

SECTION 2: QUALITY ASSURANCE

2.1 Purpose and Scope

The purpose of the Ames Laboratory Quality Assurance (QA) Program is to promote assurance practices in safety, business, and research activities in order to ensure worker safety and health, provide quality goods and services, cultivate cutting edge science, demonstrate efficient use of resources, and address the requirements contained in 10 CFR 830 Subpart A, *Quality Assurance* and DOE Order 414.1D *Quality Assurance* (an Ames Laboratory contract directive). Additional guidance for the Laboratory's quality assurance activities is derived from DOE Guide 414.1-2A and ANSI/ASQ Z 1.13-1999, when necessary and applicable.

The Quality Assurance Program applies to all employees and activities conducted at Ames Laboratory.

2.2 Approval Record

- Reviewed by: Document Control Coordinator (Hilary Burns)
- Approved by: Manager, ESH&A (Sean Whalen)
- Approved by: Deputy Director (Tom Lograsso)

The official approval record for this document is maintained in the Training and Documents Office, 105 TASF.

2.3 Revision/Review Information

The revision description for this document is available from and maintained by the author.

2.4 Introduction

The Quality Assurance Program (QAP) Plan describes how the Ames Laboratory provides reasonable assurance of adequate protection from adverse consequences for workers, the public, and the environment, taking into account the work to be performed and the associated hazards, as required by 10 CFR 830, Subpart A, and DOE O 414.1D.

2.5 Training

Quality Assurance Program Plan training (AL-222) is required for Laboratory employees identified by the Quality Assurance Manager as having a direct impact or responsibility for quality assurance. This may include, but is not limited to: Laboratory Directors and Executives; Division, Institute, and Program Directors; Program Managers; and select operational and research staff.

2.6 Program Information

Refer to the Ames Laboratory [Quality Assurance Program Plan](#) (QAP) for specific implementation information regarding the Ames Laboratory QA program criteria.

The quality assurance criteria are listed below.

DOE O 414.1D Criterion 1 - Program

1. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing and assessing work.
2. Establish management processes, including planning, scheduling and providing resources for work.

DOE O 414.1D Criterion 2 - Personnel Training and Qualification

1. Train and quality personnel to be capable of performing assigned work.
2. Providing continuing training to personnel to maintain job proficiency.

DOE O 414.1D Criterion 3 - Quality Improvement

1. Establish and implement processes to detect and prevent quality problems.
2. Identify, control and correct items, services and processes that do not meet established requirements.
3. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

DOE O 414.1D Criterion 4 - Documents and Records

1. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
2. Specify, prepare, review, approve, and maintain records.

DOE O 414.1D Criterion 5 - Work Processes

1. Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
2. Identify and control items to ensure proper use.
3. Maintain items to prevent damage, loss, or deterioration.
4. Calibrate and maintain equipment used for process monitoring or data collection.

DOE O 414.1D Criterion 6 - Design

1. Design items and processes using sound engineering/scientific principles and appropriate standards.
2. Incorporate applicable requirements and design bases in design work and design changes.
3. Identify and control design interfaces.
4. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
5. Verify/validate work before approval and implementation of the design.

DOE O 414.1D Criterion 7 - Procurement

1. Procure items and services that meet established requirements and perform as specified.
2. Evaluate and select prospective suppliers on the basis of specified criteria.
3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

DOE O 414.1D Criterion 8 - Inspection and Acceptance Testing

1. Inspect and test specified items, services, and processes using established acceptance and performance criteria.
2. Calibrate and maintain equipment used for inspections and tests.

DOE O 414.1D Criterion 9 - Management Assessment

1. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

DOE O 414.1D Criterion 10 - Independent Assessment

1. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance and to promote improvement.
2. Establish sufficient authority and freedom from line management for independent assessment teams.
3. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

DOE O 414.1D Attachment 3 – Suspect/Counterfeit Items Prevention

1. Include a S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact.
2. Identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
3. Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).
4. Prevent introduction of S/CIs into DOE work by
5. Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications¹ and other applications that create potential hazards. Also address the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse.
6. Conduct engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required).
7. Perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place. Disposition S/CIs identified during routine maintenance and/or inspections to prevent future use in these applications.
8. Report to the DOE Inspector General per paragraph 3 and DOE O 221.1A, Reporting Fraud, Waste, and Abuse to the Office of Inspector General, dated 04-19-08 (or latest version).
9. Collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers. Sources are identified on the DOE S/CI website (<http://www.hss.energy.gov/sesa/corporatesafety/sci/>).
10. Conduct trend analyses for use in improving the S/CI prevention process.

DOE O 414.1D Attachment 4 – Safety Software Quality Assurance Requirements for Nuclear Facilities

Note: Ames Laboratory is NOT a nuclear facility. However, the Order requirements apply to some software purchases and applications related to general safety.

Applicability is defined in the [Quality Assurance Program Plan](#).

1. Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority. Management of safety software must include the following elements.
 - a. Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.
 - b. Identify, document, control and maintain safety software inventory. The inventory entries must include at a minimum the following: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and, the responsible individual.
 - c. Establish and document grading levels for safety software using the graded approach. Grading levels must be submitted to and approved by the responsible DOE approval authority.
 - d. Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.
 - i. Software project management and quality planning
 - ii. Software risk management
 - iii. Software configuration management
 - iv. Procurement and supplier management
 - v. Software requirements identification and management
 - vi. Software design and implementation
 - vii. Software safety analysis and safety design methods
 - viii. Software verification and validation
 - ix. Problem reporting and corrective action
 - x. Training of personnel in the design, development, use, and evaluation of safety software