

ORAU POLICY AND PROCEDURE

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ATTACHMENT 1

ORISE QUALITY ASSURANCE (QA) PROGRAM

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QUALITY ASSURANCE PROGRAM (QAP)

November 1, 2002

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QUALITY ASSURANCE PROGRAM (QAP)

1. PURPOSE AND SCOPE

This plan 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. The ORAU QAP Plan complies with 10 CFR 830.120, Subpart A.

2. REFERENCES

10 CFR Part 830, Subpart A, Nuclear Safety Management
DOE G 414.1-2, Quality Assurance Management System Guide
DOE G 450.4-1A, Integrated Safety Management System Guide
DOE O 232.1A, Occurrence Reporting and Processing of Operations Information
DOE O 414.1A, Quality Assurance
DOE 5480.19, Conduct of Operations Requirements for DOE Facilities
DOE-STD-7501, DOE Corporate Lessons Learned Program
ORAU Integrated Safety Management Program Description
ORAU Policy GP-800, Excellence in Operations
ORAU Policy HR-400, Staffing
ORAU Policy GP-190, Delegation of Authority
ORAU Policy FM-800, Records Management
ORAU Policy GP-810, Quality Assurance
ORAU Radiation Protection Manual
ORAU/ORISE Visitor and Subcontractor Handbook
ORAU Policy GP-750, Audit Operations
ORO O 230, Chapter I, Chg. 3, Environment, Safety, and Health Program for Oak Ridge Operations
ORO O 420, Chapter IV, Chg. 2, Conduct of Operations Requirements for DOE Facilities
ORAU Strategic Plan

3. DEFINITIONS

Benchmarking: process of measuring an organization's performance against the performance of organizations judged to be the best in the area being measured.

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. Best practices are not keyed to laws or regulations, and a best practice's effectiveness must be based upon measured performance and be well-documented.

Conduct of operations: method for ensuring that work is performed in a formal, ethical, and disciplined manner to enhance safe and efficient management of activities and to achieve excellence.

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.

Corrective Action Report (CAR): document describing an environment, safety, and health (ES&H) or a quality assurance (QA) deficiency and how its superficial and underlying causes will be rectified in timely fashion to prevent recurrence.

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.

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 adjusts the costs of compliance to the benefits attained.

Lesson learned: documented positive or negative performance, experience, or practice that is shared to promote continuous improvement and prevent mishaps.

Manager: person with authority delegated by, or on behalf of, the ORAU president to manage an ORAU program, project, or organizational unit.

Management oversight: systematic process of using self-assessments and performance measures to gather, interpret, and communicate information related to performance, and of taking appropriate actions (e.g., CARs) that lead to continuous improvement in performance.

Near-miss: event that does not cause illness or injury but raises the possibility of a recurrence that could cause illness or injury.

Occurrence report: information submitted to DOE in accordance with directive DOE O 232.1A (Occurrence Reporting and Processing of Operations Information).

Performance measure: quantitative value used to gauge the degree to which an organization has achieved a goal.

Person responsible: employee (never more than one) with responsibility for implementing a CAR. 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.

Quality: degree to which an item, service, or process meets or exceeds the user's requirements and expectations.

Quality assurance (QA) : actions that provide confidence that quality will be achieved.

Root cause: underlying event or condition giving rise to a deficiency, the prevention of which will preclude a recurrence of the deficiency.

Safety Corrective Action Tracking System (SCATS): documented procedure for the systematic tracking of actions taken to correct ES&H deficiencies reported by both ORAU employees and external sources.

Self-assessment: process by which an ORAU employee determines and documents whether facilities, equipment, processes, and activities within an area of responsibility meet specified requirements related to their intended performance.

Walkthrough: inspection of facilities and operations by managers, site safety representatives and alternates, or ES&H specialists that documents the status of ES&H compliance.

4. MANAGEMENT ORGANIZATION AND PROCESSES

Established in 1946, ORAU is a private, not-for-profit corporation and a consortium of 86 doctoral-granting colleges and universities. 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 Department of Energy (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 manage the Oak Ridge Institute for Science and Education for the U.S. Department of Energy and to promote collaborative partnerships with universities, federal laboratories, and industry for the benefit of member institutions.”

The ORISE mission is to advance science and education in three key ways: assess and analyze the environmental and health effects of radiation, beryllium, and other hazardous materials; develop and operate medical and national security radiation emergency management and response capabilities; and manage educational programs to ensure an adequate supply of scientists, engineers, and technicians to meet future science and technology missions. ORISE meets these challenges through continuous improvement in its seven core competencies:

- Conducting research and training in workforce health, safety, and security
- Providing worldwide emergency preparedness, response, and training
- Developing and implementing technical training systems
- Performing radiological and hazardous site characterization and cleanup verification
- Developing and administering science education fellowship and research participation programs
- Integrating scientific and technical resources to build multidisciplinary programs
- Creating collaborative research partnerships

The ORAU president serves as the ORISE director. The following key ORAU positions report directly to the president:

- Vice president for Partnership Development
- Chief audit officer
- Director, National Science Foundation (NSF) Graduate Research Fellowship Program

The following key ORAU and ORISE positions report directly to him as the ORAU president and the ORISE director:

- Vice president for Business Operations (BusOps) and chief financial officer
- Vice president, general counsel and ORISE deputy director
- Corporate director for Human Resources
- Director of Business Development
- Director of Environment, Safety, and Health
- Program directors (seven)

All of these positions entail QA responsibilities with corresponding opportunities for continuous improvement.

All QA duties are being managed by the Director of Environment, Safety, and Health on an interim basis. During the period until the QA Coordinator position is filled, or a reorganization of responsibilities is accomplished, all interfaces are handled at the Division Director level. Once this position is filled, the QAP will be revised and specific roles and responsibilities for QA will be revised.

4.1 Officers and Departments

Business Development office provides marketing, sales, and enterprise development services to ORAU, ORISE, and their programs.

Chief Audit Officer 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.

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

General Counsel's (GC) office 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/information systems, employment, occupational health, employee relations/EEO/AA/Diversity, and human resources development and performance.

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

Business Support Services Department (BSSD) supports business operations through budget development, financial analysis, travel reservations and policy, contract administration, and cost management.

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, and procures the highest quality goods and services in a cost-effective and timely manner.

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 competencies described above, some of which are shared by several of the programs.

Basic and Applied Research (BAR) conducts research to understand better the health effects related to energy technologies and occupational exposures and to advance our understanding of nuclear physics. Groups within BAR include the Center for Epidemiological Research and the ORISE Radioactive Ion Beam and University Radioactive Ion Beam Consortium, a joint enterprise it manages for 11 universities. Results of research projects are published in peer-reviewed professional journals.

National Security Operations (NSO) provides management and technical expertise in counter proliferation and counter terrorism activities and in human reliability studies and personnel security. Staff in the National Security Program are experts in operations planning, readiness preparation, and response to terrorist incidents involving weapons of mass destruction. The Center for Human Reliability Studies, which is a DOE Center of Excellence, 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.

Performance Systems (PS) 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. PS also provides comprehensive assistance in coordinating peer and merit review of research proposals for DOE and other agencies.

Radiation Emergency Response and Dose Assessment (RERDA) brings together the unique talents of the Radiation Emergency Assistance Center/Training Site (REAC/TS) and the Radiation Internal Dose Information Center (RIDIC) 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. REAC/TS also conducts training courses in medical management of radiation accidents. RIDIC develops and applies methods for internal dose assessment for intake of radioactive materials from accidents; terrorist incidents; and medical, occupational, and environmental exposure.

Radiological Safety, Assessments, and Training (RSAT) combines the survey activities of the Environmental Survey and Site Assessment Program (ESSAP) with the environmental training function of the Professional Training Programs (PTP). ESSAP provides DOE and the Nuclear Regulatory Commission with independent verification that radiologically contaminated sites have been remediated to regulatory standards. ESSAP participates in national programs that develop and update regulations and establish standard survey techniques and equipment. PTP has trained more than 30,000 persons in health physics and related courses in industrial hygiene and environmental monitoring. RSAT also provides scientific and support staff to NOAA's Atmospheric Turbulence and Diffusion Division for studies in atmospheric physics.

Science and Engineering Education (SEE) 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. SEE annually supports over 2,500 individuals in fellowship, scholarship, internship, research participation, and similar educational programs. SEE also conducts complementary research in workforce needs and in employment and degree trends.

Health, Safety & Emergency Management Program (HSE) applies its expertise on behalf of DOE in emergency management; industrial hygiene; environment, safety, and health (ES&H); occupational health; and database management. Innovative technologies are applied to enhance worker performance through distance learning, computer-based and multimedia training, and self study. ORISE's Emergency Management Laboratory is an integral part of the HSE program unit.

Another key ORAU program is not part of ORISE. The NSF Graduate Research Fellowship Program is the National Science Foundation's premier federally funded graduate research support program for individuals pursuing advanced degrees in science, mathematics, and engineering.

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 us 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.

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 quality 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 then are 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, five policies describe corporate-level ES&H goals:

- Policy ESH-100 Integrated Safety Management
- Policy ESH-110 Environment, Safety, and Health
- 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 three of those first tier policies are implemented by procedures in four second tier documents:

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

The corporate-wide procedures in these second tier documents flow down as necessary to third tier, unit-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.

5. PERSONNEL TRAINING, QUALIFICATIONS, 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, Attachment 2, Recruitment, Employment, And Placement Guidelines For Supervisors.) In addition, every position description 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 ES&H 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, the Human Resources Development and Performance Department (HRDP) 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. HRDP documents employee attendance at internal and external training courses, which are tracked by type, including ES&H, safeguards and security, compliance, and computer skills.

HRDP 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 the HRDP's activities and explain how employees might benefit from them. Training points of contact across the organization serve as liaisons between HRDP 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 HRDP 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. In addition, the HRDP Resource Room 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 ones 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

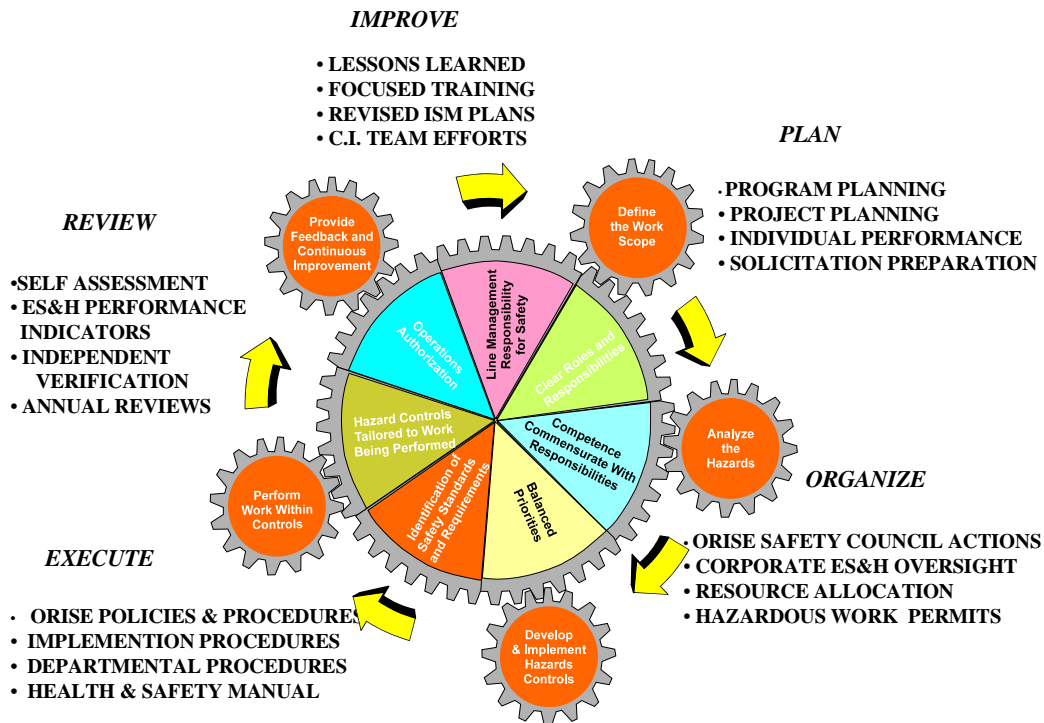
Managers are responsible for continuous improvement of work processes, products, and services; and they encourage employees to explore and suggest ways to improve them. In addition, every employee is empowered to stop or suspend work if an unsafe condition or serious hazard is suspected or discovered.

Managers document, evaluate, and report problems of more than routine importance to higher managers and to ORAU employees with the necessary expertise to address them. Corrective actions for ES&H 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 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. The ORAU business management cycle (plan, organize, execute, review and improve) readily accommodates and enhances the 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, ES&H 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.

7. DOCUMENTS AND RECORDS

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 must complete an ISM Pre-Job Hazard Checklist prior to the beginning the work. 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 the first time, 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 regulations 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 232.1A, Occurrence Reporting and Processing of Operations Information, as implemented by the occurrence reporting procedure in the Health and Safety Manual.
- Chapter XI, Logkeeping, of directive DOE 5480.19, Conduct of Operations Requirements for DOE Facilities, and standard DOE-STD-1035, Change 1, Guide to Good Practices for Logkeeping, provide 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. Radiological instruments are calibrated no less frequently than annually. 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. Authorized government or commercial calibration facilities are used as required.

9. DESIGN

ORAU has established a design process in the Facilities and Transportation Department (FTD) Facilities Management Section (FMS) that provides control of design inputs, outputs, verification, changes, and technical considerations, appropriate to the importance 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. In consideration of individual items, designs consider expected use and life expectancy in order to allow appropriate disassembly and disposal requirements to be addressed. Design records 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, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements.

The ORISE design process translates design input into design output documents that are technically correct and compliant with the end-user's needs. 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, including risk assessments, procurement, assembly, construction, testing, inspection, maintenance, and decommissioning. All design documents that are prepared by FMS are reviewed by appropriate 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, drawings, specifications, test/inspection plans, maintenance requirements, and reports. As-built drawings are maintained after construction to show actual configuration, clearly indicating responsibilities for design output documents that include mark-ups and updating during construction and operation phases and the requirements for document control and records management.

Design verification is a formal, documented process that ensures that the resulting designed systems comply with the identified requirements. Design verification methods include technical reviews, peer reviews, alternate calculations, and qualification testing. When appropriate, the verification process considers previous verifications of similar designs or verifications of similar features of other designs.

Design changes, including field changes and nonconforming items dispositioned for "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design. ESH and FMS provide guidance to help avoid the procurement and use of suspect/counterfeit items. Inspections are conducted to assure that suspect/counterfeit items are not used in all ORISE operations.

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
- ES&H 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.

Procurement works in conjunction with FTD and ESH to ensure that only correct and accepted materials, parts, and assemblies are purchased or used. ORAU Policy ESH-110, Environment, Safety, and Health, describes safeguards with respect to suspect and counterfeit parts.

11. INSPECTION AND ACCEPTANCE TESTING

ORAU inspects and/or tests key components, equipment, and process systems in accordance with manufacturers' specifications and in compliance with the regulations and guidelines of DOE; the Occupational Safety and Health Administration; and other agencies. The preventive maintenance program covers key equipment and systems, including elevators; lockout/tagout equipment; heating, ventilation, and air conditioning systems; boilers; fire safety systems; eye washes and safety showers; emergency generators; chemical fume hoods; roll-up doors; and waste holding tanks. The procedures for maintaining and calibrating equipment can be found in the ORAU Radiation Protection Manual (Section on Radiological Instrument Calibration and QA Checks).

All inspections and tests are conducted by technically qualified employees (see HR-400, Staffing) who are familiar with provisions of relevant codes, directives, standards, and regulations. These employees fully document their findings, which are reviewed for accuracy by the ORAU project manager. These technically trained employees also are qualified to calibrate and maintain equipment and processes used in performing tests and inspections. Individual qualifications are found in each individual's position description.

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 routinely are tested by the submission of spikes and background blanks to ensure accuracy of a vendor's services. ORAU retains a NVLAP-certified vendor for dosimetry services. Procedures for testing and inspection are maintained in the FTD/FMS Safety Procedures.

12. MANAGEMENT ASSESSMENT

12.1 Introduction

ORAU management oversees a range of rigorous activities designed to ensure that the company meets regulatory standards, best business practices, customer expectations, and the provisions of this policy. A key element of this coordinated effort 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 (e.g., direct observations, self-assessments, external ES&H reviews, customer and employee interviews, regularly scheduled and unannounced walkthroughs, and results of drills and exercises) to identify their organization's specific and systematic weaknesses and how they are to be corrected.

12.2 Internal Audits

The ORAU 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 auditor's own 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 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 the ones described here focus on ES&H areas, the values of self-assessments are 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 ES&H 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. ES&H 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, 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), 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 (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 unambiguously 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 ES&H performance measures that convey maximum information at affordable cost.

12.5 Horizontal Integration

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 by the following mechanisms:

- *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.

- *Just Ask* 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, ES&H training documents, ISM plans, safety job aids, ES&H 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, general counsel, vice president for business operations, vice president for partnership development, and corporate director for human resources) meets twice monthly to discuss strategic issues that cross organizational lines.
- Quality Management Team (vice president for business operations, department directors, and other appointed persons) meets twice monthly to share information and discuss cross-organizational issues.
- General staff 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.
- Safety Council (members of Corporate Leadership Team, Quality Management Team, program directors, site safety representatives and alternates, and other persons with ES&H responsibilities appointed by the president) meets regularly to share information, review ES&H 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’t 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. 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. Our management systems contain quality requirements interwoven throughout and include criteria for planning, implementing, and assessing work.

ORAU further believes that our QAP must provide processes and tools for ensuring that our ISM achieves its objectives by verifying compliance with approved standards and having the expectation for performing all work safely within appropriately established controls. This reassures that workers, the environment, and the public are reasonably protected from harm. In this sense, the QAP and ISM process share a management systems approach to achieving their objectives.

[Policy GP-810, Quality Assurance](#)

[Summary of Changes](#)