

QUALITY MANAGEMENT SYSTEM REVIEW AND APPROVAL TEMPLATE

(DOE G 414.1-2A, Appendix A, 6-17-05)

This review template is intended for use by the DOE for evaluating a DOE Site Office or Contractor Quality Assurance Program submittal consistent with DOE O 414.1C or 10 CFR 830. It may also be used by DOE or contractors to review other QAPs.

This appendix refers to various DOE Orders, Policies, Standards, and Guides. The user is advised to use the current revision of the referenced documents.

1. Reviewer Qualification

Federal personnel assigned to lead review teams and recommend approval of contractor quality management systems should have completed, at a minimum, the Department of Energy (DOE) Quality Assurance Functional Area Qualification Standard, DOE-STD-1150-2002, consistent with the Federal Technical Capabilities Manual, DOE M 426.1-1A, dated 5-18-04. Team members may also be qualified but at a minimum should have demonstrated proficiency in quality assurance and should be technically qualified and/or knowledgeable in the areas that they are assigned to review.

2. Quality Management System Review

The DOE reviewer/approval authority should do the following as part of planning and performance of the review.

- List the requirements, in addition to the QA Rule 10 CFR 830 and DOE O 414.1C, applicable to the quality management system, such as—
 - safety structures, systems, and components identified and discussed in the safety basis documents;
 - appropriate standards selected (e.g., NQA-1, ISO 9001); and
 - integration with other management system and quality requirements [e.g., integrated safety management (ISM), QC-1].
- Use DOE G 414.1-2A, Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance, dated 6-17-05, and ASME NQA-1-2004 in the review to ensure adequate rigor exists for nuclear and radiological facilities. (The Guide and NQA-1 may also be used in a graded fashion for other high-risk and hazardous activities.)
- Apply the review to all project quality related activities.
- Determine the responsibilities for review and approval of initial submittals and revisions of the QAP.
- As part of the review, evaluate the implementation of the QAP where possible.
- Understand the applicable contract quality requirements and expectations.

3. General Requirements for the Review

- Prepare a review plan in advance.
- Base the review plan on DOE G 414.1-2A and NQA-1-2004 (or other appropriate standards for non-nuclear work) and the contract.
- Identify the quality criteria that apply to the work.
- Prepare checklists for the review.
- Use the questions identified below as a starting point and expand them using the contract, DOE G 414.1-2A, and NQA-1-2004.
- Complete the review and document the results.
- Notify the contractor of the review results, provide any directed changes to the contractor's QAP, and inform the contractor of the approval status (approved, conditionally approved, disapproved) in the time allotted by 10 CFR 830.
- Notify the contractor of any work restrictions relating to conditional approvals or disapprovals.

4. Checklist (see corresponding paragraphs of DOE G 414.1-2A as listed below)

4.1 Program

Does the quality management system (QMS) describe the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work?

- Has the organization designated the senior management position responsible for development and maintenance of the QMS?
- Does the organization demonstrate senior management leadership for quality and the QMS?
- Are senior management expectations for implementation adequately defined and delineated?
- Have the requirements for ISM been adequately addressed and integrated into the QMS?
- Are there organizations excluded from the scope of the quality assurance program? If so, is there sufficient justification for the exclusion?
- Are the internal and external interfaces documented?
- Have adequate resources been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, calibration, etc.?

Does the QMS describe management processes, including planning, scheduling, and providing resources for the work?

Does the QMS define a process for grading the application of requirements? Does this process adequately address hazards and mission?

Has the QMS been prepared using NQA-1-2000 (or 2004) for organizations responsible for nuclear facilities or nuclear facility oversight applications? If not related to a nuclear facility, were other consensus standards appropriate for the mission used (ISO 9001, ASQ Z 1.13, QC-1)? Does the QMS include a commitment to the standard? Does the QMS include any exemptions from portions of the selected standard? Are those exemptions supported by an adequate basis?

Is the process for determining the quality requirements applicable to subcontractors/suppliers and passing those requirements down through contracts clearly defined? Is this process applicable to all contracts?

Has DOE Site Office or contractor senior management endorsed the QMS through a written quality policy statement?

4.2 Personnel Training and Qualification

Is the methodology described for establishing requirements to train and qualify personnel so that they are capable of performing their assigned work?

- Is there evidence that the organization has an established and documented training plan?
- Have adequate resources been identified to support the selection, training, and qualification of personnel conducting work?
- Does the training and qualification program describe the positions and functions to which it applies?
- Are the requirements defined for the qualification and/or certification of personnel in the various functional areas (e.g., auditors, subject matter experts, nondestructive examination personnel, welders, etc.)?
- Is the methodology described for providing continuing training to personnel to maintain their job proficiency?

4.3 Quality Improvement

Has the organization established, implemented, and documented processes to detect and prevent quality problems?

- Do work processes, procedures, etc., call for identification and reporting of quality problems?
- Does senior management policy encourage problem detection and prevention?
- Are there processes for communicating lessons learned and performance information?
- Is there a method for categorizing the significance of quality problems?

Is the approach to identify, control, and correct items, services, and processes that do not meet established requirements (nonconforming) adequately described?

- Does this approach include the requisite discipline involvement to adequately evaluate and disposition the nonconforming item, service, or process?
- Does this approach address the identification and control of nonconforming items such that it prevents inadvertent use consistent with DOE G 414.1-3?
- Does the QMS address documentation and correction of quality problems associated with services and processes?

Does the QMS provide for the identification of the causes of problems and require identification of actions to prevent recurrence as a part of correcting the problem?

Does the QMS describe methods for addressing cause, extent, and remedial and preventative actions for quality problems?

Is a process identified to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement?

- Is there a quality performance analysis system (e.g., six sigma, metrics and indicators, trending)?
- Does the performance analysis system provide a mechanism for feedback to affected and related entities in the organization?

4.4 Documents and Records

How does the organization prepare, review, approve, issue, use, and revise documents to prescribe such things as processes, requirements, and design? Is there a document control system that provides these functions?

- Verify key functions relating to the quality criterion (e. g., design, procurement, work control, inspection, testing) are described in approved document, such as procedures.
- Verify that documents prescribe internal processes, as well as, processes to oversee contractors and suppliers.
- Verify that the DOE Site Office key work processes and the activities in their functions, responsibilities, and authorities (FRA) are supported by Documents.
- Verify that the DOE Site Office has a documented process for the receipt and distribution of government furnished information from one contractor to another contractor.

How does the organization specify, prepare, review, approve, and maintain records?

- Is there a documented records management system that provides these functions?

- How are the requirements of the National Archives and Records Administration addressed?
- What is the quality records standard applied to the contract?

4.5 Work Processes

How does the QMS provide methods for ensuring work is performed consistent with technical standards, administrative controls, and other hazard controls?

- Are the core functions and guiding principles of the DOE Integrated Safety Management System addressed consistent with DOE O 450.1, DOE P 450.4 and applicable chapters in DOE O 5480.19?
- Do the approved documents (instructions, procedures, or other appropriate means for the work processes) meet regulatory or contract requirements?

Does the quality management system provide methods to identify and control items to ensure their proper use consistent and is it with DOE G 414.1-3 or suspect counterfeit items?

Is the method to maintain items to prevent their damage, loss, or deterioration adequately described? Does this method address the requirements (e.g., DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities, dated 6-1-01)? Are S/CIs addressed in the context of maintenance?

Does the QMS describe an adequate calibration and maintenance system for equipment used for process monitoring or data collection?

Does the process for development, use, control, and oversight of software include elements that are consistent with those described in DOE G 414.1-4?

4.6 Design

Determine if the Site Office performs design work as the design authority. If not, oversight of contractor design activities should be covered by a documented process (see “Documents and Records”). The DOE oversight activities may include setting of high level requirements for the facility/system, review and comment on completed systems design descriptions, or approval of critical decision points for moving from preliminary design to final design.

- Do design items and processes use sound engineering/scientific principles and appropriate Standards and Orders (i.e., DOE O 420.1A)?
- Is the use of software in the design and safety analysis process controlled consistent with DOE G 414.1-4?
- What method is used to incorporate applicable requirements and design bases in design work?
- Are design changes controlled at the same level as the design?

- How are design interfaces identified and controlled, within the design authority and externally with customers and suppliers, including subcontractors?
- Does the quality management system describe a process for design verification and/or validation for design products? Does the process require the use of individuals or groups other than those who performed the work?
- Is the work verified/validated before approval and implementation of the design?
- Is there a system for engineering involvement in the identification, analysis, and control of suspect/counterfeit items that could affect safety consistent with DOE G 414.1-3?
- How does the design authority control changes to procurement documents that include design requirements?

4.7 Procurement

- How are the requirements for the procurement of items and services established? Do the requirements include performance specifications provided by the design authority and expectations?
- Are procurement document changes managed and controlled at the same level as the original? Does this process require design authority approval of changes to their requirements?
- Is there a system to evaluate and select prospective suppliers based on specified criteria?
- Is there a system for identification of potential of suspect/counterfeit items and the prevention of their procurement consistent with DOE G 414.1-3? Does the organization have standard contract clauses for this purpose?
- Is supplier documentation managed and controlled?
- How are processes to ensure that approved suppliers continue to provide acceptable items and services established and implemented? Is it graded to ensure safety-related items and mission critical items are subject to more rigorous methods (e.g., inspection and testing at the manufacturer and upon receipt)?

4.8 Inspections and Acceptance Testing

- How are inspections and tests specified for items, services, and processes? How are acceptance and performance criteria established and used?
- Are inspection and acceptance tests planned and controlled consistent with DOE G 414.1-3?
- Is there a system for documenting the results of inspections and tests?
- Is inspection and test equipment controlled by a process to ensure it is calibrated and maintained?

4.9 Management Assessment

- Does the QMS describe how managers, at all levels, assess their management processes?
- Does the QMS provide for the identification and correction of problems that hinder the organization from achieving its objectives?
- Do managers take responsibility for, and directly participate in, the assessments?
- Has third party certification been considered? Used?
- Is DOE G 414.1-1 used to develop the process?

4.10 Independent Assessment

- Has the independent assessment process been adequately defined and documented?
- Are independent assessments (e.g., audits) planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement?
- Does the group performing independent assessments have sufficient authority and freedom from line management (i.e., not directly responsible for the work being assessed)?
- Are the persons conducting independent assessments technically qualified and/or knowledgeable in the areas to be assessed?
- Is there a process to obtain technical experts for assessments when they are not available in the organization?
- Has third party certification been considered? Used?
- Is the process applied to internal and external organizations?
- Is there a system for reporting assessment results to responsible management and for assuring that action is taken to correct identified issues?
- Is senior management informed of the assessment results and engaged in ensuring responsible management response to identified issues?
- Are DOE G 414.1-1 and appropriate national standards used to develop the process?