| ORAU | Policy Number: | GP-810 |
|-------------------|--------------------------|-------------------|
| QUALITY ASSURANCE | Issued Date: | May 26, 2016 |
| | Initiating Organization: | Office of Quality |
| | Applicability: | All Employees |

POLICY STATEMENT

This policy identifies the responsibilities for all ORAU staff to embrace and implement quality practices and continuous improvement. Through its attachment—the Quality Assurance Program—this policy also describes how ORAU/ORISE fulfills the contractual requirements of Department of Energy (DOE) Order 414.1D, Quality Assurance, and Title 10 of the Code of Federal Regulations Part 830 Subpart A, Quality Assurance Requirements.

POLICY REQUIREMENTS

All employees will implement quality practices, pursue continuous improvement, and comply with the requirements detailed in the:

- Quality Assurance Program (QAP) Description, and
- Management Review Procedure.

RESPONSIBILITIES

A. Employee

- 1) Follows approved procedures and incorporates best practices into daily operations to ensure customers' needs are met and quality products and services are delivered.
- 2) Suggests ways to promote continuous improvement.
- 3) If a condition contrary to meeting quality objectives is suspected or discovered:
 - a. Exercises the authority to stop or suspend work, and
 - b. Reports the condition to a manager.
- 4) When nominated by the respective manager, completes the Quality Management System (QMS) team training, and participates on QMS teams.

B. Manager

- 1) Ensures that the requirements of this policy flow down to subcontractors for which he/she is the technical representative.
- 2) Encourages employees' participation in quality assurance (QA) planning and incorporation of QA into daily work practices.
- 3) Provides for appropriate QA training of employees and holds them accountable for their QA performance.
- 4) Nominates employees to attend the QMS team training and participate on QMS teams.
- 5) Includes QA concepts in regular staff meetings.
- 6) Sets the organizational unit's objectives and routinely uses a set of performance measures to gauge how well those objectives are being met.
- 7) Reports to a next-level manager any expected or confirmed changes in either customer, contractual, or regulatory requirements that might affect the current QAP or ISO 9001 activities.

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C. Director, Quality

- 1) Acts as the designated ORAU/ORISE Quality Assurance Coordinator.
- 2) Directs, leads, and coordinates the QMS, including working with senior leadership to establish annual Quality Goals and Objectives
- 3) Conducts assessments of processes, departments, or programs based on the risk associated with their processes and operations to evaluate how well the process, program, or department meets the applicable internal and external criteria and to identify opportunities for improvement and positive practices that need to be sustained.
- 4) Conducts, in cooperation with the chief audit officer, self-assessments that highlight strengths and weaknesses in the QA program, verify adherence to this policy, and recommend ways to promote continuous improvement toward excellence in operations.

D. Chief Audit Officer

Conducts an annual internal audit of all activities and processes comprising the QMS.

E. Director, Environment, Safety, and Health (ESH)

- 1) Assists the ORAU/ORISE QA Coordinator in integrating the environment, safety, and health and QA programs.
- 2) Includes the provisions of this policy, where appropriate, in environment, safety, and health training.

CANCELLATION

This policy cancels and supersedes policy GP-810, dated November 4, 2014.

REFERENCES

- 1) Title 10 of the Code of Federal Regulations Part 830 Subpart A, Quality Assurance Requirements
- 2) DOE O 231.1B Admin Change 1, Environment, Safety, and Health Reporting
- 3) DOE O 414.1D, Quality Assurance
- 4) DOE P 450.4A, Integrated Safety Management System Policy
- 5) DOE-STD-7501-99, The DOE Corporate Lessons Learned Program
- 6) ISO 9000:2015, Quality Management Systems Fundamentals and Vocabulary
- 7) ISO 9001:2015, Quality Management Systems Requirements
- 8) ISO 14001:2015, Environmental Management Systems
- 9) ORAU Strategic Plan
- 10) ORAU Policy ESH-100, Integrated Safety Management
- 11) ORAU Policy ESH-112, Environmental Management
- 12) ORAU Policy FM-800, Records Management
- 13) ORAU Policy GP-710, Risk, Issue, and Nonconformity Management
- 14) ORAU Policy GP-820, Assessment Program
- 15) ORAU Policy GP-850, Contractor Assurance System
- 16) ORAU Policy HR-1510, Employee Records
- 17) ORAU ISMS Program Description
- 18) ORISE Contract Clause H.2, Contractor Assurance System
- 19) Quality Goals and Objectives
- 20) Quality Manual

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ATTACHMENTS

- 1) ORISE Quality Assurance Program
- 2) <u>Definitions</u>
- 3) Management Review Procedure

Policy Changes

Policy approved and signed by H.A. Page, ORAU President and CEO, on May 26, 2016.

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