in the Survey Procedures Manual, the Laboratory Procedures Manual, and other general work process guides. Section 1 of this manual outlines specific responsibilities for quality assurance and quality control duties.

Certifications and Qualification Audits

ORAU/ORISE holds the following certifications:

- Voluntary Protection Program (VPP) Star level certification of achievement
- ISO 14001 Environmental Management System Registration

The IEAV Laboratory participates in the following Performance Evaluation Programs and Annual Audits:

- DOE Mixed-Analyte Performance Evaluation Program
- DOE Radiological and Environmental Science Laboratory (RESL) Intercomparison Test Program (ITP)
- NRC annual audit of the radiochemistry laboratory
- DOE Consolidated Audit Program (DOECAP) audit of the radiochemistry laboratory

References

The quality control procedures in this manual are based on:

- DOE Order 414.1C, Quality Assurance
- 10 CFR 830 Subpart A, Quality Assurance Requirements
- ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities
- ORAU Quality Assurance, GP-810
- ORAU Quality Assurance Manual
- Integrated Management and Assurance Program, GP-801
- ORAU Integrated Safety Management, ESH-100

Responsibilities

The general organizational structure is shown in the figure at the end of this section. Management is responsible for leadership and commitment to quality achievement and improvement within the ISM framework. A log of names, initials, and signatures for all individuals responsible for signing or initialing records is maintained for South Campus staff. Responsibilities for specific positions in IEAV are listed below.

<u>Director/Associate Director</u>

- ✓ Ensure ISM responsibilities as defined in ORAU/ORISE policies and the IEAV Integrated Safety Management plan are met.
- ✓ Approve procedures.

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

Quality Manager

- ✓ Provide independent oversight for QA/QC pertaining to work performed by the Survey Projects, Health Physics, Professional Training Programs, and Laboratory groups.
- ✓ Review and provide concurrence for release of reports that must meet Survey and/or Laboratory Procedure Manual requirements.
- ✓ Ensure data verification is performed.
- ✓ Perform or oversee performance of project file reviews.
- ✓ Oversee archival of critical records.
- ✓ Oversee the Quality Program Manual.
- ✓ Ensure required data entry to the Audit and Nonconformance data tracking systems.
- ✓ Oversee maintenance of the IEAV training and certification records.
- ✓ Ensure complete documentation of performance evaluation activities.
- ✓ Coordinate vendor/provider assessments as deemed necessary by the Program Director/Associate Director.

Group Managers

- ✓ Ensure hazards are assessed prior to commencement of work.
- ✓ Ensure Job Hazard Analyses or safety plans covering all hazards are in place and are communicated to applicable staff members.
- ✓ Ensure and project specific legal responsibilities are understood and are communicated to staff members.
- ✓ Ensure adequate quality controls are in place for new projects/tasks.
- ✓ 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.
- ✓ Ensure quality assurance requirements are understood and implemented.
- ✓ Ensure contracted services meet IEAV quality requirements, at a minimum, and that additional project specific requirements are specified in the procurement process.
- ✓ Ensure that requirements for handling sensitive, confidential, or Official Use Only (OUO) records are identified and communicated to project staff prior to start of project activities.

Project Lead

- ✓ Accept responsibility for the technical aspects of a project/task as assigned by the manager.
- ✓ Ensure adherence to procedural requirements for assigned projects/tasks.
- ✓ Confirm training and certification requirements are met for each project/task.
- ✓ Perform pre-project hazard analysis and develop project specific health and safety plans, when applicable, in conjunction with ES&H office and the manager.
- ✓ Monitor work practices and follow-up on any identified safety concern.
- ✓ Ensure adherence to quality control requirements associated with assigned projects/tasks.
- ✓ Ensure complete documentation of project/task activities.
- ✓ Ensure accurate presentation of data and technical determinations in reports.
- ✓ Ensure changes to approved plans are technically defensible and are documented in the project/task file.

All employees

- ✓ Perform work safely and responsibly with emphasis on personal safety and the safety of coworkers, the public, and the environment.
- ✓ Perform work in an ethical manner and adhere to all legal responsibilities.
- ✓ Adhere to all quality control requirements.
- ✓ Protect client confidentiality, including national security concerns and proprietary rights.
- ✓ Attend required training.
- ✓ Be continually alert for potential hazards.
- ✓ Report all potential hazards.
- ✓ Provide input to manager regarding work process improvements.

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 reports generated by the Survey Projects group for technical and editorial adequacy 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.
- ✓ Oversee software validation, including associated record keeping.
- ✓ Provide technical direction to Site Coordinators working on field sites.

Site Coordinators

Note: This role can be performed by any member designated as ORAU/ORISE's representative and field site supervisor, as determined by the Director/Associate Director or a Group Manager.

- ✓ Oversee performance of field quality control procedures including calibration and daily instrument checks.
- ✓ Ensure adherence to procedural requirements while on the field site.
- ✓ Perform field record review.
- ✓ Oversee preparation of sample chain-of-custody documentation.
- ✓ Ensure documents and records generated on field sites are adequately controlled prior to archival.
- ✓ Ensure data are accurately documented.
- ✓ Monitor safety conditions on the work site and report any potential safety concern to the Survey Projects Manager and site contact.

Health Physics Project Leaders

- ✓ Ensure adherence to procedural requirements for assigned projects.
- ✓ Confirm training and certification requirements are met for each 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 clear communication takes place with laboratory staff for sample analytical requests and data management.
- ✓ Ensure complete documentation of project activities.
- ✓ Ensure documents and records are managed according to requirements.
- ✓ Ensure accurate presentation of data and technical determinations in reports.
- ✓ Ensure changes to approved plans are technically defensible and are documented in the project file.
- ✓ Provide technical direction to Site Coordinators working on field sites.
- ✓ Apply internal standards for peer review of deliverables including reports and training materials.
- ✓ Ensure that documentation is maintained for all projects to support technical conclusions offered as part of deliverables.

Assistant Health Physics Project Leaders

- ✓ Accept delegation of duties as assigned by Project Leaders or Group Managers.
- ✓ Ensure instrumentation calibrations and operational checkout requirements are met and accurately documented prior to beginning data collection.
- ✓ Perform field quality control procedures including calibration and daily instrument checks.
- ✓ Accurately document data and information collected.
- ✓ Protect the integrity of data in paper and electronic formats during data collection and processing.
- ✓ Prepare chain-of-custody documentation in the field.

Instrument Specialist

- ✓ Ensure survey instrumentation electronic calibrations are completed according to Survey Procedure manual requirements.
- ✓ Recommend updates to calibration and check-out procedures to the Survey Projects Manager.

Senior Health Physics Technicians

- ✓ Train technicians to perform field activities.
- ✓ Maintain instrument calibration sheets in central files.
- ✓ Perform field quality control procedures including calibration and daily instrument checks.
- ✓ Accurately document data and information collected.
- ✓ Protect the integrity of data in paper and electronic formats during data collection and processing.
- ✓ Prepare chain-of-custody documentation in the field.
- ✓ Accept delegation of duties as assigned by the Survey Projects Manager or Health Physics Project Leader.

Health Physics Technicians

- ✓ Complete all required site-specific training.
- ✓ Adhere to all procedural and specific quality control requirements.
- ✓ Perform field quality control procedures including calibration and daily instrument checks.
- ✓ Prepare chain-of-custody documentation in the field.
- ✓ Accurately document data and information collected.
- ✓ Protect the integrity of data in paper and electronic formats during data collection and processing.
- ✓ Provide input to Survey Projects Manager regarding work process improvements, become generally familiar with Site Coordinator QA duties, and assist as assigned.

Project Manager

- ✓ Work with Group Managers and Project Leaders to ensure statements of work and other proposals include specifications necessary to meet all compliance, cost, delivery, and quality requirements and that required approvals are in place before transfer to customers.
- ✓ Ensure Business Support Analyst confirmation of cost estimates is received and documented prior to provision of estimates to customers.
- ✓ Ensure accurate and timely entry of resource loading, schedule, deliverables, and other project management data and information into monitoring systems.
- ✓ Ensure accessibility and timely reporting of project management data and information to requestors.
- ✓ Work with Group Managers to ensure adequate controls are in place for project management tracking systems.

Health Physics Group

Health Physics Manager

- ✓ Monitor quality control of technical information and data to ensure compliance and sound practice.
- ✓ Review and approve reports generated by the Health Physics group for technical and editorial adequacy prior to release.

- ✓ Provide (where applicable) the Purchasing Department with specifications for purchased equipment, and services.
- ✓ Establish training and certification content specific to health physics activities.
- ✓ Oversee software validation, including associated record keeping.
- ✓ Provide technical direction to Health Physicists working on technical projects.

Health Physicists

- ✓ Ensure adherence to procedural requirements for assigned projects.
- ✓ Confirm training and certification requirements are met for each project.
- ✓ Perform pre-project hazard analysis and develop project specific health and safety plans, when applicable, in conjunction with ES&H office and the Health Physics Manager.
- ✓ Monitor work practices follow-up on any identified safety concern.
- ✓ Ensure adherence to quality control requirements associated with assigned projects.
- ✓ Ensure clear communication takes place with laboratory staff for sample analytical requests and data management.
- ✓ Ensure complete documentation of project activities.
- ✓ Ensure documents and records are managed according to requirements.
- ✓ Ensure accurate presentation of data and technical determinations in reports.
- ✓ Ensure changes to approved plans are technically defensible and are documented in the project file.
- ✓ Apply internal standards for peer review of deliverables including reports and training materials.
- ✓ Ensure that documentation is maintained for all projects to support technical conclusions offered as part of deliverables.

Laboratory Group

Laboratory Manager

- ✓ Oversee the Laboratory Procedures Manual.
- ✓ Oversee modifications and maintenance of the IEAV 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.
- ✓ Review and approve reports generated by the Laboratory for technical and editorial adequacy prior to release.
- ✓ 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.
- ✓ 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.
- ✓ Perform and/or oversee inspections/tests of newly purchased items to ensure that established requirements are met.

All Laboratory Staff

- ✓ Accurately document data and information generated during work processes.
- ✓ Protect the integrity of data in paper and electronic formats during data generation and processing.

Senior Chemist

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

Programmer/Analyst

- ✓ Document IEAV Database modifications

Professional Training Programs Group

Professional Training Programs Manager

- ✓ Monitor quality control of technical information and data to ensure compliance and sound practice.

- ✓ Ensure reports and training materials are reviewed for technical and editorial adequacy and are standardized with accepted industry practice, as applicable, 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.
- ✓ Oversee software validation, including associated record keeping.
- ✓ Ensure training material format and content meet ORAU internal standards.

Health Physics Instructors

- ✓ Apply internal standards for peer review of deliverables including reports and training materials.
- ✓ Ensure that documentation is maintained for all projects to support technical conclusions offered as part of deliverables.
- ✓ Develop training materials according to internal standards.
- ✓ Perform pre-course hazard analyses and develop project specific health and safety plans, when applicable, in conjunction with ES&H office and the Professional Training Programs Manager.
- ✓ Monitor work practices during courses and follow up on any identified safety concern.

Instrument Specialist, Senior Health Physics Technician, Registrar

- ✓ Adhere to all quality control requirements.
- ✓ Provide input to the Professional Training Programs Manager regarding work process improvements.

Atmospheric Turbulence and Diffusion Division (ATDD)

ATDD Manager

- ✓ Ensure that work generated by ORISE staff members meets NOAA quality standards.

Administrative Group

Administrative Support Manager

- ✓ Oversee the training for administrative personnel.
- ✓ Monitor administrative quality control activities to ensure compliance and sound practice.

Information Management Coordinator

- ✓ Develop processes to streamline information management systems.
- ✓ Ensure accessibility of historical information and meet ORAU/ORISE/DOE requirements for records management.
- ✓ Serve as backup for data verification.
- ✓ Document distribution of controlled documents.

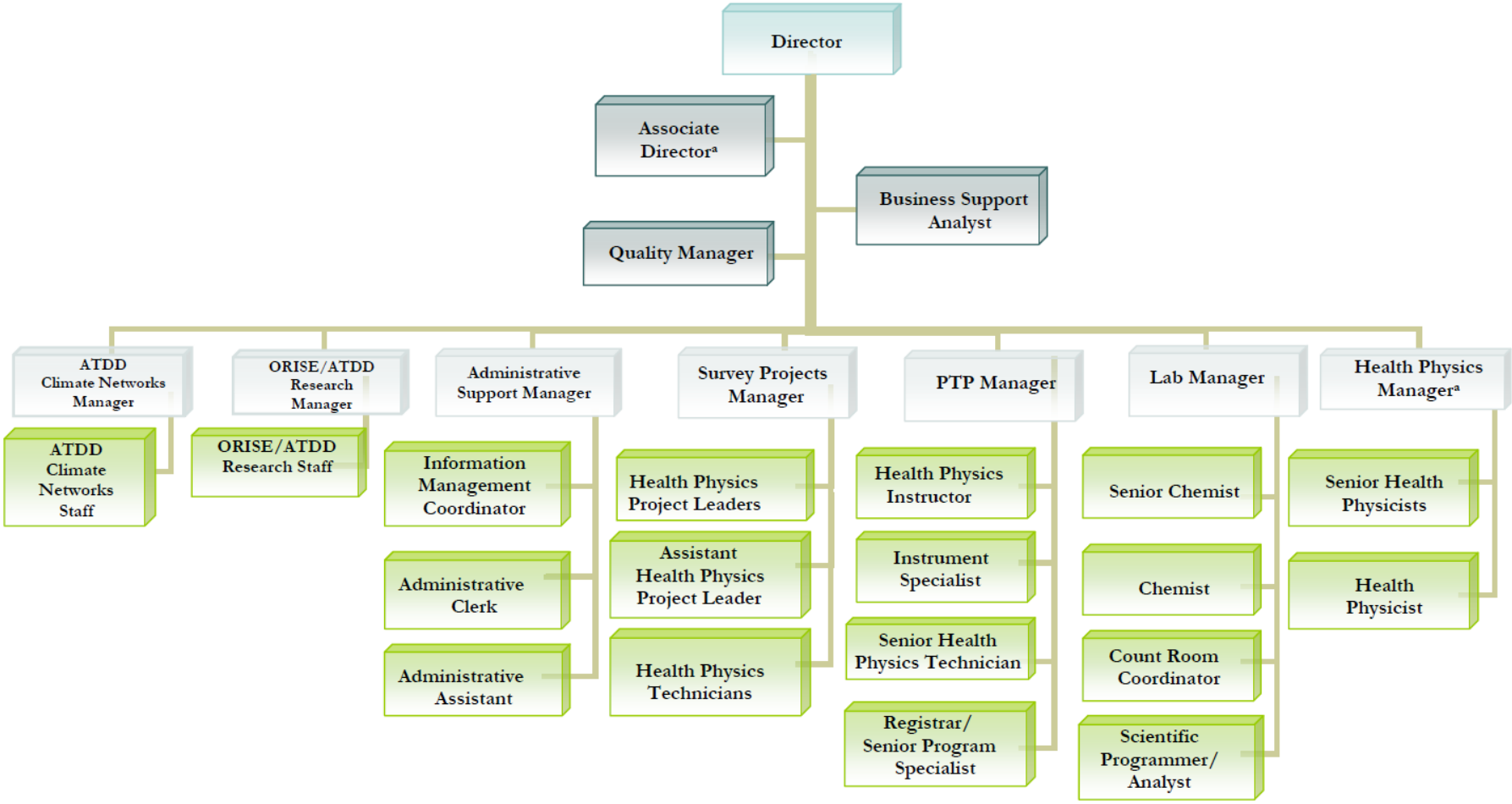
Administrative Support Staff

- ✓ Perform peer reviews of other clerical staff work.

- ✓ Perform archival of critical program records.
- ✓ Perform distribution of controlled documents.
- ✓ Maintain worker qualification training and certification records.
- ✓ Provide input regarding work process improvements.

Support Services

Business Operations support groups within ORAU/ORISE are responsible for certain quality assurance functions for IEAV as outlined in Section 10 of this document.



[a]Dual role: Associate Director/Health Physics Manager

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 include qualitative and/or quantitative acceptance criteria. Procedures 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 or non-routine procedure may also 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/Associate Director

- ✓ Review and approve procedures for implementation.

Group Managers

- ✓ Identify the need for a new or revised procedure.
- ✓ Serve as author or assign a staff member to serve as author for a new or revised procedure and the associated Job Hazard Analysis.
- ✓ 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.
- ✓ Approve implementation of procedures applicable to their group.
- ✓ Approve Quality Program Manual 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.
- ✓ Assign responsibility for adherence to controlled procedures to staff members
- ✓ Ensures that controlled versions – either paper copy or internet access - of applicable procedure manuals are available in proximity to the work area.

Quality Manager

- ✓ Review all procedures to ensure cross references between manuals are maintained and QA requirements have been met.
- ✓ Review the Quality Program Manual at least annually and update it as necessary.
- ✓ Approve Quality Assurance procedures for implementation.
- ✓ Review and provide concurrence of Survey Projects and Laboratory controlled procedures.
- ✓ Maintain tracking information for manual revisions, files of original procedure versions, and procedure approval documentation.
- ✓ Verify timely and accurate distribution of controlled procedures.

Administrative Support Staff

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

All staff members

- ✓ Complete required actions as defined on procedure distribution communications.
- ✓ Adhere to all controlled procedure requirements or obtain approval from the manager or Project Leader, or other individual assigned responsibility for the project/task, for necessary deviations.
- ✓ Communicate procedure inadequacies and suggestions for improvement to the cognizant manager.

3.0 Definitions

Nonroutine procedures: Procedures that are expected to be used infrequently.

Operator aid: Technical posting that assists workers in accomplishing specific tasks.

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 Program Manual

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

4.1.2 The current versions of all procedure manuals are maintained on the IEAV website: http://orise.orau.gov/ieav/survey-projects/index.htm

4.1.3 Group managers assign responsibility for adherence to controlled procedures to staff members based on position responsibilities

4.1.4 Paper copies of controlled procedure manuals are issued to IEAV staff members on request. Staff members who must plan, perform, or evaluate work procedures where web access is not available are required to have access to a controlled paper copy of the manual in the work area. Non-staff members will be referred to the manuals on the website.

4.1.5 Access to applicable controlled procedures must be available at all times during the performance of work.

4.1.6 A unique number is assigned to each paper copy manual to ensure updates are made to each assigned manual.

4.1.7 Staff members issued a controlled paper copy of a manual are responsible for completing updates as soon as they are received.

4.1.8 Procedure manuals are reviewed at a minimum once in each calendar year by the cognizant manager and revised as necessary.

4.1.9 The Quality Manager maintains documentation of annual reviews and revisions

4.2 Procedure Development

4.2.1 A Group 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 the 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
- ✓ 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.
- ✓ JHA has been approved by the ES&H office.
- ✓ Critical procedure steps and/or essential specifications for materials are identified and inspection requirements are stated.
- ✓ Qualitative or quantitative acceptance criteria are included.
- ✓ The level of detail is commensurate with the complexity of the activity.

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 responsible manager, Quality Manager, and Director/Associate Director. Reviews will include evaluation of editorial and technical accuracy and technical sufficiency. Reviewers will provide comments to the author. The author will work with reviewers to resolve all issues. The responsible manager will determine when the background for a technical issue should be captured in a separate document and shared with other staff members.

4.2.9 The responsible manager and the Director/Associate 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 Quality Manager for controlled distribution (see Subsection 4.4). The Quality Manager 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 responsible manager immediately.

4.2.12 The Director/Associate Director, Group 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 Subsection 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.
- ✓ Reading the procedure and JHA and attendance in a training session.
- ✓ Reading the procedure and JHA, attendance in a training session, and certification by proficiency testing.

Completion of all types of training 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 Program Manual Section 3.

4.4 Controlled Distribution and Implementation of Procedures

4.4.1 Procedures are considered to be implemented as of the approval signature date on the manual Table of Contents.

4.4.2 Procedure distribution is performed by the Quality Manager.

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 procedure revision dates. Historical copies of controlled procedures are maintained in either paper or electronic files.

4.4.5 The Administrative support staff members maintain a list of controlled manuals, the date assigned, and for paper versions of manuals, the manual number.

4.4.6 New procedures and procedure revisions will be announced using an email or paper memo including the following requirements as applicable:

- ✓ Read the procedure and JHA.
- ✓ Perform training as specified.
- ✓ Document completion of procedure review training and/or proficiency testing by completing requirements as indicated in the communication.

4.4.7 Documentation for training will be maintained when attendance in a training session is required or when proficiency testing is required.

4.4.8 The most current Table of Contents revision date is used to reference controlled manuals in documents.

4.5 Deviations from Procedures

4.5.1 The Director/Associate Director, managers, or Site Coordinator 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.

Documentation may be recorded in project logbooks.

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.

4.6 Operator Aids

4.6.1 An Operator Aid is defined as a technical posting that assists workers in accomplishing specific tasks. The content of Operator Aids will be controlled to ensure the information is up to date.

1.0 Purpose

Training is provided to ensure that employees develop and maintain the skills needed to perform their duties and to ensure that all ethical and legal responsibilities are communicated and accepted.

2.0 Responsibilities

Group Managers

- ✓ 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.
- ✓ 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.
- ✓ Document that training and/or proficiency testing was provided.

Administrative Staff

- ✓ Maintain training and certification records.
- ✓ Assist with training documentation.

All staff

- ✓ Complete training and proficiency testing as directed.

3.0 Definitions

Procedure Certification Training: Training related to IEAV controlled procedures, that is provided by the procedure author or another individual who has demonstrated proficiency.

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

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.

4.0 Procedure

4.1 Qualifications for each position are defined in approved job descriptions, including specific education and experience requirements. Position requirements and working conditions and required training are also defined.

4.2 ORAU/ORISE Required Training

ORAU/ORISE required training is defined, scheduled and tracked by the Office of Human Resources.

"Code of Ethics" training is required for all employees as part of initial orientation and includes requirement for client confidentiality.

4.3 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

The Office of Human Resources maintains "Required Training Checklists" for all employees and tracks compliance training. IEAV maintains a listing of completion dates for convenience.

4.4 IEAV Procedure Certification Training

4.4.1 Training requirements are determined by the cognizant manager for the procedure.

4.4.2 Training must be completed before a procedure is performed for direct project work activities.

4.4.3 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 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.
- ✓ Training will include discussion of associated hazards.
- ✓ 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 and certification

- ✓ 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.
- ✓ Initial certification is documented.
  Recertification of proficiency testing must be updated annually for all staff responsible for performing the procedure.
- ✓ Documentation of proficiency testing is maintained in employee training files.

4.4.4 Training effectiveness is monitored through reviews of generated data, supervisor observation of procedure use, and Individual Performance Plan reviews twice each year.

4.5 Developmental Training

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

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 IEAV 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.
- ✓ Ensure items not suitable for use are clearly identified.

Professional Training Programs Instrument Specialist

- ✓ Maintain nuclear counting equipment in working condition.
- ✓ Check out and repair instrumentation.
- ✓ Set up instrumentation for training laboratories.
- ✓ Fabricate instrumentation for special projects.

Survey Projects Instrument Specialist

- ✓ Ensure survey instrumentation is maintained in working condition.
- ✓ Ensure survey instrumentation electronic calibrations are completed in accordance with Survey Procedure Manual requirements.

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 using ORAU property identification labels to allow for independent traceability.

4.0 Calibration and Operational Checkout 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, determines appropriate methods and frequencies for monitoring, and includes specific requirements in the Survey Procedures Manual.

5.1.2 Calibration procedures are performed according to the methods defined in the IEAV 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 Instrument voltage plateau curves and gain determinations are reevaluated annually, at a minimum, and any time instrument operation is in question. Voltage and gain determinations are approved by the Survey Projects Manager prior to use.

5.1.5 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.

5.1.6 When operational check-out conditions are not met, survey instrument/detector combinations are removed from service until the discrepancy can be resolved. Instruments or detectors that do not meet acceptance criteria are clearly segregated from operating instruments/detectors or marked as out of service to prevent inadvertent use.

5.1.7 Data collected between the time valid QC measurements are obtained and when unacceptable results are obtained are designated as invalid unless technical basis for validity of measurements is documented in the project file and approved by the Survey Projects Manager.

5.1.8 Calibration documentation is reviewed and approved by the Survey Projects Manager or Project Leader prior to use of instruments for data collection on each survey site. For on-going projects calibration documentation is

reapproved by the Survey Project Manager or Project Leader any time recalibration is performed.

5.1.9 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, when feasible.
- ✓ After completion of measurements and/or scanning for the day.
- ✓ Any time detector contamination is suspected.
- ✓ Any time instrument operation is in question.

5.1.10 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 IEAV 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 or industry accepted standards.
- ✓ 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 at least 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.

1.0 Purpose

The chain of custody procedure provides the mechanism for documentation of sample accountability and integrity. Sample custody documentation is initiated upon collection or receipt of samples by IEAV 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 by an IEAV staff member, sealed in a tamper-resistant container, or is held within an IEAV controlled access facility, and the custody is documented.

2.0 Responsibilities

Managers

- ✓ Ensure that this procedure is followed for all projects where samples are handled.

Samplers

- ✓ Initiate sample chain of custody the same day samples are collected.
- ✓ Maintain accountability and integrity of samples until custody is transferred.

Survey Project and Laboratory Staff

- ✓ Initiate a chain of custody form for samples shipped from other organizations as soon as the shipping container is opened.
- ✓ Initiate a chain of custody form at the time of receipt when individual samples are received from another organization in person.

3.0 Chain of Custody Form

The chain of custody form included at the end of this procedure will be used for all sample custody documentation. A two-part carbonless version of the form is used whenever samples must be shipped or any other time for convenience. A single page version of the form can be used if samples will be transported by the sample custodian or if samples are received directly in the laboratory from another organization. When the single page version is used, a copy of the form will be placed in the project/task file after a staff member signs the form indicating receipt of sample custody. The form may be completed electronically allowing lines for additional samples to be added, however signatures indicating that samples have been relinquished/received must be handwritten on a printed version.

4.0 Initiation of Sample Custody

4.1 For samples collected by another organization and provided to IEAV, chain of custody forms are prepared at the time of sample receipt. If a chain of custody form has been initiated by the organization providing the samples, the form may be attached to the IEAV form, however sample identification cross reference information, at a minimum, must be entered on the IEAV form.

4.2 For samples collected by IEAV staff, chain of custody forms are prepared daily prior to securing the samples at the end of the work day.

4.3 The sample collector assumes initial responsibility as custodian and initiates a chain of custody form.

4.4 Samples may be listed on the form separately, or a group of samples of the same matrix may be recorded as a single entry using a sample identification number range.

4.5 Samples of more than one matrix type may be listed on the same form if the samples can be packed and transported in the same container without risk to sample integrity.

5.0 Sample Security and Integrity

5.1 Sample integrity must be protected at all times. Sample integrity includes:

- ✓ Packaging to maintain critical sample characteristics as required for successful laboratory analysis, such as moisture content.
- ✓ Packaging to minimize opportunities for cross contamination.
- ✓ Secure labeling to ensure labels are not compromised during shipment.

5.2 Samples must be in one of the following conditions at all times:

- ✓ In the possession of the sample custodian.
- ✓ Under direct surveillance of the sample custodian.
- ✓ Secured in a locked vehicle or building.
- ✓ Maintained in a tamper-resistant container.

5.3 If samples must be out of the line of sight of the sample custodian, or access to the sample container cannot be controlled for any reason, the sample container must be secured in a manner that will make any tampering evident to the sample custodian.

5.4 Sample containers affixed with security seals do not have to remain in a secured area, however precautions should be taken to restrict sample access to authorized individuals.

6.0 Sample Transport

6.1 When the sample container will be shipped, the shipping container must be secured in such a way as to make any tampering evident when the shipping container is received in the IEAV laboratory.

6.2 If the samples are shipped, or the sample container must be out of the possession of the sample custodian, the original version of the form is retained in the possession of the sample custodian. A copy of the form is sealed in the container with the samples.

6.3 As long as samples remain in the possession of the sample custodian, the original and the copy of the form are to be kept with the sample custodian.

6.4 When shipping samples, the copy of the form is sealed in the container with the samples and the original is maintained by the custodian. In cases where the custodian will not return to the laboratory prior to deadlines for sample analysis, the original must be signed in the "Relinquished By" block and mailed to the IEAV Laboratory Supervisor.

7.0 Transfer of Sample Custody

7.1 Transfer of sample custody is documented by the custodian signing the "Relinquished By" block and the receiver signing the "Received By" block, filling in the date and time of the transfer, and checking "Yes" or "No" as applicable in the "Received in Good Condition?" box. If sample integrity is in question, a note is made in the "Remarks" column and any further description of the sample condition is added to the "Comments" block. Examples of samples not received in good condition are:

- ✓ Sample received in containers with broken security seals
- ✓ Samples received in shipping containers that are not intact
- ✓ Samples that have spilled or leaked from their containers
- ✓ Shipping containers that have been damaged causing the container to open
- ✓ Labels that are not legible

7.2 Samples are inspected prior to transfer of custody to determine any evidence of tampering or other evidence of integrity breech. Evidence of tampering and/or any evidence that sample integrity may have been compromised must be explained in the "Comments" section of the form. If sample integrity is questionable for any reason, laboratory staff will contact the sample custodian responsible for shipping or otherwise transporting the samples to determine appropriate follow-up actions.

8.0 Laboratory Sample Custody

8.1 For samples shipped by IEAV staff to the ORISE facility, the custodian will:

- ✓ Open the shipping container

- ✓ Inspect the samples
- ✓ Compare contents to the chain of custody form
- ✓ Note any deficiencies in the remarks column
- ✓ Transfer custody to a laboratory staff member

8.2 For samples shipped to the ORISE facility by another organization, a laboratory staff member will:

- ✓ Open the shipping container and inspect the sample containers and contents for tampering.
- ✓ Screen the samples according to the requirements of Laboratory Procedure SP1
- ✓ Note any deficiencies in the "Comments" block.
- ✓ Initiate a chain of custody form showing the origin of the samples and the date, and time if applicable, when they were received.
- ✓ If the organization provides a chain of custody form it is maintained in the project file until the sample receives final disposition. If the samples are returned to the organization the chain of custody form that was provided is returned with the samples, including any pertinent information.
- ✓ The sample information is entered into the IEAV Database.

8.3 When the two-part chain of custody form is used, the original version of the form is kept by the Laboratory Manager. The copy is filed in the project/task file. For the single page form, a copy is made and placed in the project/task file.

8.4 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.

9.0 Sample Disposition

9.1 Samples are considered to be in an "Active" status until returned to the customer, disposed of, or consumed in analysis.

9.2 When samples are no longer in "Active" status, the disposition is noted on the chain of custody form, the copy is retained in the project/task file and the original is filed in a notebook according to the year in which the samples were finally returned to the customer, disposed of, or consumed in analysis.

9.3 Archived samples are stored in a locked, limited access building.

9.4 Sample disposal may not be performed unless approval has been received from the customer.

ORISE
P.O. BOX 117
OAK RIDGE, TN 37830

CHAIN OF CUSTODY RECORD

EMERGENCY CONTACTS
Survey Projects Manager (865) 576-5073
Laboratory Manager (865) 241-3242
FTD (865) 241-5947

Sampler (s) _____

Project/TaskName_____

SAMPLE NUMBER	SAMPLE MATRIX	SAMPLE INFORMATION	COLLECTED		REMARKS
			DATE	TIME	

Relinquished By	Received By	Date	Time	Received in Good Condition?
1. Sampler:				Yes □ No □
2.				Yes □ No □
3.				Yes □ No □
4.				Yes □ No □

Shipping Instructions: Include a copy of form clearly marked "Copy" in shipping container.
If shipping samples, enter carrier name in "Received By" space.

Receiving Instructions: If receiving samples from a carrier, enter the carrier name in "Relinquished By" space.
If integrity of samples and/or sample packaging is in question, note the concern in "Remarks" and enter any further description of the condition below.

Comments:

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 analytical results from laboratories other than DOE Sample Management Office approved laboratories.

Quality Manager

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

Laboratory staff members

- ✓ Record quality control performance data and compare to established criteria.
- ✓ 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.
- ✓ If NIST traceable material is not available, another type of material will be standardized according to the requirements of Laboratory Manual procedure QCP3.

- ✓ Standard solutions will be verified according to Section QCP3 of the Laboratory Procedures Manual.
- ✓ Uncertainties for primary standards will be established based on data results from an experimental data set including at least six analyses for which the chi-squared test indicates that the results are within the 95% confidence interval around the calculated known. The calculated known values will be determined based on the relative volume of standard material recovered, as demonstrated by weight. The relative uncertainty of the sample set will be incorporated into the total propagated uncertainty (TPU) calculation for the individual sample results.
- ✓ Standard deviation values for standard solutions will be noted at the 2 sigma level.
- ✓ Standard solution values will not be recertified.
- ✓ Standard solutions with questionable reference values will be replaced.
- ✓ Standard solutions for which trend evaluations of quality control data indicate adverse effects over time, or that become questionable for any reason, will be replaced.
- ✓ The Laboratory Manager will review the standard log information prior to use of the standard material.
- ✓ Standards and tracers will be verified annually.

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:

- ✓ Batches consist of samples to be analyzed by the same procedure for a common set of parameters.
- ✓ 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.
- ✓ 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 IEAV Database.
- ✓ Batches are analyzed in a continuous, sequential manner; processing of samples is not interrupted by processing of samples from other batches.
- ✓ Samples in the same batch are analyzed in the same area of the laboratory or facility.
- ✓ 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.

- ✓ One method blank is run per batch.
- ✓ 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).

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

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

Matrix spike, matrix spike duplicate, and/or duplicate samples

Matrix spike, matrix spike duplicate, and/or duplicate samples may be analyzed to demonstrate sample characteristics or to meet DOECAP quality control requirements. The equations used to evaluate the validity of the analyses are defined in the Laboratory Procedures Manual.

- ✓ Matrix spikes are considered acceptable if the result of the calculation is +/- 25 percent of the known concentration.
- ✓ Matrix spike duplicates are considered acceptable if the result of the calculation is +/-25 % of the known concentration.
- ✓ Radiochemical duplicate determinations are considered to agree when the 95percent confidence level uncertainties are considered. That is, the RER must be less than or equal to one. This control criterion is not applied, and reanalysis

or data qualification are not required, when both of the measured values are less than their associated MDCs.

The review of the analytical data will include persistent negative data for a batch and negative data for a single sample that is outside the negative 3 sigma limit. The review of negative data will determine if the cause of the negative data is related to a systematic error or a random error. If the cause is systematic, it will be corrected before submitting data. If the cause is random it will be documented in the Case Narrative for data submitted under a DOE Sample Management Office statement of work.

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/Associate 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.

- ✓ Method Blanks are charted as the gross counts per minute of total activity.
- ✓ Laboratory Control Standards are charted as a ratio of the measured value to the known value.
- ✓ Chemical Recovery/Yields are charted as the percentage recovery.

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:

- ✓ Initial evaluation of process stability
- ✓ Ongoing evaluation of process variation

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

Upper Control Limit (UCL_x) = $\overline{X} + 3\left(\frac{\overline{R}}{d_2}\right)$

Central Line (CL_x) = $\overline{X}$

Lower Control Limit (LCL_x) = $\overline{X} - 3\left(\frac{\overline{R}}{d_2}\right)$

$\frac{\overline{R}}{d_2}$ = estimate of sigma

$\overline{X}$ = Average of individual points

$\overline{R}$ = 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.

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

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. The following conditions require investigation by the Laboratory Manager:

- ✓ Occurrence of a point outside the three standard deviation control limit.

- ✓ Eight successive values falling on the same side of the central line.
- ✓ Persistent negative results.
- ✓ Any time a recurring pattern is observed.

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

Follow-up actions are completed by the Laboratory Manager or Quality Manager and are documented using the tracking system.

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

DOE Sample Management Office (SMO) approved analytical laboratories are utilized for outside analytical services whenever possible. Analytical services are procured directly through the SMO to ensure data quality reviews and data validation are performed by technically qualified individuals.

When unapproved 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. The Laboratory Manager or other technically qualified individual performs the data quality reviews. Documentation of the quality review is maintained in the project file.

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/Associate Director

- ✓ Approve standardized IEAV data calculation and presentation approaches.

Group Managers

- ✓ Approve technical approach to project specific data determinations.
- ✓ Perform data validation to ensure data meet project requirements.
- ✓ Approve release of final data.
- ✓ Approve development and implementation of new software applications.
- ✓ Ensure software purchase and software development are coordinated through the ORAU Information Systems Department to meet all requirements.

Laboratory Manager

- ✓ Ensure that Analyst Review, QC Review, and Managers Review are completed and documented for all analytical results.
- ✓ Approve release of final data.

All Staff

- ✓ Record data accurately and in a legible manner.
- ✓ Perform data transcription and calculation reviews as assigned.

Project Lead

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

Laboratory Staff

- ✓ Perform "Analyst Review" of analytical results.
- ✓ Perform Quality Control review.

Quality Manager

- ✓ Confirm completion of data reviews.
- ✓ Verify that reported data were generated according to approved procedures and were accurately reported as documented in the project file.
- ✓ Evaluate software development documentation, software controls, and on-going documentation of software change management to ensure software integrity is maintained and adequate administrative or programmed controls are in place and sufficient to protect content and prevent inadvertent system changes.

3.0 Definitions

Critical records: See Section 11 for definition.

Data review: The act of confirming that data have been recorded, transcribed, and/or calculated accurately.

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.

Electronic data acceptance: Documentation in an electronic system that a review of input data has been completed.

External data: Data obtained from a referenced source or provided by a non-IEAV group.

Calculated data: Data obtained from calculations performed either by hand or by using computer programs.

Raw data: Measured values recorded from instrumentation or equipment by IEAV staff.

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 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 QP Manual Section 11 requirements.
- ✓ Computer programs used to process data must be verified before initial use and after modification to the programming to ensure accuracy.
- ✓ 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.

- ✓ 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 analytical data, the analyst reviews the data sheets to confirm accurate entry of initial parameters. The Laboratory Manager evaluates the Quality Control sample results and approves the data for release. 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
    - Problems identified in the review process will be resolved prior to release of data for further use.

5.0 Data review

The following specifications constitute minimum review requirements. Additional review will be performed in cases where concerns are identified during the data review process or any time additional review is deemed to be warranted.

Raw Data

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. Raw data review includes evaluation of:

- ✓ Legibility
- ✓ Completeness
- ✓ Technical appropriateness
- ✓ Procedural compliance

Reviews are documented by placing initials or signature and review date on the printed data sheet or final report, or by entry in an electronic or hard copy project log specifying the review outcome.

Raw data measured in the field, except GPS scan data, are reviewed prior to leaving the field site by the Site Coordinator. Acceptability of GPS scan data is evaluated in the field by the operator based on operational parameters monitored during data collection. GPS scan data are reviewed by the Site Coordinator or Project Leader after they have been downloaded into an accessible format on the network system.

Analytical raw data are reviewed by the analyst to ensure all input parameters have been entered correctly.

Raw data obtained for non-survey related projects are reviewed by the project lead.

Data reviews for verification or validation are documented by placing initials, or signature, and the review date on the printed data sheet or final report, or by entry in an electronic or hard copy project log specifying review outcome.

External Data

External data included in IEAV reports will be reviewed for accurate transcription.

Hand Processed Data

- ✓ Hand processed data are reviewed by a technically qualified person not involved with the initial processing or collection of the raw data.
- ✓ At least two hand calculations are replicated for each equation used.
- ✓ Reviews are documented by placing initial, or signature, and the date on the paper record.

Computer Processed Data

- ✓ Software used for capture, evaluation, calculation, reporting and maintenance of data and information critical to technical determinations or reporting must be documented, verified, and validated to perform as expected before initial use and after each modification to the software, or software system.
- ✓ Equations included 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.
- ✓ 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. Use of a blank spreadsheet is encouraged to ensure that data was not inadvertently carried over from a previous use.
- ✓ Documentation will consist of computer printouts, hand calculation sheets, or electronic files showing input parameters and results. Equations not identified in approved procedures must be included in the documentation for the project.
- ✓ Reviews of printed data are documented by placing initials, or signature, and the date on the record.
- ✓ Reviews of electronic data files are documented by adding the reviewer name and the date of review to the electronic file and converting the file to Portable Document Format (PDF).

Transcribed Data

- ✓ Transcribed data will be reviewed for accuracy by a technically qualified person not involved with the initial processing.
- ✓ A minimum of ten percent of transcribed items will be checked for accuracy.
- ✓ Reviews of paper data files are documented by placing initials, or signature, and the date on the paper record.
- ✓ Reviews of electronic data files are documented by adding reviewer name and date of review to the electronic file and converting the file to PDF.

6.0 Data Corrections

- ✓ Data may not be obliterated from critical paper records using an eraser or white-out.
- ✓ 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.
- ✓ Data may not be deleted from electronic files serving as critical records after the electronic data has been marked as accepted by the operator.
- ✓ Corrections to electronic data must be either documented in an electronic change log linked to the electronic data file in a traceable manner, or documented in the project or task paper file.

7.0 Data Verification

The Project Lead is responsible for confirming that reported data conform to the requirements of the procedure manuals and to any additional uniquely established project requirements. Documentation of this review is performed by one of the following methods:

- Sign the cover letter for the final report
- Sign the signature page of a report

The Quality Manager is responsible for confirming that generated data have been reviewed, and reported data values match raw or processed data as documented in the project file. Documentation of this review is performed by initialing the concurrence block on a report cover letter or by signing the signature page.

8.0 Data Validation and Approval

The cognizant manager is responsible for confirming that data meet the project requirements, and for approving data to be released outside of the IEAV Program. The Laboratory Manager is responsible for approving release of laboratory data for further internal processing. Documentation of this review is performed by one of the following methods:

- Sign the cover letter for the final report
- Sign the signature page of a report
- Initial the concurrence block of a letter report.

9.0 Measurement Uncertainty

Single Analytical Values

Total Propagated Uncertainties (TPU) will be reported at the 95% confidence interval 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 σ relative uncertainty of the efficiency

RQ = 1 σ relative uncertainty of the quantity

RY = 1 σ relative uncertainty of the yield

Repeated Analytical Measurements

Uncertainties for the average of repeated analytical measurements will be calculated at the 95% confidence interval according to the following equation:

$$2\sigma\, TPU = \frac{\sqrt{RC_1{}^2 + RC_2{}^2 ... + RC_n{}^2}}{n} = pCi/unit$$

Where: n = Total number of repeated measurements

RC = 1 σ relative uncertainty of the concentration

Field Measurement Values

Uncertainties will not be reported for field survey instrument measurements.

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

Total Uranium

Uncertainties for total uranium data will be calculated according to the following equations:

For gamma spectroscopy

Natural uranium

$$\sigma TPU = \sqrt{4RE_{U238}{}^2 + RE_{U235}{}^2} = pCi/unit$$

Depleted and enriched uranium

$$\sigma TPU = \sqrt{RE_{U238}{}^2 + (21.7^2 * RE_{U235}{}^2)} = pCi/unit$$

Note: the 21.7 value can vary based on the level of uranium depletion or enrichment.

For alpha spectroscopy

$$\sigma TPU = \sqrt{RE_{U238}{}^2 + RE_{U235}{}^2 + RE_{U234}{}^2} = pCi/unit$$

Where: RE = Relative error

TPU = Total propagated uncertainty

10.0 Reporting Data

Minimum Detectable Concentrations (MDC)

- ✓ Minimum detectable concentrations for each laboratory radiological measurement and matrix are determined prior to using a new procedure or instrument type for sample analysis.
- ✓ MDCs are reevaluated when a significant change in test method or instrument type occurs.
- ✓ When MDCs are included in reports, sample specific values will be reported. MDC will be calculated according to the following equations.

Laboratory analysis MDC:

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

Where: B = Detector background counts

E = Counting efficiency

Q = Sample quantity

T = Count time in minutes

Y = Tracer or carrier yield

Survey instrument measurement MDC:

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

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

ε_{tot} = total efficiency = $\frac{\text{counts}}{\text{disintegration}} = \varepsilon_i * \varepsilon_s$

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

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

Significant Figures

- ✓ Direct measurement data from field survey instruments will be reported using whole numbers with no more than two significant figures. Uncertainties will not be reported.
- ✓ Scan data will be reported using whole numbers with no more than two significant figures. Uncertainties will not be reported.
- ✓ The number of significant figures used for values included in reports will be representative of procedural limitations.
- ✓ Calculated values will be reported to a level of precision matching the input value having the lowest number of significant figures.
- ✓ Significant figures for the uncertainty will be matched to the least certain value used in the calculation.
- ✓ Significant figures for the core value will be reported to present the data value to the same level of precision as the uncertainty.
- ✓ In cases where data end use requires application of statistical tests, all available digits may be reported to avoid outcomes resulting in ties, for example ranked set sampling.
- ✓ Group Managers are responsible for approving any alternative significant figure reporting methods for individual documents.

1.0 *Purpose*

Project reports, project plans, proposals, contract documents, training materials, and other deliverables must be controlled by the author during development. Deliverables must be reviewed and approved for release prior to issuance to the customer or use in a training course to ensure accuracy and completeness of the information, adherence to all project and quality assurance requirements, and acceptability to meet contract requirements. Client confidentiality, including national security concerns and proprietary rights, must be protected during all phases of the report development and delivery process.

2.0 *Responsibilities*

Director/Associate Director

- ✓ Approve project level contracting documents.
- ✓ Review technical documents for special projects.
- ✓ May act in place of any manager or author.

Group Managers

- ✓ Confirm that Integrated Safety Management requirements were documented for the project.
- ✓ Evaluate documents for conformance to ORAU/ORISE design standards.
- ✓ Evaluate documents for adherence to regulatory requirements, industry standards, and internal procedural compliance, when applicable.
- ✓ 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.
- ✓ Ensure client confidentiality and security requirements are communicated to project staff.
- ✓ Approve release of task level work plans and general correspondence to the customer.
- ✓ Approve release of reports and training materials.
- ✓ Ensure staff members comply with this procedure.
- ✓ Integrate the requirements of this procedure into work processes.

Quality Manager

- ✓ Verify documentation of procedural compliance.
- ✓ Ensure final data verification is performed and documented.
- ✓ Maintain oversight of Document Control Tracking System.

Author

- ✓ Has overall responsibility for the document.
- ✓ 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.
- ✓ Ensure completion and documentation of report reviews and approvals.
- ✓ Select effective document format.
- ✓ Ensure document conforms to ORAU/ORISE design standards.
- ✓ Coordinate the assembly of the text, figures, and tables as applicable.
- ✓ Work with other technical staff to determine appropriate presentation of information.
- ✓ Select report format, in conjunction with the Group Manager.
- ✓ Ensure data in figures match raw information provided.
- ✓ Ensure documents are handled to maintain security and client confidentiality requirements.

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.
- ✓ Communicate with the Project Leader or Survey Projects Manager to resolve any concerns about data prior to release.

Instructors

- ✓ Communicate problems or inconsistencies in training materials to Group Manager and assist with resolution of concerns.

Document Control Officer

- ✓ Issue Document Control Numbers.
- ✓ Maintain Document Control Log.

Administrative Staff

Ensure that the following processes are completed.

- ✓ Report is formatted following the IEAV 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 requirements of this procedure.
- ✓ Reproduction services are as requested.
- ✓ Final deliverables are converted to PDF and saved according to the requirements of this procedure.

Business Support Analyst

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

3.0 Definitions

Business development document: Any correspondence related to business development activities.

Deliverable(s): The collection of letters, documents, attachments, etc. that satisfy contract/Statement of Work requirements.

Document Control Number (DCN): A unique identifying number assigned to a document (letter, report, etc.) that will stay with the document throughout the document life cycle.

Document Control Officer (DCO): The individual assigned the responsibility to issue, track, and otherwise control the document numbering system and associated records.

Document Control Number Log: The electronic log used to track document control numbers and their associated information. The DCN Log includes the following information for each controlled document: DCN, project number, document title, primary author, authoring group, customer name, hyperlink to folder location, and issue date.

Document review report: Commentary on the outcome of a technical review conducted for an external document.

Draft report: A preliminary document of project work prior to preparation of a final report, which would include summaries of activities, collected and analyzed data, and when requested, technical conclusions. Any type of report can be prepared as a draft version. Draft reports may be prepared at the request of the customer to allow for customer input before the report is finalized. A draft report is issued as a deliverable to a customer with the *intent* that there will be comments, reviews, etc., followed by issuance of a final report. A document labeled draft should NOT be confused with a document in the pre-release developmental stages.

Final report: The ending product that presents the descriptions of project work, summaries of collected and analyzed data and project phases, and when requested by the customer, technical conclusions. A final report is issued as a deliverable to a customer with the *intent* that there will be no more iterations of the document. Note that future changes are not precluded (changes initiate a revision cycle), however the *intent* at the time of issuing is that there will be no more iterations or changes.

Interim report: Prepared to communicate the results of each multiple work phase for a large specific project to the client. The expectation in this case is that a final report summarizing all of the results into one document will be produced when all work has been completed for the project/task.

Laboratory review: Confirmation that all laboratory related information and data have been accurately represented in the document. The laboratory review must be performed by the Laboratory Manager or individual delegated responsibility by the Laboratory Manager.

Letters: Formal communications regarding general project or task activities.

Letter report: Project results summarized 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

Monthly Letter Status Reports: Reports prepared to satisfy contractual requirements, or at the request of the customer, to communicate actual costs and status of work objectives.

Plans: Instructional guidelines for communicating project design and implementation. Project or Program plans do not contain results of data evaluations, technical evaluations, or general outcomes.

Preliminary data: Results 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.

Pre-release: A document in the developmental stages is referred to as pre-release. Both draft reports and final reports can go through pre-release versions prior to internal issuance of a draft or final for internal review. Iterations of a pre-release document are referred to as *versions*. Pre-release documents are not provided to the customer.

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.

Project log: Paper or electronic record of activities related to a task or project.

Proposals: Documents created for submission in response to Requests for Proposals (RFPs) and other new work initiatives.

Quality Review: Includes data verification; editorial review; confirmation of appropriate use of ORAU corporate identity standards; addition of applicable disclaimers to address OSTI submission, document distribution, applicable security issues, and general professionalism of the overall document. The quality review must be performed by the Quality Manager or other individual delegated responsibility by the Quality Manager. The quality review cannot be performed by any individual who generated data or information reported in the document or by the same individual performing the laboratory or technical reviews for a particular document.

Revision: Iterations of a deliverable provided to a customer. The revision number of a document indicates how many times it has been changed since the original issuing to the customer. Revision 0 (Rev. 0) is the original document as it was issued to the customer,

before changes. *Revisions are upon-release file designations.* When a draft document is issued to the customer the draft status will be indicated in the revision portion of the DCN. The draft status should also be indicated within the title page and/or body of the document, such as by adding "Draft" as appropriate on the title page or as a watermark.

Survey Report: A description of project work, summaries of collected and analyzed data, and, when requested by the customer, technical conclusions for tasks such as characterizations, scoping, confirmatory, and verification survey efforts.

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 Report: Any document created to communicate the outcome from direct projects.

Technical Review: Includes evaluation of adherence to regulatory requirements, industry standards, and internal procedural compliance; evaluation of clarity of presentation, reasonableness, consistency and completeness of data; confirmation that project goals were adequately met and conveyed to the reader.

Training Materials: Notebooks and other handout materials distributed to students to support material presented in lectures.

Version: Internal iterations of a document during the development process. Version numbers are assigned and incremented by the primary author and are not tracked in the DCN log. Version numbers are removed from a deliverable before it is sent to a customer. *Versions are pre-release file designations.*

4.0 General

Projects or tasks are assigned to staff members by a Group Manager. Generally, the assigned staff member serves as the author for development of related documents. However, responsibility may be delegated to any staff member with significant technical knowledge to meet contract requirements, as determined by the Group Manager. The author, once assigned, is responsible for the entire document development process.

5.0 Author designation of document type

The author is responsible for determining the type of document(s) necessary to meet contract requirements.

Documents can be categorized as any one of the following types:

- LT = Letter
- TR = General technical report (examples – lessons learned, response documents)
- LR = Letter report (Lab letter reports)
- DR = Document review report (examples – document reviews, license reviews)
- BD = Business development document

- PLN = Plan (examples – project specific plans, program plans)
- PR = Procedure developed for a specific task that will not be included in one of the controlled procedure manuals.
- PRO = Proposal
- SR = Survey reports (examples characterization, scoping, confirmatory, verification)

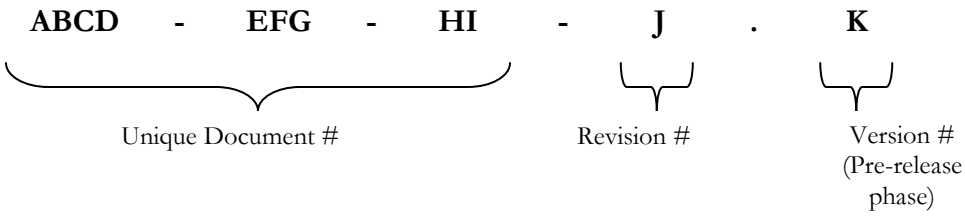
The author provides descriptive information about the document to the Document Control Officer and specifies any special document handling requirements such as those supporting Official Use Only (OUO) or sensitive documents. If an appropriate category does not exist the DCO can establish and document a new category.

Note: Project or Task specific designations for documents may be requested by the customer, such as interim report, proposed survey plan, initial results, etc. However, the author is responsible for working with the Document Control Officer to determine which standard IEAV category best represents the document, and processing the document according to procedural requirements using one of the standard categories.

6.0 Assignment of Document Control Number

6.1 Author requests a document control number (DCN) from the Document Control Officer (DCO) upon creating the electronic file for a document, or upon identifying a document as requiring control. Author provides descriptive information (task code, document type, new document or revision, Y drive folder location, etc.)

6.2 Document Control Number format:



Where:

ABCD = Task code

EFG = Two or three-character alphabetic code indicating the type of document, for example LT for a letter.

HI= Sequential numbering of the reports of this type for this task

J = Revision number (Rev. 0 is the original issue)

K = Version number (pre-release iterations, removed from DCN upon release)

For example:

DCN# 0456-TR-15-2.5

Is the 15th Technical Report (TR) for WBS Task # 0456, Revision 2 of the report, 5th pre-release (internal) version.

DCN# 1712-DR-02-0

Is a document review (DR) report for Task # 1712. It is the second DR document for 1712. It is the original issue of the document (Rev. 0), and is the out-the-door released version (version number after the period has been dropped).

DCN# 1673-SR-01-Draft

Is a survey report (SR) report for Task # 1673. It is the first SR document for 1673. It is the externally issued (i.e. provided to the customer) draft of the document (Rev. Draft).

6.3 Document Control Officer (DCO) generates the DCN and performs the following steps:

- Check the DCN log to determine if there was a previous revision.
- Create a new DCN for a new document, or next revision number of an existing document.
- Assign a number and enter the following information in the DCN log:
  - ✓ Project and task numbers
  - ✓ Document title
  - ✓ Primary author
  - ✓ Customer name
  - ✓ Hyperlink to electronic folder location
  - ✓ Anticipated issue date – this date will be updated when the document is issued in final form.
  - ✓ Distribution Statement requirement.
  - ✓ Special handling requirements such as those for Official Use Only or sensitive documents.
- Issue the DCN to the author.

The number issued by the DCO will be the DCN up through the revision number (up to the period). Version numbers (internal iterations on a document), which are indicated to the right of the period, are assigned and controlled by the author. Version numbers are not tracked in the DCN log.

7.0 Author incorporation of DCN into the document

The author will use the DCN as the first part of the electronic file name, appending a version number of "1" to the right of the period. A descriptive title may be added following the DCN, but the DCN *must* be the first portion of the file name. The author will place the DCN in the right-hand corner of the document footer for reports, or in the subject line for letters.

Note: Tracking version numbers (.1, .2, .3 etc.) in the document footer is optional due to the effort required to change the footer and the frequency of version changes. Tracking version numbers in the filename, however, is mandatory.

8.0 Pre-release Document Development

8.1 The author creates the document, incorporating input from any coauthors, using professional judgment to increment version numbers.

Version incrementing is intentionally designed to be flexible. Version numbers should be incremented in a way that aids the author. Examples of how version incrementing should be used are:

- Tracking significant changes
- Reaching development milestones
- Pre and post-comment resolution
- Any changes that warrant preservation of previous versions.

Version numbers are incremented by copying the electronic file of the current version and renaming the copy with the next Version number. Version numbers are NOT incremented by renaming existing versions (this would lose previous file versions).

During the pre-release stage, use of the "Track Changes" feature in MS word is encouraged, but not required. Ideally, Track Changes is used to show all changes from the previous version. When a new version is created, all currently tracked changes are accepted, and the process is begun again.

8.2 Author may elect to send the document through a pre-release technical review. This may involve reviews by co-workers, management, etc., to make sure the document is on-target for technical content. Pre-release documents are not provided to the customer.

9.0 Internal review

9.1 When the author has completed work on the document and resolved any pre-release comments about technical content, he/she posts the document to the IEAV SharePoint site.

9.2 The author notifies reviewers that the document has been posted and is ready for review, and includes the requested completion date for reviews.

9.3 Reviewer checks the document out of SharePoint, enters review comments using the Track Changes feature, and checks the document back in to SharePoint when finished.

9.4 Author resolves any comments, incrementing version numbers if necessary.

9.5 Author documents significant technical issues in a manner that can be shared with other staff.

10.0 Approval for Release

Note: Author confirms security and/or client confidentiality requirements for the data and information to be released.

Preliminary Data or Technical Conclusions by email or on a field site

- Author prepares email text including preliminary information, such as data forms or written summaries, as requested by the customer and includes disclaimers stating that quality reviews have not been completed.
- 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 the Group Manager, or discusses the situation with the manager by phone or email if at a field site.
- Group Manager reviews all information to be provided to the customer (text and data) and sends an email to the author or provides verbal approval by phone, if at a field site, approving release of the information to the customer.
- If author issues information by email to the customer, he/she saves copies of the approval email and the email to the customer in the project file. If author issues information verbally or at the field site, the situation is documented in the project log.

Monthly Letter Status Reports

- Draft Monthly Letter Status Reports may be prepared by any staff member. The Group Manager is responsible for the report and signs the letter. The Project Leader or other knowledgeable staff member reviews the report and initials in a concurrence box at the bottom of the cover letter.

Project or Task Related General Correspondence

- Group Manager determines appropriate signature responsibility.
- A second reviewer, knowledgeable of the technical content, signifies concurrence by initialing in the distribution approval block.

Contract Documents

- Task level contract documents
  - ✓ Author indicates acceptance by signing letter or memo.
  - ✓ Group Manager signifies acceptance by initialing in the distribution block of the letter or memo, for external distribution of Task level documents.

- Project level contract documents
  - ✓ Director/Associate Director signs the cover letter or memo documenting approval for external distribution of Project level documents.

- ✓ Group Manager signifies acceptance by initialing in the distribution block of the letter or memo.

Plans

- Author indicates acceptance by signing letter or memo.
- Group Manager signifies acceptance by initialing in the distribution block of the letter or memo, for external distribution of task level documents.

Draft reports

- Author indicates acceptance by signing the letter.
- Technical reviewer indicates acceptance by initialing in the concurrence block at the bottom of the cover letter.
- Laboratory reviewer indicates acceptance by initialing in the concurrence block at the bottom of the cover letter, when laboratory data are included.
- Quality reviewer indicates acceptance by initialing in the concurrence block at the bottom of the cover letter.

Final reports

- The author determines the documentation method for reviews.
- Author, technical, laboratory - when laboratory data are included, and quality reviewers indicate acceptance by signing in the applicable space on the signature page or in the concurrence block at the bottom of the cover letter.

11.0 External document release

Once the author has obtained all required approvals for release, he/she prepares the document for external distribution or requests assistance from the administrative staff. The author ensures any applicable requirements for special handling such as Official Use Only or sensitive designations are addressed. The author ensures that the following specific tasks are performed:

- ✓ Ensure no format problems have been inadvertently introduced during processing.
- ✓ Copy and rename the electronic file, dropping the Version number portion of the DCN (i.e. 4205-TR-001-0.18 becomes 4205-TR-001-0). If Track Changes has been used, the author should have already resolved the changes and removed the Track Changes notations. This new file is the official revision that will be signed and sent to the customer.
- ✓ Save the document to the IEAV Task folder.
- ✓ Document resolution of significant technical issues in the file. Produce hard copy, if applicable.
- ✓ Circulate document for approval signatures.
- ✓ Create PDF version of the document and save it to the electronic task folder.
- ✓ Issue the document per the authors' direction.

12.0 Post-release

- ✓ Retention of internal pre-release versions is at the discretion of the author. Author ensures PDF of final document is saved in the task folder and completed documents are removed from SharePoint.
- ✓ Author provides DCO with release information final title, release date, updated folder hyperlink, etc.
- ✓ DCO updates DCN log to reflect status of the document.
  Note: If a revision becomes necessary, the author contacts the DCO, who issues a new DCN (same as old DCN, but with next Rev. # increment). The author then proceeds through the pre-release process as with the initial revision.

13.0 Final Deliverables Sent by Email

PDF versions of final deliverables may be sent by email when requested by the customer. If no follow-up paper copy will be sent the email will be saved in the electronic Task folder. Reviews as defined in this Section must first be completed and documented. The electronic transmission will be followed by a paper copy of the document, if applicable. Electronic files will not be provided in forms that can be modified unless it is a requirement of the project work scope.

14.0 Minimum Requirements for Reporting Laboratory Data

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

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

15.0 Documentation of Report Review and Approval

The author will ensure that documentation of substantial review comments is included in the electronic or paper project files. Documentation of spelling, grammar, and punctuation comments is not required.

16.0 Training Materials

16.1 Author prepares draft training materials.

16.2 Author confers with other technical staff as necessary to ensure that the training materials are complete and meet all applicable quality assurance requirements and industry training standards.

16.3 The lead instructor approves distribution of the training materials for each course.

Section 9 – PERFORMANCE ASSESSMENT AND CORRECTIVE ACTION

1.0 Purpose

Assessments of IEAV activities are performed to ensure continuing adequacy and effectiveness of processes, 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 improvement activities, are evaluated through the processes set forth in this section. Operational requirements are defined in IEAV 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. Once identified, deficiencies and quality improvements are documented and tracked through resolution. Deficiencies are communicated to affected staff and efforts to minimize the potential for recurrence are included in corrective action plans.

2.0 Responsibilities

Director/Associate 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

- ✓ Plan and organize internal audits.
- ✓ 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/Associate Director and Managers.
- ✓ Approve technical qualifications of individuals performing internal audits.

All Staff

- ✓ Notify the cognizant Manager, the Quality Manager, or the Director/Associate 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 pans to the Quality Manager.

3.0 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.

Customer Questionnaire: Electronic questionnaires sent to field survey customers requesting ratings of field survey activities.

External Audit: A systematic, independent, and documented process, performed by non-ORAU/ORISE individuals, 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.

Internal Quality Assessment: Generic term for any quality assessment that does not fall into another defined category.

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

Management Assessment: Annual assessment performed by the IEAV Director/Associate Director and 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: For projects involving laboratory and survey procedures, 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.

Performance Targets: Measures established to evaluate performance related to the ORISE contract.

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

Student Ratings: Responses to training course satisfaction survey questions.

4.0 Internal Assessments

4.1 Nonconformances and conditions adverse to quality

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 tracking system.

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 the Quality Manager. The Quality Manager enters a description of the situation, the date, and the name of the individual identifying the situation into the tracking system.

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 tracking system. Follow-up actions are performed according to the requirements in Subsection 6 of this procedure.

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 communicated to the Quality Manager upon return from the field site. The Quality Manager enters the information into the tracking system.

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 tracking system entries are complete.

4.2 Project File Reviews

4.2.1 A minimum of ten percent of project files, for projects where laboratory and survey manual procedures apply, are 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 entered into the tracking system 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 the requirements in Subsection 6 of this procedure.

4.2.6 Items not meeting requirements are addressed prior to release of the final deliverable to the customer.

4.2.7 Documentation of Project File Reviews is 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/Associate Director and managers will not delegate responsibility for Management Assessments.

4.3.3 Management Assessments will follow a plan developed and maintained by the Quality Manager and approved by the IEAV Director/Associate 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 tracking system by the Quality Manager.

4.3.6 Follow-up is performed according to the requirements in Subsection 6 of this procedure.

4.3.7 A summary report will be distributed to IEAV staff.

4.4 Internal Audits

4.4.1 Internal quality assessments of any scope may be initiated at the request of the Director/Associate Director, a Manager, or the Quality Manager.

4.4.2 Internal audits will be performed by the Quality Manager or by any technically qualified staff member who did not perform the work or serve in a direct oversight role for the activities being audited.

4.4.3 Internal audits will be performed at a minimum annually according to a predetermined schedule.

4.4.4 Audit content will include key operational areas of the IEAV South Campus groups with the purpose of confirming compliance with IEAV Quality Program Manual requirements.

4.4.5 The responsible Manager will draft corrective action plans for all improvement actions identified by the audit. The corrective action plans will include:

- ✓ Assignment of responsibility for completion of the corrective action plan.
- ✓ Correction of errors when possible
- ✓ Actions to minimize possibility of recurrence
- ✓ Testing requirements
- ✓ Completion dates for each item

4.4.6 The Quality Manager enters the audit results and corrective action plans into a tracking system.

4.4.7 The Quality Manager verifies completion of the corrective action plan requirements and enters the information into the tracking system.

4.4.8 Items are tracked and reported according to the requirements in Subsection 6 of this procedure.

4.4.9 Assessment status is reported quarterly, at a minimum, to the Director/Associate Director and managers.

5.0 External Assessments

5.1 Laboratory Performance Evaluation

5.1.1 The 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 IEAV 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 defined as unacceptable by the evaluation program are considered nonconformances, entered into the tracking system, and investigated at the earliest possible time. Items are tracked and reported according to the requirements in Subsection 6 of this procedure.

5.1.7 If enough of the original material is available the unacceptable analysis is 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 is 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.

5.1.11 The Quality Manager maintains all paper performance evaluation files or ensures they are archived as paper or electronic records.

5.2 Laboratory Traceability Program

The 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 is contracted.

5.3.3 Audits contracted by the IEAV Program are performed according to plans or checklists.

5.3.4 On receipt of the audit report the Quality Manager works with the cognizant Managers to draft corrective action plans for all audit findings and observations. The corrective action plans will include:

- ✓ Determination of probable cause.
- ✓ Correction of errors when possible.
- ✓ Actions to minimize possibility of recurrence.
- ✓ Testing requirements.
- ✓ Completion dates for each item.

5.3.5 The Director/Associate Director will approve the corrective action plans.

5.3.6 Once corrective action plan approval is received from the customer, or other audit group, work begins on the corrective action plan requirements.

5.3.7 The Quality Manager enters the findings, observations, and corrective action plans into the tracking system.

5.3.8 Assignees provide status information to the Quality Manager as work progresses.

5.3.9 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.

5.3.10 The audit team leader and the customer are notified when the corrective action plan requirements for the findings and observations have been completed.

5.3.11 Subsection 6 provides the steps for tracking of items through completion.

5.3.12 Paper records of audits, findings, and closures are kept in the Quality Manager's office or in record archival.

5.3.13 Audit status is reported quarterly, at a minimum, to the Director/Associate Director and Managers according to the requirements of Subsection 6 of this procedure.

5.4 Customer Questionnaires

5.4.1 Electronic questionnaires are sent to Survey Projects and Health Physics customers requesting ratings of field survey activities.

5.4.2 Responses to questionnaires are tracked and reported by the Quality Manager.

5.4.3 Customer questionnaire results are reported quarterly to the Director/Associate Director and Managers according to the requirements of Subsection 6 of this procedure.

5.5 Student Ratings

5.5.1 Surveys are given to course participants requesting ratings of course quality.

5.5.2 Responses to surveys are tracked by the PTP Registrar.

5.5.3 Student rating results are reported quarterly to the Director/Associate Director and Managers according to the requirements of Subsection 6 of this procedure.

6.0 Tracking and Follow-up

6.1 Tracking and follow-up of all nonconformances, conditions adverse to quality, and quality improvement activities are performed using an electronic tracking system. The Quality Manager ensures that all required information is entered.

6.2 The customer is notified of conditions casting doubt on the validity of technical results of their project as soon as possible.

6.3 Response to assessment items or audit findings is initiated in a timely manner. Response deadlines set by external audit groups will be met or, if approved by the Director/Associate Director, new deadlines will be negotiated.

6.4 Items and findings are tracked through completion using an electronic tracking system.

6.4.1 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.

6.4.1.1 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.

6.4.1.2 A "Hold" tag may not be removed until the Quality Manager verifies closure of the nonconformance.

6.4.2 The Quality Manager enters the review date and "Hold" tag information, if applicable, into the tracking database.

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

Assignment of a program group designation:

A – Administrative
C- Counting
F – Field Survey Projects
G – General
H – Health Physics
R – Radiochemistry
T – Training

Categories:

1 – Quality 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.

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

6.4.5 The assignee investigates the situation, determines the probable cause, prepares a corrective action plan, determines a proposed completion date, and submits the information to the Quality Manager for entry into the tracking system.

6.4.6 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 the IEAV Program.
- ✓ 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.

6.4.7 The Quality Manager works with the assignee to enhance the plan, if necessary, and notifies assignee when final plan is approved.

6.4.8 Assignee completes the corrective action plan requirements, notifying the Quality Manager of status.

6.4.9 The Quality Manager maintains updated status in the tracking system.

6.4.10 The Quality Manager works with the line manager to verify successful completion of the corrective action plan, marks the item as closed in the tracking system, and notifies the assignee and the Manager.

7.0 Quality Status Reports

The Quality Manager will provide the status of performance evaluation activities to the Director/Associate Director and other managers quarterly, at a minimum.

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 of deficiencies, over multiple years when applicable.

1.0 Purpose

The quality of IEAV services is enhanced by ORAU/ORISE Business Operations support. Business Operations staff members provide support to IEAV projects as requested. They ensure all regulatory and ORAU/ORISE requirements are met. However, the quality of final IEAV deliverables is the responsibility of the IEAV Group Managers.

2.0 Environment Safety and Health Office

The Environment Safety and Health office manages the ORISE Integrated Safety Management Program and the Voluntary Protection. The Environment Safety and Health office works to protect ORAU employees in their workplace by integrating safety and health programs into daily practices, and to prevent damage to the environment and adverse exposure to the public. Safety requirements are available on the ORAU intraweb Safety 1st site.

3.0 Communications and Marketing

Communications and Marketing is responsible for providing the following services to the Program:

- Advertising
- Brochure
- Exhibits or displays
- Reproduction and binding services
- Signs
- Web site updates and design

4.0 Facilities and Transportation

Facilities and Transportation provides high-quality services in the areas of engineering and construction management, facility operations, transportation services, materials distribution, property and vehicle management, records management and relocation services. Specific services provided by Facilities and Transportation include:

- Facility design and maintenance activities
- Record management
- Custodial services
- Engineering
- Maintenance
- Property and Vehicle management
- Shipping and receiving
- Telecommunication

IEAV Program staff members develop conceptual plans, identify the quality requirements and equipment, and work with Facilities and Transportation and the Environment, Safety and Health office to develop specifications.

Plans and drawings are developed and related critical documents are maintained by Facilities and Transportation.

Actions to ensure compliance with government regulations for safety and health are either mandated or approved by the Environment Safety and Health office.

Shipping of hazardous or potentially hazardous materials is coordinated through Facilities and Transportation to ensure that shipping papers and other shipping documentation are prepared in accordance with applicable regulations and ORAU/ORISE policy.

5.0 Financial Operations

Financial Operations is responsible for the following services related to the quality of IEAV operations.

The Business Support Analyst:

- Provides business and cost information for developing business proposals.
- Ensures business practices are carried out within policy guidelines.
- Provides timely, informative, and accurate responses to financial requests from internal and external customers.
- Provides financial data and advice to staff.

Procurement:

- Helps to ensure compliance with all applicable regulations.
- Controls original documents relating to procurement processing.

6.0 Information Systems

Information Systems is responsible for the following areas:

- Computer security
- Computer purchases
- Computer accounts
- Desktop support
- Internet
- Systems development – applications programming
- Electronic file system backup

Specific responsibilities include:

- Providing a standards-based, reliable, and secure IT infrastructure based on the most appropriate current platforms.
- Laying the technological groundwork for future growth and anticipated customer needs.

- Providing company-wide data strategies and solutions.
- Building technology skills in our customers and users.
- Partnering with customers to meet their strategic goals from development through implementation.

7.0 Safeguards and Security

Safeguards and Security works to provide a secure work environment for all employees, and to ensure effective protection of government property, assets, information, and other national security interests.

Safeguards and Security staff members are responsible for:

- Processing personnel security actions including security clearance requests, personnel security administration, clearance extensions, security in-briefs and exit briefs
- Visitor request processing and procedures
- Security training and awareness program
- ORAU/ORISE Watchforce operations
- ORAU/ORISE security policy and procedures
- Limited Security Area access policy and procedures
- Organizational liaison for DOE security issues

1.0 Purpose

Records documenting IEAV Program 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 the ORAU South Campus.

Project Lead

- ✓ 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 IEAV Program record archival process.
- ✓ Ensure that project files are archived on request and that the archive location is entered into the IEAV 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, or any information essential to the audit trail of the project. For comparison, non-critical records are of a support nature and are easily replaced; such as reports from other organizations or topographical maps.

Electronic Records: Records or documents stored in an electronic format on system servers, hard drives, or portable storage devices.

Procedure Training/Certification Records: Records documenting in-house training and certification provided by IEAV staff, for IEAV 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 The staff member assigned lead responsibility for a project/task will ensure that an electronic file is created prior to start up of work activities. A paper file will also be established when paper records are required.

4.5 All records critical to the project will be maintained in the file(s). Electronic records/documents must be printed and added to the paper file or saved on the ORAU network to ensure a system for adequate backup is in place. Electronic files of critical records must be protected from inadvertent changes by converting to PDF format.

4.6 A paper or electronic logbook may be used to document major decisions, verbal communications, work activities, and other pertinent information. Electronic logbooks must be maintained in the project folder on the ORAU network.

4.7 Records are retained according to DOE record retention requirements, unless otherwise specified by the customer.

4.8 A log of names, initials, and signatures for all individuals responsible for signing or initialing records is maintained by the Quality Manager.

5.0 Record Completion Standards

5.1 Records will be legibly written in ink or prepared in an electronic version.

5.2 Paper records must be dated and initialed or signed to be valid. Electronic records must include the reviewer name and the date of review. The record must be saved in a format protecting the document from changes.

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 documented in the paper file.

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/task files 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 information is entered
- ✓ Designated Site Coordinator
- ✓ Signature of individual completing an entry
- ✓ List of IEAV 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 Program Manual Section 7.

6.3.7 The Site Coordinator will ensure that records are transported to the ORAU South Campus either in the possession of an IEAV 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 ORAU South Campus facility.

6.3.9 The ORAU South Campus 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
- ✓ Original chain-of-custody forms for all samples
- ✓ Copies of chain-of-custody 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 and Training 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 IEAV
- ✓ Report review and data verification documentation
- ✓ Documentation of special technical determinations
- ✓ Final deliverable
- ✓ Training notebooks

8.2 Technical Project Record Requirements

8.2.1 Original records are the responsibility of the initiator.

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

8.2.3 The individual assigned the lead responsibility for the project 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
- ✓ Performance Target documentation
- ✓ 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 Building SC-1, 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 electronically on the ORAU network.

9.2.6 Documentation of controlled procedure manual numbers and distribution of controlled procedure updates are maintained on the ORAU network.

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 project related records must be maintained for a minimum of 75 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 The staff member responsible for the project will:

- ✓ Remove non-critical records from the paper and electronic files.
- ✓ Locate any related laboratory, calibration, and administrative records and add them to the file.

10.2.2 A "Request for Archival" form will be submitted along with an Administrative work request including the form shown at the end of this procedure.

10.2.3 The administrative staff member will:

- ✓ Verify the contents of the project file based on the inventory list on the form.
- ✓ Acknowledge receipt of the file by signing the "Records received by admin" space on the form.
- ✓ Confirm that the admin records have been included, if applicable.

10.2.4 The administrative staff member will ensure that the file contents are scanned into an electronic file and saved on the ORAU network in the project folder.

10.2.5 The administrative staff member will assign an archive cabinet and drawer location to the file if paper records are to be maintained, note the electronic file path on the "Request for Archival" form, and ensure that all pertinent information is entered into the IEAV Database.

10.2.6 When archival is complete, the administrative staff member will sign and date the "Request for Archival" form and include it in the electronic project file, and if applicable in the paper file.

10.3 Check Out of Archived Records

Removal of material from the paper archive files should be accomplished through an administrative work request. 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/Associate 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.

IEAV REQUEST FOR RECORD ARCHIVAL

Archival Requested By: _____ Date Submitted: _____

Site/Project Title: _____

_____

City/State/Zip: _____

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

ORAU/ORISE Project Supervisor: _____

Project Contact(s)/Phone: _____

Project/Task Start Date: _____ Project/Task Completion Date: _____

Projects/Tasks for Cross Reference: _____

Final Report(s): _____

Records have been relinquished to admin staff member, including any related calibration or laboratory records.

Name: _____ Date: _____

Records received by admin staff member

Name: _____ Date: _____

Paper records scanned into electronic format

Name: _____ Date: _____

Electronic folder moved to electronic archive area

Name: _____ Date: _____

APPENDIX A: ABBREVIATIONS AND ACRONYMS

ASME	American Society of Mechanical Engineers
ATDD	Atmospheric Turbulence and Diffusion Division
CFR	Code of Federal Regulations
CL	Center Line
DCN	Document Control Number
DCO	Document Control Officer
DOE	Department of Energy
DOECAP	Department of Energy Consolidated Audit Program
ES&H	Environment Safety and Health
HAZWOPER	Hazardous Waste Operations and Emergency Response
ID	Identification
ISD	Information Systems Department
IEAV	Independent Environmental Assessment and Verification
ISM	Integrated Safety Management
ITP	Intercomparison Testing Program
JHA	Job Hazard Analysis
LCL	Lower Control Limit
LCS	Laboratory Control Sample
MAPEP	Mixed-Analyte Performance Evaluation Program
MDC	Minimum detectable concentration
NA	Not applicable
NIST	National Institute of Standards and Technology

NOAA	National Oceanic and Atmospheric Administration
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NRM	Nuclide Reference Material
ORAU	Oak Ridge Associated Universities
ORISE	Oak Ridge Institute for Science and Education
OUO	Official Use Only
PDF	Portable Document Format
PE	Performance evaluation
PTP	Professional Training Programs
QA	Quality Assurance
QC	Quality Control
QIP	Quench Indicating Parameter
RESL	Radiological and Environmental Sciences Laboratory
RFP	Request for Proposal
RFTA	Request for Technical Assistance
SMO	Sample Management Office
SPAF	Survey Plan Approval Form
SR	Survey Report
TPU	Total propagated uncertainty
TR	Technical Report
TRM	Tailings Reference Material
UCL	Upper Control Limit
VPP	Voluntary Protection Program