

**Management System:** [Quality](#)

**Program Description: Quality Assurance Program**

Major Revision Date: **Jan 11, 2012**

**Last Revision Date:** [12/30/2019](#)

Subject Matter Expert: [Deborah Jenkins](#)

Management System Owner: [Deborah Jenkins](#)

[SBMS Home Page](#) | [Program Descriptions](#) | [Instructions](#) | [Definitions](#) | [View Comments](#) | [Revision Record](#) | [Highlight Changes](#)

**Contents**

[Introduction](#)  
[Applicability](#)  
[Approach](#)  
[Policy](#)  
[Quality Assurance Program Approval and Changes](#)  
[Quality Assurance and Integrated Safety Management \(ISM\)](#)  
[Graded Approach](#)  
[Criteria Descriptions](#)

[Management/Criterion 1 - Program](#)  
[Management/Criterion 2 - Personal Training and Qualification](#)  
[Management/Criterion 3 - Quality Improvement](#)  
[Management/Criterion 4 - Documents and Records](#)  
[Performance/Criterion 5 - Work Processes](#)  
[Performance/Criterion 6 - Design](#)  
[Performance/Criterion 7 - Procurement](#)  
[Performance/Criterion 8 - Inspection and Acceptance Testing](#)  
[Assessment/Criterion 9 - Management Assessment](#)  
[Assessment/Criterion 10 - Independent Assessment](#)  
[Suspect/Counterfeit \(S/C\) Items Prevention Process](#)  
[Software Quality Assurance Requirements](#)  
[DOE O 414.1D, Quality Assurance - General Quality Requirements Matrix](#)

**Introduction**

ORNL's Quality Assurance Program (QAP) supports excellence in our science and technology missions through development of a quality culture that contributes to scientific and operational excellence (see [Laboratory Agenda](#)), research integrity, and continual improvement by defining the processes to deliver quality products and services to both our internal and external customers. The QAP program description (QAPD) describes the UT-Battelle approach to the integration of quality principles and methodologies into work planning and control processes to address contractual quality requirements and to achieve consistent success.

**Applicability**

ORNL implements the requirements of DOE Order 414.1D, *Quality Assurance* for all programs, projects, and activities; and 10 CFR 830 Subpart A, *Quality Assurance Requirements* for nuclear facilities, radiological areas, and programs and activities that have the potential to impact nuclear or radiological safety. ORNL has adopted ISO 9001:2015 as the laboratory consensus standard. Adoption of ISO 9001:2015 provides the level of rigor and flexibility necessary for the wide range of activities conducted at ORNL. Consideration of the applicability of additional QA requirements or guidance documents (for example., ASME NQA-1 and ANSI Z1.13) is provided on a project or process-specific basis based on potential risk factors and customer requirements.

This QAPD provides an overview of the ORNL Quality Program including its conformance to ISO 9001:2015. The scope of the QAPD includes UT-Battelle research and development (R&D) and support facilities supporting DOE. There are no exclusions identified relative to the requirements of ISO 9001:2015. The QAPD provides references to established procedures and addresses the interaction between the processes of the management systems supporting research and operations.

ORNL invokes the applicable requirements of ASME NQA-1 2000, *Requirements for Quality Assurance Programs for Nuclear Facilities* for the operation of its current nuclear facilities and other activities (such as safety software) determined to require compliance to specific sections of this standard. Compliance with this set of requirements includes the processes defined by this QAPD and Work Smart Standards. As needed, additional procedures may be developed to provide organizational, project or facility specific details.

New nuclear facilities or major modifications to existing nuclear facilities will comply to the requirements of NQA-1 2008 with the NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II upon completion and approval of an applicable Work Smart Standard review.

**Approach**

The web-based Standards Based Management System (SBMS) is ORNL's institutional mechanism for ensuring that applicable laws, regulations, orders, policies, and best practices are adequately translated and incorporated into policies and procedures. SBMS provides a point of access to all requirements necessary for staff to safely and effectively perform work. The basic premise of the management system approach is that work is a process that can be effectively planned, performed, controlled, assessed, and improved. Each management system is designed to enable or support the wide range of activities conducted at ORNL in support of the Laboratory Agenda. The [Quality](#) management system (QMS) represents one of the management systems comprising SBMS.

**Policy**

Quality expectations for laboratory staff are communicated through [policies and standards](#) approved by the laboratory director. Policies represent ORNL's overarching philosophy for the conduct of research, operations, and related support activities and form the context of the organization at the institutional level. These policies and [standards of performance](#) include those [specific to quality](#) and communicate ORNL's commitment to quality and continual improvement as follows:

- Provide and continually improve research, services, products, and management systems of the highest quality consistent with the needs, expectations, and resources of our customers.

- Provide a safe and healthy workplace by developing and implementing work processes and equipment that abate hazards, operating in a manner that protects and restores the environment, and integrating pollution prevention into planning and decision-making.
- Comply with applicable requirements for performing work and work-related activities on and off site, including requirements in ORNL's Standards Based Management System.
- Communicate appropriate environmental management system information to staff, subcontractor personnel, customers, and other stakeholders.
- Comply with legal, contractual, and other applicable requirements.

The established policies provide a basis for evaluation of risk and identification of quality objectives for management and staff that are applicable to the detailed activities conducted in support of the science and technology (S&T) missions. Policies are periodically reviewed to determine suitability. ORNL enacts its policies through the implementation of requirements that comprise the SBMS.

### Quality Assurance Program Approval and Changes

In accordance with DOE Order 414.1D and 10 CFR 830, the QAPD is reviewed annually and updated as needed. A summary of the annual review or, if necessary, a modified QAPD is submitted to DOE for approval. The QAPD is updated on a regular basis to accommodate changes in the program and incorporate new requirements.

### Quality Assurance and Integrated Safety Management (ISM)

The QAP promotes and implements the integration, consistency, and mutual support between the QA function and [Integrated Safety Management \(ISM\)](#) Program as advocated in the guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and DOE O 414.1D, *Quality Assurance*.

**Note:** A [crosswalk](#) has been established to depict the integration between quality assurance criteria and the corresponding core safety functions/guiding principles of ISM.

### Graded Approach

ORNL management supports the application of quality assurance requirements in a graded manner by tailoring the formal controls for all work activities to reduce a wide range of potential risks and to meet the customer expectations and requirements. Activity analysis and application of quality requirements using the graded approach is a process for ensuring that levels of pre-activity evaluation, application of management controls, extent of documentation, and actions necessary to comply with a requirement are appropriate, based on the following risk and hazard considerations:

- Relative importance to safety, safeguards, security, environment, and missions
- Type and consequence of any risk involved
- Life-cycle stage of the facility, activity, or item (for example, age, status, and condition of the facility or process)
- Programmatic mission of a facility or activity (complexity of products or service involved)
- Any unique characteristics of the facility, activity, or item
- Relative importance to managing radiological and non-radiological hazards

The QAP is customer-focused, with the flexibility to address the specific requirements of each customer. Line and program managers may develop and implement additional processes and controls as necessary to meet specific quality requirements.

Details concerning application of the graded approach process for safeguards and security, nuclear and facility safety, worker safety and health, software quality, work and project planning and control, and acquisition management are provided in the applicable management system descriptions. The implementation strategies of each management system are tailored based on the nature and degree of the potential risks, applicable requirements, and the activities under the purview of each management system.

Examples of the application of the graded approach process include the following:

- Research safety summaries for research activities
- Quality significance determination for procurement of items and services
- Work packages or plans for operations, maintenance and service activities
- Issues management significance determination
- Project-specific quality assurance plans and procedures for unique or singular customer activities

A graded approach does not allow internal or external requirements to be ignored or waived. Rather, it is intended to allow the degree of controls, verification, and documentation to be varied in meeting requirements based on environment, safety, health and quality (ESH&Q) considerations; customer needs; and associated programmatic considerations.

A graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements (TSRs) when the requirements of 10 CFR 830, Subpart A, have been determined to be applicable (Ref: 830.7, Graded Approach).

When applying the graded approach as a planning tool, the following success factors are considered in the work-planning phase to address the mitigation of risk:

- Relative significance of accomplishing the proposed activity to the customer and other stakeholders
- Relative priority or ranking of the activity among other competing activities
- Potential consequences to customers and other stakeholders resulting from completing (or not completing) the work;
- Impact of producing invalid or unsuccessful results
- Probability of adverse outcomes resulting from the identified risks

QA requirements for activities that have the potential to impact nuclear, radiological, industrial, and related activities are implemented as part of the Integrated Safety Management System (ISMS) Program. Hazards are identified, analyzed, and categorized, and controls are developed in response. Hazard identification and mitigation activities may include development of a documented safety analysis (DSA) or other formal hazards analysis (HA) activities. Further activities may include development or conduct of research safety summaries, work plans and other pre-work evaluation processes. The graded approach supports the integration of ISMS principles with the systems, processes, and tools deployed through the QMS.

### Criterion Descriptions

The following sections of the QAPD address the criteria requirements identified in DOE Order 414.1D and 10 CFR 830, and describe where the requirements are addressed in the various management systems that comprise the SBMS. A summary illustration of this alignment is provided in DOE O 414.1D, *Quality Assurance - General Quality Requirements Matrix*.

#### Criterion 1 - Management/Program

ORNL's organizational structure provides the framework to enhance the diverse capabilities necessary to achieve success in meeting the Laboratory Agenda commitment to promote simultaneous excellence in the areas of science and technology, laboratory operations and ESH&Q, and community service.

Each individual at the laboratory is responsible and accountable for the quality of the work that they perform or supervise. Specific responsibilities for the positions and assignments within the laboratory are established and documented in the Human Resources management system (that is, [Roles](#)).

[Responsibilities, Accountabilities and Authorities \(R2A2s\)](#)). In relation to the quality function, the following synopsis describes the laboratory's structure for ensuring effective QMS deployment.

- The laboratory director approves the [policies](#) and institutional standards governing work at the laboratory.
- [Management system owners](#) are authorized to establish and implement the mechanisms and processes by which ORNL implements its policies and institutional standards. Management system owners have direct access to the director, and report at a management level that provides the required authority and organizational freedom to develop and implement the management systems necessary to support the Laboratory Agenda.
- The [associate laboratory directors and level 1 support directors, division directors](#), and management system owners are responsible for implementing [ORNL policies and institutional standards](#) and are accountable for the quality, efficiency, and effectiveness of all work performed within their organizations and management systems.
- The [Integrated Performance Management \(IPM\)](#) director reports to the deputy director for operations and is the senior management representative responsible for developing, implementing, assessing, and improving the QAP described in the Quality management system description and associated quality standards, subject areas, and procedures. The [Performance Analysis and Quality \(PAQ\) manager](#) is responsible for analyzing and appropriately implementing external quality requirements through management systems and interfacing with external customers on issues associated with quality requirements implementation. The PAQ manager, through the effective implementation of the QMS, provides professional assistance, guidance, and training to ORNL personnel in matters pertaining to quality, assists laboratory management with independent and management assessment activities, and develops and promotes initiatives to ensure continual improvement.

The [Integrated Performance](#) management system (IPMS) provides the ORNL business processes that include the development of the laboratory-level Performance Evaluation and Measurement Plan (PEMP), as well as the subordinate business plans and associated assessment plans. The performance results associated with the PEMP provide one of the bases for the determination of the effectiveness of the QMS in support of higher-level goals and objectives. Lower-level management reviews are conducted in support of the PEMP, and periodic reporting provides a regular source of feedback with which to gauge performance across the laboratory.

Management reviews are conducted at planned intervals to ensure the continuing suitability, adequacy and effectiveness of the QMS. Management reviews include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. Management reviews follow a structured format for inputs and outputs and results are documented.

### Criterion 2 - Management/Personnel Training and Qualification

The [Training and Qualification](#) management system (TQMS) identifies the processes for employees and non-employee staff to develop the baseline of knowledge and skills necessary to perform their jobs safely, effectively, and efficiently. This is accomplished by establishing laboratory-level procedures and guidance for training program implementation with the associated infrastructure of supporting systems, services, and processes. Training may include project-specific, facility-specific, and functional training for identified positions. Training is updated as work requirements, individual experience and expertise, and/or hazards change to ensure consistent maintenance of job proficiency and competency. Training content is updated as needed to ensure current information is provided and to address feedback provided during delivery. Periodic retraining is required in areas where requalification and maintenance of proficiency is identified. Competency is addressed within the [Work/Project Planning & Control](#) management system (WPPC). The WPPC includes research, operations, maintenance, service, nonemployee and other work processes for the assignment of competent personnel based on the analysis and hazard identification of the defined work activity. Appropriate records are created and maintained as necessary.

Subcontractor training activities are governed by the requirements specified in each individual subcontract with oversight provided by a trained ORNL technical project officer.

### Criterion 3 - Management/Quality Improvement

The SBMS processes for quality improvement incorporate quality methodologies to promote the identification of candidate processes for improvement. Line managers and management system owners assess their processes and are provided access to various operational experience results (for example, event reports, lessons learned, best management practices information) as resources from which they may identify candidate areas for improvement associated with activities under their purview.

The IPMS implements the [Issues Management and Analysis](#) and [Audits and Assessments](#) subject areas to promote and achieve effective quality improvement initiatives. This document prescribes the appropriate means for the identification; cause and corrective action determination; and the reporting of issues that result from defects, non-compliances, or inefficient practices. Corrective action-related activities are conducted to ensure the following:

- Appropriate review of identified issues
- Determination of the causes
- Evaluation of the need for the actions necessary to prevent recurrence
- Determination and implementation of the actions needed with disposition for hardware (items, components or systems)
- Capture and maintenance of the records associated with the results of the actions taken
- Review of corrective actions to discern their effectiveness

Quality improvement encompasses not only detection, correction, and continual improvement efforts, but problem prevention or preventive actions as well. Institutionalized preventive actions include the use of the peer review processes, design reviews, inspection activities, research reviews, procurement reviews, work control processes, safety and health-related hazard evaluations, and the conduct of management and independent assessments to identify problems before they occur or become significant.

The Issues Management and Analysis subject area includes procedures which describe the expectations and provide the processes to address the following:

- Identification of potential problems and their causes
- Evaluation of the need for actions to prevent initial occurrence
- Identification and implementation of effective preventative actions
- Capture and maintenance of records associated with the actions taken and their results
- Review of preventive actions taken to discern their effectiveness.

The IPMS defines the processes for the development of performance measures and metrics used for evaluation of laboratory-level and sub-tier organizational results and identification of candidate areas for improvement. Processes provided in the QMS further support quality improvement efforts. The IPMS and the QMS also provide guidance, systems, processes, and tools that enable effective performance monitoring, assessment and evaluation of outcomes and results, identification of laboratory-level trends and issues, and characterization of overall laboratory-level performance to ensure continual improvement through effective business and performance assessment planning.

Quality improvement activities and processes within a number of management systems also describe the contractor assurance elements that support the ISMS philosophy and the interface with QA requirements intended to provide assurance that laboratory performance, potential risks, and information garnered from both event-related and assessment-related results are managed effectively.

### Criterion 4 - Management/Documents and Records

The [Records Management](#) subject area establishes effective and efficient processes to facilitate the capture, use, retention, maintenance, and preservation of records. The Requirements, Documents and Records management system (RDR) directly supports the validation of research quality by providing processes for archiving, maintaining, and retrieving key project records.

The processes for the development, review, approval, communication, use, and revision of controlled documents are provided in the [Document Management](#) subject area, which defines the process for control of laboratory-level documents as well as internal operating procedures that may be applicable to each facility, organization, or project.

The Records Management subject area addresses contractual requirements by providing a life cycle approach for hardcopy and electronic records in order to preserve sufficient information to document the management and accountability of ORNL projects and activities, address the legal and financial consideration of ORNL and customers, and ensure the proper use of documents, records, and other information resources.

#### Criterion 5 - Performance/Work Processes

All management systems are developed and deployed to provide processes and controls necessary to conduct work. The management system descriptions define their purpose, requirements, processes, and responsibilities.

The concept of product realization is primarily encompassed by ORNL's work control processes and supported through related management systems. Product and service realization includes the processes that address customer-related needs and expectations, planning, design, procurement, production/service provision, and control of monitoring and measuring devices.

Work control processes provide a graded approach to the development of controls for a defined set of activities. Specifically, work at ORNL can be classified into one of three categories:

- Activities associated with R&D programs and projects, including theoretical work
- Activities associated with operations, maintenance and services, including those performed in support of R&D
- Activities associated with other work (for example, office and non-office activities where work-specific hazards are unlikely to result in hard to workers, environment, or the public)

The [Work Control](#) subject area addresses the management of work to ensure compliance with applicable environment, safety and health (ES&H); quality; security; and technical requirements to enhance worker safety at all organizational levels.

Work controlling documents provide the bounding conditions for planned activities and the associated actions necessary to mitigate any related hazards. When applicable, these documents are also implemented to address a gamut of secondary requirements including identification and control of items; handling, storage, and shipping; calibration and maintenance of measuring and test equipment; design control, procurement control, inspection and acceptance testing; and any additional customer-specific quality requirements. Requirements for the provision of appropriate infrastructure and work environment are also addressed through the work control process.

The maintenance of items to prevent their damage, loss, or deterioration is addressed in the [Integrated Facility](#) management system (IFMS) relative to the maintenance of facilities and in the [Engineering](#) management system (EMS) for other applications.

Work is evaluated through these mandated processes prior to the commencement of associated activities. Completion of the appropriate work control-mandated documentation constitutes line management authorization for work to proceed within the limits imposed by the applicable work authorization documentation. The processes that constitute the evaluation of planned activities also include the participation of subject matter experts (SMEs) to ensure that all associated hazards are effectively identified and fully mitigated.

The [Configuration Management](#) (CM) subject area provides the processes to document each applicable structure, system, or component's (SSC) previous history and current configuration including the status of compliance of each SSC to related physical and functional requirements. An associated objective of the described CM processes is to ensure that staff conducting activities pertinent to each SSC or who have the potential to affect its configuration use correct, accurate, and current documentation.

ORNL staff use equipment of known accuracy based on appropriate calibration requirements that are traceable to established standards when appropriate. The equipment is maintained according to a defined process described in the [Calibration](#) subject area deployed through the QMS. The ORNL metrology laboratory maintains accreditation from the National Voluntary Laboratory Accreditation Program and is a calibration/standards maintenance service provider registered to meet ISO 17025: 2017.

#### Criterion 6 - Performance/Design

The [Design](#) subject area addresses the design control function that ensures the following:

- Design of SSCs and associated processes are developed and planned using sound engineering principles and appropriate technical standards.
- Appropriate technical and industrial standards are incorporated into initial design activities and any subsequent changes.
- Design interfaces, including organizational and design product interfaces, are identified and controlled.
- Design adequacy is verified by independent, multi-discipline reviews before implementation.
- Changes to the original design receive reviews and approval comparable to the reviews and approvals of the original design.

Specifications, drawings, and other design documents are prepared to define the appropriate design parameters. These documents present a verifiable engineering delineation of the associated SSC and any related processes. Design documents incorporate design inputs, calculations, and analyses; engineering reports; design outputs; design verification activities; and other documentation and processes that provide evidence that design activities were completed correctly.

The processes for commercial grade dedication (CGD) of items and services are applicable to select systems associated with nuclear facilities. SMEs experienced in the planned use of the items or services are responsible to determine the applicability of CGD process and to develop and implement the necessary organization-specific procedures that will ensure the effectiveness and consistency of these targeted items and services.

The ORNL chief engineer delegates design authority to various SMEs who possess the skills and expertise necessary to establish the appropriate standards for the laboratory.

#### Criterion 7 - Performance/Procurement

The [Acquisition](#) management system (AMS) deploys the subject areas and subordinate procedures that comprise the approved procurement system used at ORNL. Procurement documents including requisitions, orders and specifications are developed to identify technical and quality assurance requirements, to prevent the introduction of S/CIs, and to enable inspection to verify that items meet established requirements. Procurement program procedures provide a detailed methodology for preparing, reviewing, and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures ensure procured items and services meet established requirements and perform as specified.

The process for evaluation and selection of prospective suppliers of **quality-significant** items and services for ORNL operations and programs is deployed through the AMS. The process provides the basic structure and approach for evaluating potential suppliers. Supplier evaluations for nuclear suppliers include shared information available through ORNL's membership on the Nuclear Industry Assessment Corporation (NIAC), Energy Facility Contractors Group (EFCOG), and other sharing committees. When sufficient information cannot be obtained from these memberships and associations, ORNL's process for specific evaluations is detailed in the AMS and implemented through PAQ internal operating procedures [PAQ-AP-003, Supplier Evaluation Desk Review](#), and [PAQ-AP-007, Instructions for Conducting an At-Site Supplier Evaluation](#).

The process for ensuring that evaluated suppliers continue to provide acceptable items and services is detailed in the PAQ internal operating procedure [PAQ-AP-009, Monitoring Performance of Evaluated Suppliers on the ESL](#).

The flow-down of QAP requirements to suppliers is based on a graded approach and the requirements of each customer as they are defined. This includes the outsourcing of activities to obtain necessary products or services. During the procurement planning phase, the responsible staff member identifies the items, services, and related activities that require adherence to QA requirements and the associated actions that provide reasonable assurance that procured items or services will meet pre-established critical characteristics associated with the planned use.

#### **Criterion 8 - Performance/Inspection and Acceptance Testing**

Inspection and acceptance testing ensure that specified items, services, and processes are evaluated and qualified using appropriate acceptance and performance criteria. The need for inspection and acceptance testing is determined during work planning for procured items, services, or related activities. Inspection and acceptance testing requirements described in the QAP are addressed through the [Inspection and Acceptance Testing](#) subject area.

Designated inspections/tests are performed using equipment that is calibrated and maintained to nationally or internationally traceable standards. The [Calibration](#) subject area describes the calibration process for measuring and test equipment.

Trained and qualified workers are responsible for inspection and witnessing or verifying acceptance testing activities by implementing the requirements contained in the organization-level inspection and test procedures. This includes, where appropriate, the nondestructive examination (NDE) procedures maintained by the Facilities and Operations Directorate to address the nationally recognized standard for NDE, ASNT-TC-1A, referenced in ASME NQA-1 and other related quality assurance standards.

Responsible managers ensure that detailed test plans and procedures are identified, developed, and documented based on the requirements derived from implementing associated design processes and referenced industrial codes and standards, including ORNL engineering standards.

#### **Criterion 9 - Assessment/Management Assessment**

Management assessments are performed by managers or their designees and are intended to be evaluations of business and management processes to assess adequacy and effectiveness. Assessments are used to determine how well management is providing the leadership to enable an organization to continuously meet internal and external customer expectation and requirements, and in identifying and planning for future systems improvement. This includes assessment of the effectiveness of management controls, adequacy of resources and workers assigned to perform work, process and system performance, technical and programmatic verifications to support ORNL divergent mission-related activities, and compliance with requirements.

The IPMS subject areas for [Laboratory Strategy and Planning](#) and [Audits and Assessments](#) provide the tools and processes for scheduling, performing, documenting, tracking, and trending management assessment results.

#### **Criterion 10 - Assessment/Independent Assessment**

Independent assessments (including internal audits as required by ISO 9001:2015) focus on performance of work with significant consideration given to performing activities in both a safe and compliant manner while achieving the goals of the organization. The purposes associated with independent assessment activities are to improve performance and process effectiveness through assessing item and service quality, measuring adequacy of work performed, and promoting continual improvement. Independent assessments are conducted by technically qualified and knowledgeable personnel who are not responsible for supervising or performing the work under review. Independent assessments fulfill a wide range of commitments including validation of previous ORNL internal management assessments, performance reviews required by contract, and evaluation of the effectiveness of past preventive and corrective actions. Independent assessments may also be used to verify or validate previously identified conditions or in the conduct of directed senior management reviews.

The process for scheduling, planning, conducting, and reporting independent assessments is provided in the Audits and Assessments subject area deployed through the IPMS. Additional details related to independent assessments are included in internal procedures maintained by PAQ and the Internal Audit Directorate. Formal certification of assessment personnel is provided for where required to meet customer-related commitments and requirements.

The Independent Oversight (IO) Program and function is an element of the IPMS that provides assurance to ORNL management and DOE that the laboratory's performance assessment and assurance processes effectively provide information to support critical management decisions, identify candidate areas for improvement, and facilitate high-value input to future business planning.

#### **Suspect/Counterfeit (S/CI) Items Prevention Process**

The ORNL [Suspect/Counterfeit Items \(S/CI\) Program](#), provides the implementation strategy for S/CI controls commensurate with the risks within facilities and projects at ORNL and in compliance to DOE requirements. This program is deployed through the incorporation of appropriate controls within relevant subject areas such as [Suspect/Counterfeit Items and Defective Items](#), Design, Inspection and Acceptance Testing, [Nonconformance Control](#), [Event Reporting and Follow-up](#), and [Purchasing Goods and Services](#). S/CI controls used by this program are based on two long-standing DOE safety principles: defense-in-depth and graded approach. The S/CI Program represents a laboratory-wide approach for prevention, identification, disposition, removal, destruction, restricting S/CI use to only the items that have been found acceptable through engineering analysis and formal disposition process, and reporting of S/CIs via the QMS. The objectives of S/CI Program are to prevent the introduction and use of S/CIs through engineering involvement, design, procurement, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls. Appropriate personnel, within their areas of responsibility including engineering; procurement; environment, safety, and health; quality assurance; receiving inspection; warehouse and storage; maintenance; operations, and occurrence reporting receive specific S/CI training to provide the necessary information for the identification, prevention, detection, disposition, reporting, and control of S/CIs.

#### **Software Quality Assurance Requirements**

The [Software Quality Assurance \(SQA\)](#) subject area deployed through the [Information Technology](#) management system (ITMS) applies to all ORNL staff members who procure, develop, modify, or maintain software, whether the software is developed in-house, licensed from a commercial vendor, obtained from another organization, or otherwise acquired.

ORNL staff members engaged in the use of software must adhere to the requirements as stated in the ITMS requirements associated with SQA. The risks and the degree of SQA-related considerations are evaluated in the context of work activities as defined in previously described laboratory work control processes. SQA requirements are applied using a graded approach to ensure the software performs its intended specific function in relation to the applicable categorization, grading, and type.

The requirements of ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (including Part II, subpart 2.7), will be implemented to ensure that safety software effectively meets stated functional requirements. Safety software owners and developers must meet the requirements when developing, using, and procuring safety software.

The [Software Registration System](#) (SRS) allows the owners and developers of software at ORNL to register the required SQA information for their software. SRS also provides an inventory of software at ORNL and serves as a central repository for related information/documentation. ORNL adheres to the software grading levels established in DOE G 414.1-4, *Safety Software Guide* (6/17/05), section 2.2 (Levels A, B, and C) to provide the necessary level of rigor applicable to safety software.

In accordance with Paragraph 2.a. (1) of Attachment 2 of DOE Order 414.1D, the QAP must address the ten criteria associated with program management, performance and assessment; suspect/counterfeit items Prevention Process; and Safety Software Quality Requirements. The following table provides a listing of the implementing management system(s) and subject area(s) as well as the associated requirements from ISO 9001:2015 and NQA-1 2000:

DOE Order 414.1D	ORNL Management System	ISO 9001:2015 Requirements	NQA-1 2000 Requirements
Criterion 1: Management/Program	Human Resources Management, Requirements, Documents, and Records Management System, Work Project Planning & Control, Integrated Facility Management, Integrated Performance Management	4 and 5	1 and 2
Criterion 2: Management/Personal Training and Qualification	Training & Qualification Management	7	2
Criterion 3: Management/Quality Improvement	Quality Management, Integrated Performance Management	9 and 10	2, 15, and 16
Criterion 4: Management/Documents and Records	Requirements, Documents, and Records Management	7	5, 6, and 17
Criterion 5: Performance/Work Processes	Work Project Planning & Control, Engineering Management, Quality Management	6 and 8	5,8,9,12, 13 and 14 and Part 1, Introduction
Criterion 6: Performance/Design	Engineering Management, Quality Management	8	3
Criterion 7: Performance/Procurement	Acquisition Management	8	4 and 7
Criterion 8: Performance/Inspection and Acceptance Testing	Quality Management	8 and 9	8, 10, 11, and 12
Criterion 9: Assessment/Management Assessment	Integrated Performance Management	9	2 and 18
Criterion 10: Assessment/Independent Assessment	Integrated Performance Management	9	1, 2, 10, 11, 15, 16, and 18
Graded Approach	Quality Management	Not addressed	1, 2, and Part 1, Introduction , appendix 2A-2
QAP Development and Implementation	Quality Management	4	2 and 5
Integrated Safety Management Systems	Quality Management, Worker Safety and Health	Not addressed	Not addressed
Ensuring Subcontractor and Supplier Quality	Quality Management, Acquisition Management	8	1, 2, 4, 7, and 18
DOE-Wide Suspect/Counterfeit item Prevention Process	Quality Management, Acquisition Management, Engineering Management	Not addressed	Not addressed
Safety Software Quality Requirements	Quality Management, Information Technology	Not addressed	3, 11 and Part II, Section 2.7

The only **OFFICIAL COPY** of this document is this on-line electronic version in SBMS. Before using a printed copy, verify that it is the most current version by checking the **Last Revision date** at the top of each subject area page and the **Last Modified web page date** at the bottom of other pages.

[| SBMS Home Page](#) | [Program Descriptions](#) | [Instructions](#) | [View Comments](#) | [Revision Record](#) |

[Directives Home](#) [ORNL Internal Home](#)

[Questions/Comments](#)

[Disclaimer](#)

This web page was last modified on: 02/12/2020 10:29:21 AM

Web page name: /sbms/SBMSearch/ProgDesc/QAPD/NQAProgPD.cfm Document ID: PROG-50

Documents provided from the Web server were sponsored by a contractor of the U.S. Government under contract DE-AC05-00OR22725