

**ORAU POLICY AND PROCEDURE
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ATTACHMENT 1

**ORISE QUALITY ASSURANCE PROGRAM (QAP)
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Quality Assurance Program (QAP)

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QUALITY ASSURANCE PROGRAM (QAP)

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QUALITY ASSURANCE PROGRAM (QAP)

1. PURPOSE AND SCOPE

This document describes the Quality Assurance Program (QAP) for the Oak Ridge Associated Universities (ORAU) and is applicable to all ORAU work performed for the Department of Energy (DOE). The ORAU QAP complies with DOE O 414.1C, Quality Assurance.

2. REFERENCES

- 1) DOE O 210.2, DOE Corporate Operating Experience Program
- 2) DOE O 226.1, Implementation of Department of Energy Oversight Policy
- 3) DOE P 226.1, Department of Energy Oversight Policy
- 4) DOE O 231.1A, Environment, Safety, and Health Reporting
- 5) DOE G 414.1-2A, Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance
- 6) DOE O 414.1C, Quality Assurance
- 7) DOE G 450.4-1B, Integrated Safety Management System Guide for use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); the Functions, Responsibilities, and Authorities Manual; and the Department of Energy Acquisition Regulation
- 8) DOE P 450.4, Safety Management System Policy
- 9) DOE-STD-7501-99, The DOE Corporate Lessons Learned Programs
- 10) ORAU Strategic Plan
- 11) ORAU Policy ESH-100, Integrated Safety Management
- 12) ORAU Policy ESH-112, Environmental Management
- 13) ORAU Policy ESH-150, Lessons Learned Program
- 14) ORAU Policy GP-810, Quality Assurance
- 15) ORAU Emergency Preparedness Manual
- 16) ORAU Health and Safety Manual
- 17) ORAU ISMS Program Description
- 18) ISO 14001:2004, Environmental Management Systems

3. DEFINITIONS

- 1) **Assessment:** A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively (from DOE O 414.1C).
- 2) **Assurance:** Actions that provide confidence that one's intentions are achieved.
- 3) **Assurance Systems:** All aspects of the processes and activities designed to identify deficiencies and opportunities for improvement, report deficiencies to the responsible managers, complete corrective actions, and share in lessons learned effectively across all aspects of operation (from DOE O 226.1).
- 4) **Benchmarking:** Process of measuring an organization's performance against the performance of organizations judged to be the best in the area being measured.
- 5) **Best Practice:** Time-tested or innovative method that improves performance by increasing productivity, enhancing quality of a product or service, lessening time required, or reducing cost.

The effectiveness of a best practice should be based upon measured performance and be well-documented.

- 6) **Continuous Improvement**: Result of ongoing and coordinated processes that produce positive employee and institutional attitudes and actions toward enhancing the quality of performance in all activities at all organizational levels.
- 7) **Corrective Action Report**: Document describing an environment, safety, and health or a quality assurance deficiency and how its root cause will be rectified in a timely fashion to prevent recurrence.
- 8) **Deficiency**: Physical condition, written procedure, or ongoing practice not in compliance with a law, regulation, best practice, or contractual provision. This generic term includes notices from regulatory agencies; recommendations of internal and external auditors; contractual infringements reported by customers; findings of self-assessments and external appraisals, surveillances, and inspections; root causes in occurrence reports; infractions discovered by employees; and other instances of noncompliance, however reported.
- 9) **Graded Approach**: Process for establishing compliance measures that is commensurate with their relative contribution to safety, safeguards, and security; the hazards involved; the programmatic mission and particular characteristics of a facility; and other relevant factors. This approach balances the costs of compliance with the expected benefits.
- 10) **Integrated Management**: A systematic approach to planning, program execution, and performance management that employs vertical and horizontal organizational involvement in key operational and business decision making.
- 11) **Lesson Learned**: Documented positive or negative performance, experience, or practice that is shared to promote continuous improvement and prevent mishaps.
- 12) **Manager**: Person with authority delegated by, or on behalf of, the ORAU president to manage an ORAU program, project, or department.
- 13) **Management Oversight**: Activities performed by management to determine whether programs and management systems, including assurance and oversight systems are performing effectively and/or complying with internal and external requirements. Oversight programs include operational awareness activities, onsite reviews, assessments, self-assessments, and performance evaluations (adapted from DOE O 226.1).
- 14) **Near-miss**: An event or circumstance which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage, but did not actualize due to chance, corrective action, and/or timely intervention.
- 15) **Occurrence Report**: Information submitted to DOE in accordance with the manual, DOE M 231.1-2, Occurrence Reporting and Processing of Operations Information.
- 16) **Performance Measure**: A quantitative or qualitative characterization of performance.
- 17) **Person Responsible**: Employee (never more than one) with responsibility for implementing a Corrective Action Report. This person usually is the manager within whose area of responsibility

the deficiency arose, but the manager can delegate this duty to a direct report who is responsible for the condition, procedure, or practice that brought about the deficiency.

- 18) **Quality**: Degree to which an item, service, or process meets or exceeds the customer's or user's requirements and expectations.
- 19) **Quality Assurance (QA)**: Actions that provide confidence that quality will be achieved.
- 20) **Quality Assurance Program (QAP)**: ORAU document that describes the programs and processes used at ORISE to fulfill the requirements of DOE O 414.1C.
- 21) **Root Cause**: The most basic cause (or causes) that can reasonably be identified that management has control to fix and, when fixed, will prevent (or significantly reduce the likelihood of) the problem's recurrence.
- 22) **Safety Corrective Action Tracking System (SCATS)**: Documented procedure for the systematic tracking of actions taken to correct environment, safety, and health deficiencies reported by both ORAU employees and external sources.
- 23) **Self-assessment**: Process by which an ORAU employee or team determines and documents whether facilities, equipment, processes, and activities within an area of responsibility meet specified requirements related to their intended performance.
- 24) **Walkthrough**: A compliance inspection of facilities and operations by managers and other specified staff.

4. MANAGEMENT ORGANIZATION AND PROCESSES

Established in 1946, ORAU is a university consortium leveraging the scientific strength of major research institutions to advance science and education by partnering with national laboratories, government agencies, and private industry. A Council of Sponsoring Institutions, composed of one representative from each member university, governs the corporation and elects a 21-person board of directors to establish broad policy guidelines and to manage corporate property and affairs. Since 1947, ORAU has managed for the DOE and predecessor agencies a group of facilities and programs now known as the Oak Ridge Institute for Science and Education (ORISE).

The ORAU mission is to create and promote as a university consortium collaborative partnerships with national laboratories, and to operate ORISE, providing expertise in three core areas:

- Worker and public health and independent verification of environmental cleanup
- Weapons of mass destruction national preparedness and emergency response
- Science education, workforce development, and scientific review programs

The ORAU Values Statement, adopted in 1991 and affirmed in 2001, underscores ORAU's long-standing dedication to QA principles:

Our employees are our most valuable resource. We commit ourselves to:

- Creating an innovative, productive, harmonious, safe, and comfortable environment in which to work.

- Advocating and expecting fairness, openness, integrity, teamwork, courtesy, and high ethical standards in our personal and professional dealings with others.
- Promoting a talented and diverse workforce by hiring quality individuals, appreciating their differences, and developing employees to their fullest potential for the benefit of the organization, the individuals, and society.
- Encouraging and rewarding the highest level of performance through objective review and recognition.
- Empowering employees to make decisions in fulfilling their responsibilities.
- Holding ourselves accountable for actions.
- Leading through innovations and creativity.
- Providing products and services of the highest quality in a timely and cost-effective manner.
- Respecting and protecting our environment and encouraging that respect by others.

In accordance with these guiding principles, management empowers employees to make responsible decisions in performing their work, promotes open channels of communication across the organization, and provides employees with the training and resources needed to accomplish their work, and encourages employees to enhance their trade or professional qualification.

The ORAU President serves as the ORISE Director. The following are senior positions reporting directly to the ORISE Director:

- Chief Audit Officer
- Vice President for Business Operations (BusOps), ORISE Deputy Director for Operations, and Chief Financial Officer
- General Counsel
- Corporate Director for Human Resources
- Director, Environment, Safety, and Health
- Director, Integrated Management and Assurance
- Program Directors (seven)

All of these positions have quality assurance responsibilities with corresponding opportunities for continuous improvement.

Overall responsibility for QA at ORISE lies with the Director, Integrated Management and Assurance, who is also designated as the Quality Assurance Coordinator for ORAU and ORISE.

4.1 Offices and Departments

Audit Services: Provides independent evaluations of management control processes to ensure that financial information is accurate and timely; employees comply with applicable laws, regulations, standards, policies, and procedures; program objectives are achieved; resources are economically acquired, efficiently used, and adequately protected; and quality and continuous improvement are fostered in management control systems.

Office of Integrated Management and Assurance: Communicates and leads the implementation and ongoing assessment of integrated management and assurance systems and processes.

Environment, Safety, and Health (ESH): Protects the environment and provides safe and healthful workplaces by controlling, reducing, or eliminating hazards, and by providing oversight services to managers.

General Counsel (GC): Advises and assists employees in complying with applicable laws, regulations, and policies; anticipates operational and programmatic needs and initiates preventative legal efforts as required; and represents the organization's interests to external entities in an advocacy role. The office provides advice to employees on ethical concerns through the ORAU Ethics Program, coordinates policy development, and offers guidance on using the Policy and Procedure Issuing System.

Human Resources (HR): Attracts, develops, and motivates qualified, diverse, and productive employees. Specific functions include compensation, benefits, HR information systems, employment, human resources development and performance, employee relations/EEO/AA/Diversity, and occupational health.

Vice President for Business Operations (BusOps): Oversees a broad range of services by and for the organization through Communications, Printing, and Design Department; Facilities and Transportation Department; Financial Operations Department; Information Systems Department; and Safeguards and Security Department, as described below.

Communications, Printing, and Design Department (CPD): Provides products and services in media relations and public information, writing and editing, advertising, library science, graphic design, conference support, Web-site development and maintenance, and printing and reproduction.

Facilities and Transportation Department (FTD): Provides high-quality services in engineering and construction management, facility operations, transportation, materials distribution, asset management, and telecommunications, along with long-range planning for future requirements in these areas.

Financial Operations Department (FinOps): Establishes and maintains sound financial management systems for revenues and expenditures, provides accurate and uniform financial information, procures the highest quality goods and services in a cost-effective and timely manner, and supports business operations through budget development, financial analysis, travel reservations and policy, contract administration, and cost management.

Information Systems Department (ISD): Provides effective technology solutions for its employees and customers. It maintains a reliable computing infrastructure, develops employees' information management skills, works with customers to meet their software needs, provides real-time information at the desktop, and controls costs by using standardized technologies and quality-tested methods.

Safeguards and Security Department (SGS): Implements all DOE security provisions to protect employees, property (including small quantities of controlled substances and special nuclear materials), operations, and communications; manages the security clearance program for ORAU

employees; administers the unclassified foreign visits and assignments program; and supervises the Watch Force staff.

4.2 Programs

The expertise and experience of the seven ORISE programs continuously strengthen the core areas described earlier, some of which are shared by several of the programs.

Independent Environmental Assessment and Verification (IEAV): Provides independent radiological surveys along with applied health physics evaluations, audits, and training. Specifically, IEAV provides DOE and the Nuclear Regulatory Commission (NRC) with independent verification of radiologically contaminated sites that have been remediated to regulatory standards, and provides health physics solutions in a number of technical areas for DOE and NRC, as well as other federal agencies and contractors. IEAV participates in national programs that develop and update regulations and establish standard survey techniques and equipment. IEAV also provides scientific and support staff to the National Oceanic and Atmospheric Administration (NOAA) Atmospheric Turbulence and Diffusion Division for studies in atmospheric physics.

National Security and Emergency Management (NSEM): Provides management and technical expertise in counter proliferation and counter terrorism activities and in human reliability studies and personnel security. NSEM staff in the National Security Program are experts in operations planning, readiness preparation, and response to terrorist incidents involving weapons of mass destruction. NSEM also includes the Center for Human Reliability Studies has pioneered research into the prevention of workplace violence and has educated workforces throughout DOE in the warning signs demonstrated by persons who might become violent at work. ORISE's Emergency Management Laboratory, another part of NSEM, provides emergency preparedness support services and expertise to assist industry and government agencies, such as Homeland Security, in emergency response and recovery.

Occupational Exposure and Worker Health (OEWH): Conducts research to better understand the health effects related to energy technologies and occupational exposures and to advance our understanding of nuclear physics. OEWH capabilities include the Center for Epidemiological Research, beryllium exposure studies and testing, illness and injury surveillance, radiation exposure data collection and dose reconstruction, and protection of human subjects involved in research.

Professional and Technical Training (PTT): Applies its expertise on behalf of DOE in industrial hygiene; environment, safety, and health; occupational health; and database management. Innovative technologies are applied to enhance worker performance through distance learning, computer-based and multimedia training, and self study. PTT also provides comprehensive management of training operations, including performance measures, annual plans, procedures, registration and course coordination, cost reporting and analyses, and on-site assessments of DOE contractor training and qualification programs.

Radiation Emergency Medicine (REM): Brings together the unique talents of the Radiation Emergency Assistance Center/Training Site (REAC/TS) and the Cytogenetics Biodosimetry Laboratory to provide DOE and other federal, state, and international agencies with medical advice, specialized training, dosimetry, and on-site assistance for treating all types of radiation exposures. REM also conducts training courses in medical management of radiation accidents, and develops and applies methods for internal dose assessment for intake of radioactive materials from accidents, terrorist incidents, and medical, occupational, and environmental exposure.

Science Education Programs (SEP): Develops, manages, and evaluates programs that encourage faculty, students, and recent graduates to study, conduct research, and pursue careers in science, engineering, mathematics and other technical fields. SEP annually supports almost 5,000 individuals in fellowship, scholarship, internship, research participation, and similar educational programs. SEP also conducts complementary analyses of workforce trends and evaluations of education program impacts.

Scientific and Technical Resources Integration (STRI): Provides comprehensive assistance in coordinating peer and merit review of research proposals for DOE and other agencies. ORISE Radioactive Ion Beam and University Radioactive Ion Beam Consortium is also a business unit of STRI that conducts basic nuclear physics research using radioactive ion beams.

4.3 Policies and Procedures

ORAU maintains a comprehensive set of policies and procedures that implement regulations and directives applicable to ORAU, as outlined in ORAU Policy ADM-200, Overview of the ORAU Policy and Procedure Issuing System. This process is described in greater detail in Policies ADM-201, Policy Statement; ADM-202, Immediate Policy Directives; ADM-210, ORAU Policy and Procedure Manual; and ADM-212, ORAU/ORISE Implementation Procedure Manuals. Policies and procedures are reviewed by appropriate managers and technical experts before being submitted to the President for review and approval. These documents are then reviewed and revised or amended on a regular schedule or whenever warranted by changes in regulations and directives.

This system provides flow-down of responsibilities from higher-order policies to lower-order procedures. For example, four policies describe corporate-level environment, safety, and health goals:

- Policy ESH-100 Integrated Safety Management
- Policy ESH-112 Environmental Management
- Policy ESH-130 Implementation of National Environmental Policy Act
- Policy ESH-150 Lessons Learned Program

Specific provisions in the first two of those first tier policies are implemented by procedures in four second tier documents:

- ORAU Emergency Preparedness Manual
- ORAU Health and Safety Manual
- ORAU ISMS Program Description
- ORAU Radiation Protection Manual

The corporate-wide procedures in these second tier documents flow down as necessary to third tier, organization-specific procedures. For example, ORAU uses the ISM Pre-Job Hazard Checklist, an ISM Plan for New or Modified Work, or a Health and Safety Plan to plan, schedule, and provide resources for work.

4.4 Integrated Management and Assurance (IM&A) Systems

The foundation of programmatic and business support operations is excellence in safety, security, quality, and diversity. Virtually all ORAU work involves multiple organizations that contribute to the accomplishment of the work. Building on this foundation and organizational involvement, line managers

carry out their program, project, and business duties through existing formal and informal integrated management and assurance systems.

Integrated management systems are those processes and activities that incorporate the following essential business functions into program and project management:

- Integrated safety management system
- Environmental management
- Emergency management
- Security to include physical security, personnel security, and cyber security
- Financial management
- Procurement
- Facility management
- Legal counsel
- Human resources to include diversity
- Occupational health
- Subcontractor oversight

Assurance systems are those processes and activities that ensure compliance with applicable requirements, address continuous improvement, facilitate identification and correction of deficiencies, and verify the completion of correction actions. Such assurance processes and activities include the following:

- Management oversight
- Policies and procedures
- Quality assurance
- Internal audit
- Functional self-assessments
- Programmatic quality assessments
- Lessons learned
- Risk management

Line managers are responsible for managing programmatic and business support operations. The use of integrated management systems, aside from being a good business practice, improves the likelihood that line managers will deliver a satisfactory product or service. An assurance system will provide the framework for line managers to validate compliance, quality, and effectiveness.

An example of integrated management in action is the hiring of a subcontractor to supplement an organization's staffing. In this case, the Procurement Department and the Safeguards and Security Department (S&S) are involved to acquire and badge the staff. Additionally, the Information Systems Department (ISD) also sets up the new staff person with computer access and equipment as needed, while the Office of Human Resources (HR) provides required technical and administrative training.

Similarly, each of the above business functions and assurance activities are complementary; for example, ISMS is a safety assurance system in that its goal is to ensure that safety is woven into all work activities. Further, the ISMS contributes to the overall quality and assurance of quality of ORAU's products and services, such that all work resulting in a product or service must be performed safely. ISMS and quality assurance share a general approach to implementation, as depicted and discussed in more detail in Section 6.

5. PERSONNEL TRAINING, QUALIFICATION, AND PERFORMANCE MANAGEMENT

ORAU maintains policies, procedures, and programs to ensure that both new hires and current employees have and maintain the skills needed to perform their duties and responsibilities (see HR 400, Staffing; Attachment 2, Recruitment, Employment, and Placement Guidelines for Supervisors). In addition, every position description (also known as a position questionnaire) includes the minimum applicable requirements for education, experience, and skills.

New employees must meet the requirements of the job for which they are being hired. The hiring process includes required interviews and reference checks. New employees are given a security briefing, an overview of ORAU policies and procedures, and environment, safety, and health training. Additional training is provided as required to ensure that all personnel are qualified to do the specific tasks required by their position.

Annually, or as frequently as needed, HR conducts a training needs assessment of all employees and their managers. The results are compiled in an annual training catalog that is used to ensure that ORAU meets the training and development needs of its employees. HR documents employee attendance at internal and external training courses, which are tracked by type, including environment, safety, and health; safeguards and security; compliance; and computer skills.

HR also tracks information on hours of training and training-related costs, including administrative, development, delivery, travel, and materials and supplies. ORAU Policy HR-810, Human Resources Development, and the Human Resources Development Plan, both of which are available to employees, describe HR's activities and explain how employees might benefit from them. Training points of contact across the organization serve as liaisons between HR and departments and programs.

Training goals, lesson plans, and related training materials are updated as needed, and the instructors possess the necessary knowledge, experience, and training skills to ensure effective training sessions. Training participants are asked to evaluate courses and instructors as appropriate to help HR improve the training programs. A variety of other processes and programs promote the development and maintenance of job skills. These include the developing job system that prepares employees for positions of greater responsibility, educational assistance that reimburses employees for courses successfully completed outside working hours, and professional memberships that provide each employee one membership a year in an organization specifically related to the employee's position and responsibilities. Second memberships are available as justified and approved by management. In addition, HR makes available to employees several hundred books, audio and videotapes, and periodicals on a wide range of professional and business topics.

ORAU maintains a performance management system for all full-time and part-time regular employees who have been at ORAU for over six months. The system operates on an annual cycle that begins with the employee and his or her manager completing an Individual Performance Plan (IPP) that sets out the manager's expectations of the employee for the coming year. Expectations include those that are ORAU-wide (e.g., commitment to safety and continuous improvement), unit-specific, and employee-specific, including developmental opportunities. The plan can be changed during the year to add, delete, or modify expectations. The manager evaluates the employee's performance during an informal mid-year review and a formal year-end review.

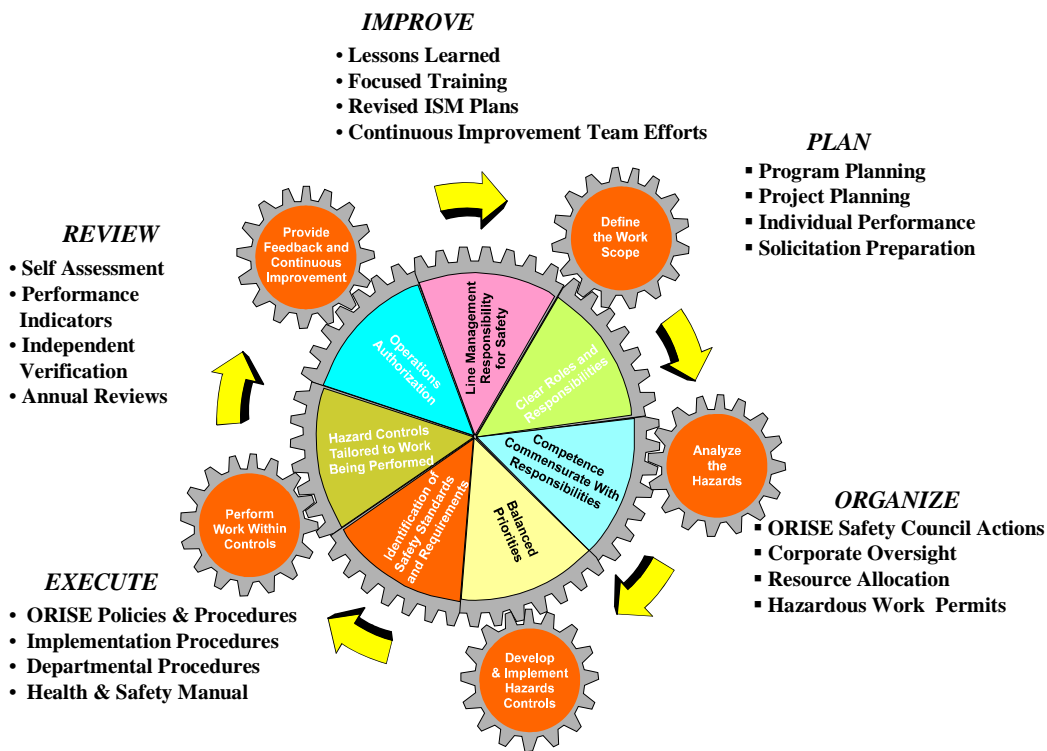
6. QUALITY IMPROVEMENT

Managers are responsible for continuous improvement of work processes, products, and services; and they encourage employees to explore and suggest ways to improve them. The following continuous improvement and related performance expectations are part of a baseline for fully performing behavior for all employees at ORAU and are contained in the individual performance plans. These expectations are in addition to every employee being empowered to stop or suspend work if an unsafe condition or serious hazard is suspected or discovered.

- **Continuous Improvement:** Continuously improves the quality of products and services to ensure customer satisfaction, including lessons learned feedback.
 - Uses CI tools to measure customer satisfaction and improve processes, products and services.
 - Takes responsibility for personal growth and development.
 - Focuses on implementing solutions rather than focusing on problems.
- **Initiative:** Initiates action to meet the organization's goals within the scope of the job.
 - Takes initiative to identify/develop/support new and ongoing business opportunities.
 - Explores creative and innovative methods.
 - Maintains regular attendance and fitness for duty.
 - Accepts challenges and changed roles as opportunities.
 - Effectively handles multiple tasks.
- **Teamwork:** Develops productive work relationships with colleagues.
 - Puts organizational interests ahead of personal gain.
 - Effectively manages or resolves conflict.
 - Partners with others to optimize opportunities and results.
 - Meets agreed upon milestones and deadlines.
 - Follows through on commitments.
- **Communication:** Effectively interacts with others to send and receive information.
 - Takes responsibility for seeking and/or sharing appropriate information.
 - Chooses appropriate channels for communicating.
 - Presents messages clearly and effectively (orally and in writing).
 - Uses communication technology effectively.

Managers document, evaluate, and report problems of more than routine importance to the next level managers and to ORAU employees with the necessary expertise to address them. Corrective actions for environment, safety, and health deficiencies discovered by ORAU employees are entered in the Safety Corrective Action Tracking System (SCATS), where they are tracked until the required corrective action has been completed and verified. The Environment, Safety, and Health Office (ESH) director is responsible for the data entry and maintenance of SCATS.

Externally identified deficiencies, recommendations and opportunities for improvement are also included and tracked in the SCATS database. Formerly, externally identified items were tracked in a separate system, but recently the two systems have been combined into the SCATS process. In addition to the deficiency identifier, the revised SCATS database contains fields listing the issue/concern, location, person responsible for corrective action, dates (identified, planned and actual closure), and closure confirming official.



ORAU contends that a fully functional corrective action tracking process is a vital component of a successful Integrated Safety Management (ISM) System and stands firmly committed to its principles and core functions. ORAU relies on a combination of line management leadership and employee involvement to drive quality improvement focusing on attitude, awareness, and action as the key outcomes and measures of success. Both ISM and QAP implementation depend on our management commitment, successful communication, and dedication to feedback and improvement for continued success. Specific items used to ensure that the ISM Guiding Principles and Core functions are followed include an ISM Plan for New or Modified Work, or in the case of construction, maintenance, or maintenance-like projects, a formal Health & Safety Plan (see Work Processes below for more details).

The ISM Guiding Principles and Core Functions work together to provide an effective model for performing work safely. The principles power the functions, and the functions engage the principles as a process for continuous flow of safe and productive work. As depicted below, the ORAU business management cycle (plan, organize, execute, review and improve) readily aligns with the ISM Guiding Principles and Core Functions.

ORAU Policy ESH-150, Lessons Learned Program, plays an integral role in ISM by identifying, documenting, evaluating, and disseminating the salient positive and negative experiences gained at ORAU and other organizations that also can promote safe and productive workplaces elsewhere.

Other interlocking QA and ISM programs and processes that promote continuous improvement include near-miss reporting, self-assessments, occurrence reporting, environment, safety, and health performance measures, Safety Council meetings, site safety representative program, and safety presentations at staff meetings. Each is presented in greater detail in ORAU Policy ESH-150 or related policies.

Further, in an overarching role to quality improvement and assurance, the ORISE Integrated Management and Assurance (IM&A) Program Description details ORISE’s management functions and assurance processes that integrate key performance elements and business support operations into the management of programs and projects. This results in a management system that assures compliance, continuous improvement, identification and correction of deficiencies, verification of corrective actions and the sharing of lessons learned effectively across all aspects of operations.

7. DOCUMENTS AND RECORDS

Policies and procedures provide the expectations and guidance for ORISE staff to carry out their assigned mission and tasks. There are over 100 ORAU/ORISE policies and procedures, some of which describe ORISE assurance systems; for example, quality assurance in GP-810, excellence in operations in GP-800, directives management in GP-1200, delegation of approval authority in GP-190, and business continuity in GP-722.

Moreover, each program and department has developed its own procedures and tools for its staff. The level of detail and formality is based on safety, risk, and operational need. Some procedures are very simple and less formal (e.g., weekly notification for refrigerator cleanout), while others are very detailed and formal (e.g., the analysis of radiological samples).

Under the comprehensive ORAU Policy FM-800, Records Management, the ORAU records manager works with records custodians throughout the organization to ensure that ORAU complies with DOE directives and related federal regulations, standards, and guidelines, including those of the National Archives and Records Administration.

Documents are reviewed and approved as outlined in ORAU Procedure GP-190, Delegation of Approval Authority. Both FM-800 and GP-190 are consistent with all DOE and ORO requirements for records management and authorized approvals. In addition, administrative controls are provided by a hierarchy of up-to-date policies and procedures described in ORAU Policy ADM-200, Policy and Procedure Issuing System, and companion policies in the ADM series.

All employees are responsible for following the policy's procedures when generating and processing records.

8. WORK PROCESSES

Whenever a program or department is planning new work or modifying existing work, the responsible manager completes an ISM Pre-Job Hazard Checklist prior to beginning the work, unless that work does not differ substantially from the work basis for the program/department's existing hazard analysis. The purpose of this document is to serve as a hazard assessment of the work to be performed. However, it is not intended to be used as a plan or a work process control document. If a plan is required, the responsible manager must complete an ISM Plan for New or Modified Work or, in the case of construction, maintenance, or maintenance-like projects, a formal Health & Safety Plan may be substituted.

The ESH Director, or his subject matter expert designee, is required to review and approve each completed ISM Pre-Job Hazard Checklist, ISM Plan for New or Modified Work, or Health & Safety Plan. The approval of any of these documents consists of a series of reviews for appropriateness, completeness, standards used, and controls imposed.

In addition, managers extend the ISM guiding principles and core functions to include cooperation with workers on improving all work processes. ORAU holds its employees responsible for performing their work correctly, sharing their experiences and ideas for improving work processes with managers and fellow employees, and protecting all property they use in the course of their work.

This QAP relies on feedback and improvement measures that identify and correct potential shortcomings in work processes. Some of these measures include:

- All work at ORISE is conducted in a manner that protects federal property, as described, for example, in ORAU Policy LEG-124, Reporting of Fraud, Waste, and Abuse, and ORAU Policy FM-700, Property, Inventory, and Materials Management, with its accompanying implementation plans.
- The ORAU lockout/tagout program, described in the Health and Safety Manual, complies with 29 CFR 1910 and 29 CFR 1926 regulations, and is designed to protect personnel from injury, prevent property damage, and maintain operability of plant systems.
- Abnormal events are reported and investigated in keeping with directive DOE O 231.1A, Environment, Safety, and Health Reporting, as implemented by the occurrence reporting procedure in the Health and Safety Manual.
- DOE Standard DOE-STD-1035, Guide to Good Practices for Logkeeping, provides guidance on QA aspects of maintaining logbooks.
- All ORAU facilities are equipped with public address systems, or managers and site safety representatives have been issued bullhorns and been trained in their use and maintenance, for use in emergency situations. As appropriate to their responsibilities, FTD and ESH staff members are issued cellular telephones or radios to ensure they are available without delay when needed.
- ESH policies and procedures require the proper labeling and storage of all laboratory chemicals, radioactive materials, and laboratory samples; each item is assigned a unique identification number for tracking and control. Each sealed radioactive source that is classified as being a nonexempt quantity must be logged out prior to removal from its approved storage location and logged in upon its return.
- Laboratory equipment is maintained and routinely calibrated in accordance with regulatory requirements, manufacturers' guidelines, best business practices, and any customer specifications. Authorized government or commercial calibration facilities are used as required. For example, some radiological instruments are recalibrated annually while others in process control systems are recalibrated if the process strays from the acceptance range. When possible, calibration sources are traceable to the National Institute of Standards and Technology (NIST). If NIST-traceable standards are not available, calibration sources provided by organizations generally recognized by the health physics community may be used.

9. DESIGN

ORAU has established a design process in the FTD Facilities Management Section (FMS) that provides control of design inputs, outputs, verification, changes, and technical considerations, appropriate to the type and complexity of the design. All design work is based on safety requirements, sound engineering judgment, scientific principles, and applicable codes and standards. The design of structures, systems, and components is subject to definitive design process control and verification requirements as established by the local authority having jurisdiction.

In all cases, designs provide for appropriate inspection, testing, and maintenance to ensure continuing reliability and safety of the facilities. Design records can include documentation of design input, calculations and analyses, engineering reports, design output, design changes, and design verification activities.

Design input is based upon mission requirements, DOE contractual requirements, and customer expectations, and includes such information as health and safety considerations, environmental considerations, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements.

The ORISE design process translates design input into design output documents that meet established objectives. During the design phase, critical issues related to performance, safety, or reliability of the designed systems are identified. Design output documents are also prepared to support other processes, such as risk assessments. When appropriate, design documents are reviewed by ORISE ESH office subject matter experts before finalization.

FMS performs design analyses and checks to ensure that design output documents meet design input requirements and that any changes have been approved and documented. The completed designs are recorded in design output documents, such as drawings, specifications, test/inspection plans, maintenance requirements, and reports. As-built drawings are maintained after construction to show actual configuration.

Design verification is a documented process that ensures that the resulting designed systems comply with the identified requirements. Design verification methods include technical reviews and peer reviews.

Field changes are controlled by design and review processes commensurate with those applied to the original design. During construction, inspections are conducted to assure that only specified equipment and components are purchased and installed.

10. PROCUREMENT

The Procurement Department's QA program is designed to ensure that products and services acquired in support of ORAU activities are customer focused and performance based and that they advance DOE's socioeconomic and environmental objectives.

Purchasing procedures comply with DOE's contracting requirements and other government regulations. These written procedures define the relationships among ORAU requisitioners, procurement staff, and DOE representatives.

As appropriate to the product or service being procured, requisitioners prepare preprocurement documents that specify the following:

- Scope of work
- General QA requirements
- Safety requirements
- Required documentation
- Technical requirements
- Special QA requirements (e.g., inspections)
- Right of access
- Nonconformance controls

Qualified procurement staff evaluate a potential supplier's capability to provide a product or service of acceptable quality at the most economical cost. Suppliers are evaluated on their ability to comply with project requirements specified in procurement documents. ORAU's experiences with suppliers (e.g., customer ratings) play a key role in this evaluation. Requisitioners and procurement staff, assisted as needed by technical personnel, follow written procedures in reviewing potential suppliers' proposals against ORAU requirements.

A number of factors are considered, depending upon the product or service:

- Technical considerations
- Environment, safety, and health requirements
- Supplier's QA plan
- Supplier's prior performance
- QA requirements
- Supplier's personnel qualifications
- Supplier's production capability
- Reasonableness of cost

Subcontractors and suppliers are informed of ORAU and DOE requirements in the ORAU/ORISE Visitor and Subcontractor Handbook and are held responsible for meeting these requirements. Upon delivery of goods, procurement staff review the supplier-generated documents (including certifications) for completeness and conformance to contract requirements. The staff validate any certifications by independent analyses or inspections, as required by requisitioners, and they document the results. The extent of analyses and inspections depends upon a supplier's prior performance, quality requirements, lot size, and other factors.

ORAU and its suppliers agree upon and document the disposition of goods and services that do not meet contractual requirements.

The ORAU radiation safety officer must approve all purchase requisitions for radioactive materials, and the ORAU environmental/hygiene officer must approve all purchase requisitions for laboratory chemicals. Chemicals will not be accepted if not accompanied by a Material Safety Data Sheet (MSDS) if the chemical's MSDS is not on file.

The Procurement organization works in conjunction with FTD and ESH to ensure that only correct and accepted materials, parts, and assemblies are purchased or used.

11. INSPECTION AND ACCEPTANCE TESTING

ORAU inspects and/or tests specific components, equipment, and systems in accordance with manufacturers' specifications and in compliance with the regulatory requirements and DOE guidelines; and best business practices. The preventive maintenance program covers key equipment and systems, including elevators; heating, ventilation, and air conditioning systems; boilers; fire safety systems; eye washes and safety showers; emergency generators; emergency lighting; chemical fume hoods; roll-up doors; rotating equipment; ladders; electrical tools; and building envelope, electrical, and structural components. Preventative maintenance inspections and tests are conducted and documented by technically qualified employees.

Project engineers identify key components when they are installed. Key components are inspected to ensure that they meet the operating specifics per the operating criteria for each item at that time. ORAU calibrates key equipment, with special attention to the accuracy and reliability of radiological instruments on the schedule recommended by the manufacturer. Dosimetry services are routinely tested by the submission of spikes and background blanks to ensure accuracy of a vendor's services. ORAU retains a vendor for dosimetry services that is certified by the National Voluntary Laboratory Accreditation Program. Procedures for testing and inspection are maintained in the FTD/FMS Safety Procedures.

Other forms of inspection and acceptance testing include piloting training programs conducted internally by HR, ISD's testing of project and financial database components and upgrades, and those conducted for various clients; in both cases, the training material is tested to ensure its accuracy and instructional effectiveness. Another very common type of inspection and acceptance testing is the "dry run" process many managers and staff use to improve and practice presentations.

12. MANAGEMENT ASSESSMENT

12.1 Introduction

ORAU management oversees all its activities to ensure that the company meets regulatory standards, best business practices, customer expectations, and the provisions of this policy. A key element of this

oversight is the use of objective, clearly defined, and results-oriented performance measures to gauge how well organizational units are meeting their goals and objectives and contributing to those of ORAU.

All managers personally assess how well their organizations meet their expectations. Managers may invite other employees from their own or other organizational units to participate in these assessments, but the manager's personal involvement in every stage of these assessments is essential. The responsibility to keep abreast of an organization's performance cannot be delegated.

Managers use information from all internal and external sources (such as direct observations; self-assessments; external environment, safety, and health reviews; customer and employee interviews; regularly scheduled and unannounced walkthroughs; and results of drills and exercises) to identify their organization's vulnerabilities, weaknesses, strengths, and opportunities for improvement.

12.2 Internal Audits

ORAU Audit Services, under the direction of the Chief Audit Officer, assists upper management by examining and evaluating management systems throughout ORAU; suggesting how they might be improved; and recommending ways, where needed, to achieve compliance with applicable laws, regulations, contracts, DOE directives, professional standards, and best practices. Deficiencies are tracked until corrected in the Audit Services tracking system. The auditor functions independently from other ORAU activities and has access to all relevant records and property. Audit resources are allocated in accordance with estimated levels of risk across the range of auditable functions and activities; audits are scheduled and the schedule published on the ORAU intranet. ORAU Policy GP-705, Audit Operations, describes the scope of these activities and the annual audit plan under which they are conducted.

12.3 Self-Assessments

ORAU benefits from a hierarchy of self-assessments. While those described here focus on environment, safety, and health areas, the value of self-assessments is applicable throughout ORAU.

- 1) The individual employee is the first level of assessment. Workers are charged with the responsibility of working safely and productively and of reviewing their equipment and workplaces for nonconforming conditions and opportunities for improvement. Employees who have been designated site safety representatives or alternates have a higher degree of responsibility for day-to-day awareness of environment, safety, and health conditions in the workplace.
- 2) Managers are responsible for continual assessment of their unit's performance. They conduct periodic walkthroughs of their areas of responsibility at frequencies commensurate with a graded approach. Results are reported to higher managers and to the unit's workers.
- 3) Designated managers appoint site safety representatives and alternates and conduct walkthroughs during the first month of each quarter. environment, safety, and health deficiencies are reported to ESH for entry into SCATS, and maintenance concerns are reported to FTD for correction. Experiences worthy of being shared with others are reported to the lessons learned manager. Managers are encouraged to ask other managers to accompany them on walkthroughs so they might benefit from the expertise, perspectives, and experiences of others.
- 4) ESH staff conduct walkthroughs in all ORAU facilities during the second month of each quarter, periodically accompanied by site safety representatives and line managers. Findings and observations, favorable and unfavorable, are shared with managers. Deficiencies are entered into SCATS.
- 5) ESH staff conduct special self-assessments, as needed, during the third month of each quarter that focus on topical areas like ergonomics, indoor air quality, and equipment calibration.

- 6) The Environmental Review Team (ERT) conducts a comprehensive review of the ORAU/ORISE Environmental Management System (EMS) every three years combined with annual overviews of individual sections of the program. If major conditions change in the organization, the ERT will perform a full review of the EMS and make recommended changes to the program. The comprehensive review shall include, but not limited to:
 - a) results of internal audits and evaluations of compliance with legal requirements, and with other requirements to which the organization subscribes,
 - b) communication(s) from external interested parties, including complaints,
 - c) the environmental performance of the organization,
 - d) the extent to which objectives and targets are met,
 - e) status of corrective and preventive actions,
 - f) follow-up actions from previous management reviews,
 - g) changing circumstances including developments in legal and other requirements related to the environmental aspects, and
 - h) recommendations for improvement.

The output from these reviews will include any decisions and actions related to any possible changes to the ORAU/ORISE Environmental Management Policy (ESH-112), or aspects, impacts, objectives, targets, and other elements of the EMS consistent with continual improvement.

All resources and conditions that affect quality are included in these assessments, including employees' abilities and training, condition of work areas, degree to which needed information is communicated throughout the organization, and the adequacy of equipment and other material resources. Employees who conduct walkthroughs and self-assessments must have the training and experience commensurate with the scope, depth, and any special nature of the activities being reviewed.

Communicating the information generated during these self-assessments helps assure all employees that management remains dedicated to providing safe workplaces through unyielding adherence to the ISM core functions and guiding principles. Results of these assessments are also used directly as performance measures.

12.4 Performance Measures

Performance measures (and metrics) are key components of performance-based management, and they provide managers with objective gauges of how well their programs are meeting expectations. Measures are tools that drive actions toward meeting goals. These measures also provide accountability to customers, help justify changes in programmatic funding, encourage decision-making based upon demonstrable facts, reveal where improvements need to be made and whether prior improvements are working, improve communications among employees, compare competing systems, and document accomplishments.

A good performance measure is clearly defined, indicates how well a specific goal or objective is being met, is acceptable and meaningful to its users, responds promptly to changing conditions, depicts trends reliably, allows for economical data collection, and is simple, understandable, logical, and repeatable.

Strategic planning emphasizes the importance of performance measures in implementing long-term goals and their shorter-term underlying objectives. Performance measures established by upper management to help achieve strategic goals cascade to lower levels, with the result that individual workers can use job-related metrics to measure their own performance.

ORAU and ORO annually agree upon a set of organization-wide performance measures that convey maximum information at affordable cost. DOE establishes in the ORISE Performance Evaluation Plan the major performance objectives, measures, targets and percentage of award fee available to each of the critical areas (identified by the DOE Office of Science): science; leadership; environment, safety, and health; infrastructure; business operations; and stakeholder relations. ORAU conducts a self-assessment to measure its performance and submits it to DOE at the end of the contract performance period, which is used in part by DOE as a basis to rate ORISE's performance.

12.5 Communication

Integration of quality principles, processes, and information across an organization is just as important as vertical integration of responsibilities through the flow-down provisions in policies and procedures. This is accomplished primarily by the following methods of communication:

- *Newsline*, ORAU's daily electronic bulletin board, delivers to every employee a schedule of ongoing and upcoming events, important announcements, training opportunities, and other information they need to perform their work effectively.
- *ORAU Shortcuts*, ORAU's intranet site, facilitates communication throughout the organization by providing up-to-date information on a variety of topics. It also has two features of special interest in the QA context.
- *How to Raise an Issue* allows employees to ask questions, anonymously if they prefer, on any appropriate employment-related topic and receive answers from the President and other senior managers.
- *Safety 1st* provides access to SCATS and the lessons learned program, serves as a portal to DOE and other agency Web sites, and invites users to explore emergency procedures, safety alerts, environment, safety, and health training documents, ISM plans, safety job aids, environment, safety, and health performance measures, and other QA and safety topics.

QA information is communicated across the organization in regular staff meetings convened by managers, and in crosscutting staff meetings convened by senior managers such as:

- Corporate Leadership Team (President, GC, Vice President for BusOps, Vice President for Partnership Development, and CDHR) meets twice monthly to discuss strategic issues that cross organizational lines.
- Quality Management Team (Vice President for BusOps, department directors, and other appointed persons) meets twice monthly to share information and discuss cross-organizational issues.
- Leadership Team meeting for members of Corporate Leadership Team, Quality Management Team, program directors, HR directors, and other employees appointed by the President is convened monthly to share information. Performance metrics are featured at each meeting.
- Program Directors meet regularly with the ORISE Director.
- Safety Council (members of Corporate Leadership Team, Quality Management Team, program directors, site safety representatives and alternates, and other persons with environment, safety, and health responsibilities appointed by the President) meets regularly to share information, review environment, safety, and health performance measures, mark ISM accomplishments, and discuss safety initiatives.

13. INDEPENDENT ASSESSMENT

DOE personnel conduct various assessments of how well ORISE performs. ORAU welcomes these visits, and the results help ORISE managers improve their operations. ORISE, and thus DOE, also benefit from assessments conducted by other external authorities.

Not all independent assessments are conducted by external authorities. ORAU managers can arrange with other managers, or contract with outside vendors, for independent assessments of unit operations. Managers can learn much about their operations from independent evaluations that focus on either broad, goal-oriented, performance issues or on narrow, task-specific concerns. The need for an independent assessment, a “fresh pair of eyes,” can be one result of the management assessments described in the preceding section. Senior managers encourage, and may require, independent assessments, or managers may propose assessments on their own initiative.

While independent assessments can be used to confirm or address findings of management’s self-assessments, they are particularly useful in identifying opportunities for improvement. Whatever the reason for scheduling an assessment, it is imperative that managers and external assessors agree upon the purpose, scope, and duration of the assessment; the technical qualifications of the assessors; the persons who will brief or escort the assessors; and the timing and nature of oral and written reports of the assessment. The assessors, of course, should have no personal or business interest in the outcome of their assignment.

ORAU can not control the frequency of external assessments, but managers can schedule the ones they organize to meet a unit’s specific needs. The frequency of independent assessments depends upon the type of work performed and the performance record of the organization being assessed. The manager of a complex operation with stringent QA requirements and demanding customers probably would benefit more from frequent independent assessments than would a manager of a less demanding program. Assessment results that confirm acceptable performance in a particular area might suggest a reduction in scope and frequency of subsequent visits, while areas of poor or questionable performance might receive even greater attention.

14. PREVENTION AND CONTROL OF SUSPECT AND COUNTERFEIT ITEMS

FTD and ESH conduct a suspect and counterfeit items (S/CI) identification process commensurate with the risks posed by the ORISE facility to ensure that the controls are appropriate to the circumstances. Major components of the process include training, inspection, identification, and reporting (from ESH-100). In addition, the ORAU Implementation Manual, Procurement Services, Guidelines and Procedures Manual) states that:

1. Unless otherwise specified in the purchase order or subcontract, all items being supplied must be new, and not reconditioned or repaired.
2. Qualification can be obtained through audits coordinated with ORAU/ORISE quality assurance representatives or by accepting evidence of qualification from another DOE facility, DOE contractor, or other nationally recognized organization.
3. During receipt inspection of items subject to counterfeiting, the technical representative accepting the parts or material should provide verification testing on a sampling basis either at ORAU/ORISE or by a qualified independent test laboratory.
4. Appropriate verification testing should be addressed in the technical specification of work issued by the technical representative.

5. Buyers/Contract Specialists should advise bidders/offerors of suspect/counterfeit parts' material problems.
6. Buyers/Contract Specialists shall document and notify the Procurement manager of any suspected or actual occurrence of counterfeit parts.
7. Buyers/Contract Specialists should advise cognizant technical personnel to report any actual or suspected nonconformance to Procurement.
8. Buyers/Contract Specialists should develop a qualified suppliers list when deemed necessary to support the procurement mission.

15. SOFTWARE QUALITY ASSURANCE

ORAU Software Quality Assurance Policy (CT-215) defines requirements and responsibilities for software quality assurance (SQA), both commercially obtained and custom developed. All software applications and databases purchased or designed, developed, and maintained by ORAU are subject to an SQA program managed by ORAU's ISD, whereby ISD QA makes certain that any system bought or built competently fits the purpose for which it was intended, adds value for the investment, and is within the constraints of any installation, legal, or other standards. ORAU's assurance of quality includes verifying (1) that correct procedures for purchase or development have been followed; (2) that the code has been constructed and functions to specifications; and (3) that any user and technical documentation is complete, consistent, and adequate to understand what was built and how it could be changed in the future. All software and database engineering follows identified standards and best practices throughout the project and product lifecycle as specified by the guidelines and forms referenced by this policy.

16. QAP REVIEW

The Director, Integrated Management and Assurance conducts an annual review to ensure the accuracy of the QAP. Any changes are submitted to DOE for review and approval.

17. CONCLUSION

ORAU believes that implementing a comprehensive management system that includes a sound QAP will contribute to improved safety performance, management effectiveness, and reliability of products and services. ORAU's management systems contain quality requirements interwoven throughout and include criteria for planning, implementing, and assessing work. As such and as noted earlier, the QAP is an integral part of the ORISE Integrated Management and Assurance Program that establishes a systematic process to integrate key performance elements and business support operations into the management of programs and projects and to provide a management system to assure compliance, continuous improvement, identification and correction of deficiencies, and verification of corrective actions.

18. ABBREVIATIONS AND ACRONYMS

BusOps	Business Operations	ISM	Integrated Safety Management
CDHR	Corporate Director for Human Resources	MSDS	Material Safety Data Sheet
CEO	Chief Executive Officer	NOAA	National Oceanic and Atmospheric Administration
CFO	Chief Financial Officer	NRC	Nuclear Regulatory Commission
CPD	Communications, Printing, and Design Department	NSEM	National Security and Emergency Management

DOE	Department of Energy	OEWB	Occupational Exposure and Worker Health
EMS	Environmental Management System	ORAU	Oak Ridge Associated Universities
ERT	Environmental Review Team	ORISE	Oak Ridge Institute for Science and Education
ES&H	environment, safety, and health	PTT	Professional and Technical Training
ESH	Environment, Safety, and Health Office	QA	quality assurance
ESSAP	Environmental Survey and Site Assessment Program	QAP	Quality Assurance Program
FinOps	Financial Operations Department	REAC/TS	Radiation Emergency Assistance Center/Training Site
FMS	Facilities Management Section	REM	Radiation Emergency Medicine
FTD	Facilities and Transportation Department	SCATS	Safety Corrective Action Tracking System
GC	General Counsel	S/CI	suspect and counterfeit item
HR	Human Resources	SEP	Science Education Programs
IEAV	Independent Environmental Assessment and Verification	SGS	Safeguards and Security Department
IM&A	Integrated Management and Assurance	SQA	software quality assurance
ISD	Information Systems Department	STRI	Scientific and Technical Resources Integration

Policy GP-810, Quality Assurance

Summary of Changes