Preamble to DOE G 414.1-2A, *Quality Assurance Management System Guide,* dated 6-17-05

Quality Assurance (QA) Management System Guide Enhancements

DOE elements and DOE contractors should consult this Guide to develop and implement effective management systems that are consistent with the Department's quality expectations of the QA Rule, 10 CFR 830 Subpart A, and DOE O 414.1C, *Quality Assurance,* dated 6-17-05, and that support the *Safety Management System Policy,* DOE P 450.4, dated 10-15-96.

The revised QA management system guide includes enhancements arising from experience with implementing the DOE QA Rule and DOE O 414.1C. The Guide was evaluated in light of key policy initiatives, Directive changes, and other changes that have occurred within DOE since the Guide was last issued.

Evaluation and coordination with user groups have identified specific major improvements to the guide as follows.

- Clarified the scope of the guidance to include the QA Order, DOE O 414.1, and the QA Rule, 10 CFR 830 Subpart A.
- Incorporated review guidance for use by DOE in evaluating site office or contractor quality management systems for approval (it may also be tailored for use by contractors to review subcontractor QAPs).
- Incorporated a new QA Assessment Template for use in conducting assessments of QA Program implementation.
- Incorporated hyperlinks to the expanded guidance.
- Discussed the use of third party management system validation.
- Updated information pertaining to the identification and control of suspect/counterfeit items (S/CIs) and links to expanded guidance for S/CIs.
- Expanded information on the grading process to include programmatic and mission-critical considerations and a description of the steps in implementing the grading process.
- Strengthened the use of a single management system or work process for similar requirements.
- Expanded the description of identification, tracking, and resolution of quality problems.
- Clarified the guidance on procurement processes for nuclear safety applications.
- Updated the references, standards, and requirements documents.

Recommended Actions for Implementing DOE G 414.1-2A

The Office of Quality Assurance Programs recommends DOE elements and contractor organizations take the following actions to ensure maximum benefit from the management system approach defined in this Guide.

- Make this Guide available to the senior management position responsible for establishing and maintaining the quality management system and the integrated safety management system.
- Make this Guide available to employees responsible for developing implementing processes for these systems.
- Use the Guide (including the new review template in Appendix A) to review new and existing DOE and contractor quality management systems.
- Use the Guide (including the new assessment plan template in Attachment 1) to plan and implement Field Office QA assessments.
- Provide feedback on the usefulness of this Guide to the Office of Quality Assurance Programs, 301-903-2954, bud.danielson@eh.doe.gov

The existing DOE and contractor quality management systems should be reviewed to verify that—

- applicable quality criteria are addressed and applied to mission; environment, safety and health; safety system software; and radiation protection programs developed for 10 CFR 835 and safeguards and security work;
- integration with the safety management system is complete;
- appropriate national/international standards have been adopted from the established requirements set and identified to implement the QA program; and
- the senior management position responsible for the quality management system is identified and that person is appropriately qualified (ref. DOE-STD-1150-2002 for DOE qualification requirements).

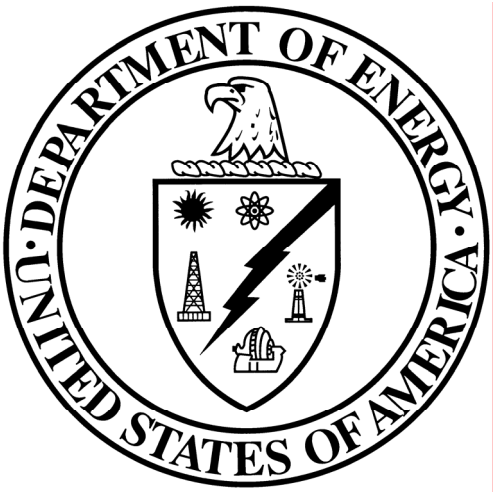
NOT MEASUREMENT SENSITIVE

DOE G 414.1-2A
6-17-05

QUALITY ASSURANCE MANAGEMENT SYSTEM GUIDE

for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, *Quality Assurance*

[This Guide describes suggested nonmandatory approaches for meeting requirements. Guides are not requirements documents and are not to be construed as requirements in any audit or appraisal for compliance with the parent Policy, Order, Notice, or Manual.]



U.S. Department of Energy
Washington, D.C.

AVAILABLE ONLINE AT:
http://www.directives.doe.gov

INITIATED BY:
Office of Environment, Safety and Health

FOREWORD

This Department of Energy (DOE) Guide is approved by the Office of Environment, Safety and Health and is available for use by all DOE elements and their contractors.

Beneficial comments (recommendations, additions, deletions, and any other pertinent data) or questions regarding this document should be sent to–

Gustave E. Danielson, Jr.
Office of Quality Assurance Programs
EH-31 /270 Corporate Square Building
U.S. Department of Energy
1000 Independence Ave., SW
Washington, DC 20585-0270
Phone (301)903-2954
Fax (301)903-4120
E-mail: bud.danielson@eh.doe.gov
Internet: http://www.eh.doe.gov/qa/

DOE Guides are part of the DOE Directives System and are issued to provide supplemental information regarding the Department's expectations of its requirements as contained in rules, Orders, Notices, and regulatory standards. Guides may also provide acceptable methods for implementing these requirements. Guides are not substitutes for requirements, nor do they replace technical standards that are used to describe established practices and procedures for implementing requirements.

This Guide is available electronically on the DOE Directives System at the following address: http://www.directives.doe.gov.

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CONTENTS (continued)

1. INTRODUCTION

To accomplish Department of Energy (DOE) missions and objectives, DOE and its contractors are responsible for a wide range of work activities, including basic and applied research; product development; design, construction, operation, modification, decommissioning, and environmental remediation of DOE facilities and sites; and management and oversight functions relating to these activities. This work must be accomplished safely while minimizing potential hazards to the public, site or facility workers, and the environment consistent with the quality assurance requirements of 10 CFR 830, Subpart A, *Quality Assurance.* The quality criteria of 10 CFR 830 and DOE O 414.1C, *Quality Assurance,* dated 6-17-05, provide for a quality management system for accomplishing and assessing DOE's work consistent with requirements.

2. APPLICATION

This Guide provides information on principles, requirements, and practices used to establish and implement an effective quality assurance program (QAP) or quality management system consistent with the requirements of 10 CFR 830 Subpart A and DOE O 414.1C, hereafter referred to as the QA Rule and the QA Order. Additional resources are available at: http://www.eh.doe.gov/qa.

This Guide may also be used by a contractor to assist in obtaining QAP approval from its DOE customer.

This guidance includes methods for the interrelated functions and responsibilities of managing, performing, and assessing work. Implementation of a quality management system will contribute to improved safety, management, and reliability of DOE products and services.

The methods and references described in this Guide are not mandatory and do not add, modify, or delete any requirements identified in the QA Rule and Order. Use of this Guide in conjunction with appropriate standards will facilitate development and approval of a QAP compliant with the QA Rule and Order. An organization may select alternative methods to document and implement its quality management system as long as the requirements of the QA Rule and Order are satisfied. The content of the quality management system must be based on an organization's unique set of responsibilities, its product/service realization process, hazards, and customer expectations.

3. DISCUSSION

The quality of a product or service is the extent to which that product or service satisfies the requirements, needs, and expectations of the customer. As used in this Guide, the term "customer" includes those entities that receive products and services from the organization, including DOE, regulators, stakeholders, the public, contractors, suppliers, and employees. The attainment of quality is the responsibility of each member of an organization. The quality

criteria of the QA Rule and Order provide the framework for a results-oriented management system that focuses on performing work safely and meeting mission and customer expectations while allowing the organization to become more efficient through process improvement.

The Department's objective is to simultaneously satisfy requirements of the QA Rule, safety management system (SMS) policies and regulations, and the quality management system of the QA Order. The development and implementation of a quality management system, integrated throughout the organization, will improve performance and provide assurance that the applicable requirements are being satisfied.

4. GUIDANCE

4.1 Program

4.1.1 Introduction

The principal measure of an organization's performance is the quality of its products and services. The QA Order and Rule require that an organization develop, document, and maintain an effective QAP, also referred to as a quality management system. The goal of the quality management system is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. To do so, the quality management system should describe methods for planning, performing, assessing, and improving the adequacy of work, including work assigned to parties outside the organization. The quality management system is intended to complement the DOE Integrated Safety Management System (ISMS).

The criteria of 10 CFR 830 prescribe a comprehensive management system for DOE work. The focus of the quality management system should be properly and safely accomplishing the mission as outlined, for example, in the organization's strategic plan. Therefore, every component and employee of the organization is included within the quality management system's scope. The scope also describes the organizational structure, functional responsibilities, levels of authority, and interfaces.

4.1.2 Responsibilities

It is the role of senior management to establish and cultivate principles that integrate quality requirements into daily work. Management is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the quality management system. However, every individual in the organization is responsible for achieving quality in his or her activities. Senior management should require and cultivate the achievement and improvement of quality at all levels of the organization and ensure that the QAP is understood and implemented.

The QA Rule and Order and the SMS Policy emphasize that management should promote effective achievement of performance objectives through implementation of the SMS Policy guiding principles.

4.1.3 Graded Approach

A graded approach that doesn't compromise public, employee, or facility safety or adversely impact the environment and complies with requirements, rules, and regulations must be used to implement the QAP. The graded application of facility/activity requirements is dependent on the hazards and/or level of risk associated with the activity or structures, systems, and components (SSCs) under consideration. The scope, depth, and rigor of the quality management system's application of requirements should be determined by the use of a grading process before performing the activity. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

Grading is encouraged if a single or uniform method of applying a requirement across a facility or activity does not add value or reduce risk. The grading process provides the flexibility to design controls that best suit the facility or activity. The grading process is not used to obtain exemptions from the requirements of the QA Rule or Order.

The grading process is used to determine the appropriate controls to address and mitigate hazards and/or risks. This process is accomplished by deliberate quality planning and is based on activity-specific or facility-specific factors such as—

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- impact/consequences on the programmatic mission of a facility;
- the particular characteristics of a facility or activity;
- the nuclear safety classification or hazard category of the item or activity;
- adequacy of existing safety documentation;
- the relative importance of radiological and nonradiological hazards;
- complexity of products or services involved;
- performance history of a facility or activity; and
- any other relevant factors.

The first step in the grading process is to identify the hazards, and for the facility level their consequences and probability of a failure, before work begins. The second step is to identify the specific requirements and controls to be applied. The third step is to determine the depth, extent,

and degree of rigor necessary in the application of the requirements and controls. The final step is to communicate and implement the selected requirements and controls and their degree of rigor by means of documented work processes (procedures, instructions, specifications, and controls). The logic, method of implementation, and basis for grading should be documented in the quality management system, periodically reviewed in light of changes that may have occurred, and if appropriate, revised to reflect those changes.

The graded approach must not be used to "grade quality assurance criterion to zero" which has the affect of eliminating all verifications of the requirement ("to get out of work"). Even in the least stringent application, compliance with applicable portions of stated requirements is mandatory unless an exemption is approved through an appropriate process.

When considering the use of grading of an item or activity, it is important to consider the impact of safety on personnel, the public, and the environment. The safety class or safety significance of the item or activity is critical to the amount of controls imposed which are necessary to assure the requisite or desired quality.

Risk is a fundamental consideration in determining to what extent controls should be applied at the facility level. The varying degrees of the controls applied should be dependent upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations.

These controls are documented and communicated to facility/activity personnel to ensure appropriate application. This documentation should take the form of written procedures, practices, requirements manuals, policy statements, standing orders, or other written and controlled means as deemed appropriate by facility/activity management. The level of approval of this documentation is also based on the hazards, complexity, and/or relative risk.

4.1.4 Integrating the Safety Management and Quality Management Systems

The quality management system complements and is integrated with the SMS, described in DOE P 450.4, *Safety Management System Policy,* dated 10-15-96, and DOE Acquisition Regulation 48 CFR 970.5204-2 (i.e., the DEAR ISMS clause). The quality management system provides processes and tools for ensuring that ISMS objectives are achieved. DOE P 450.4 expresses a fundamental expectation that all work will be performed safely. The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the quality management system ensures compliance with the approved safety standards set, so that the expectation for safe work within controls is met. This also ensures that workers, the environment, and the public are reasonably protected from harm.

At the organizational or institutional level, the DOE quality and safety requirements share a management systems approach (see table below) to achieving their objectives. As such, the required system documentation for each (ISM system description and QAP) may be integrated into a single document to describe how the organization intends to implement the requirements. In some cases, the local DOE office (Site Office or Field Element) and contractor may determine that it is expedient to maintain both the ISM system description and the QAP. In these cases, as

a minimum, the implementing mechanisms that are described in each should be integrated to the maximum extent practical, and the system description and QAP should cross-reference these procedures as applicable. For example, the processes and procedures for conducting management assessments should be referenced in both the QAP and the ISM system description.

QA Criteria / SMS Principles and Functions	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
Line Management Responsibilities	X			X					X	
Clear Roles & Responsibilities	X			X					X	X
Competence Commensurate with Responsibilities		X		X					X	X
Balanced Priorities	X			X					X	X
Define the Work				X	X	X	X	X	X	X
Analyze Hazards				X	X	X	X	X	X	X
Develop & Implement Controls, Safety Standards, Requirements				X	X	X	X	X	X	X
Perform Work within Controls/Operations Authorization				X	X		X	X	X	X
Feedback & Improvement			X	X	X			X	X	X

Note: X indicates cross reference delineating (a) when the QA criteria and the principle/function have shared intent or (b) when the QA criterion is applied to the ISM principle or function.

Likewise, a single process (e.g., procedures and plans) that satisfies quality and safety requirements at the facility level and the activity level should be used.

Some shared attributes of quality and safety management systems may include:

- expectations for implementation [DEAR 970.5204-2 (c)] (10 CFR 830.121),
- documentation of the management system (ISMS Principle 7) (10 CFR 830.121),
- clear roles and responsibilities (ISMS Principle 2) (QA Criterion 1),
- balanced priorities (resources) (ISMS Principle 4) (QA Criterion 1),
- feedback and improvement (ISMS Core Function 5) (QA Criteria 3, 8, 9 and 10),
- line management responsibility (ISMS Principle 1) (QA Criterion 1, General Requirements),
- competence and qualifications (ISMS Principle 3) (QA Criterion 2)
- standards and controls for work (ISMS Principle 5 and Core Function 4) (QA Criteria 9 and 5), and
- graded and tailored controls (ISMS Principle 6) (10 CFR 830.7).

DOE G 450.4-1B, *Integrated Safety Management System Guide for Use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); The Functions, Responsibilities, and Authorities Manual; and the DOE Acquisition Regulation,* dated 3-1-01, contains information on safety management principles, supporting attributes, references on the subject, and integration methods.

4.1.5 Use of Technical Standards

The Government-wide philosophy of using performance expectations in combination with national and international consensus standards is consistent with the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and Office of Management and Budget (OMB) Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, dated 2-10-98. The QA Rule and Order requirements are stated as performance expectations and do not always specify methods for achieving the desired performance. Consequently, unless otherwise specified, organizations should identify, document, and use appropriate standards to develop and implement the management system. In certain cases, DOE does specify national standards. For example, the QA Order specifies NQA-1 2000 for Safety Software. Clearly-defined standards will also support SMS Policy Principle 5, Identification of Safety Standards and Requirements.

Current appropriate standards include the following:

American Society of Mechanical Engineers (ASME) NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications, 2004 (for nuclear-related activities). Note that NQA-1-2004 Part 4 includes new guidance for determining how the standard may be used to implement DOE QA requirements;

American National Standards Institute (ANSI)/International Organization for Standardization/American Society for Quality (ASQ) Q9001:2000, Quality Management Systems: Requirements (for nonnuclear activities); and

ANSI/ASQ Z 1.13-1999, Quality Systems Guide for Research, 1999, (for nonnuclear research activities).

Additional standards may be used, where practicable and consistent with contractual or regulatory requirements, as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

In many cases, the particular standards to be used are specified by the customer. Organizations with multiple customers must often develop their management systems using several standards. For example, a single facility may adopt ISO 9001 for corporate reasons, ASME NQA-1-2004 for an Environmental Protection Agency/Nuclear Regulatory Commission regulation, and DOE Quality Criterion 1("QC-1") for nuclear weapons activities. The standards selected should suit the products and services of the organization and its customers. The organization must assure that the standard selected addresses the work presenting the most hazardous/mission critical

risks, and in need of the most rigorous QAP and implementing processes. The QAP may then be graded to address the needs of less hazardous/mission critical work.

4.1.6 Quality Management System Review and Approval

The contractor quality management system requires DOE review, for compliance with the QA Rule and Order, and DOE approval. Similarly, DOE field organization QAPs may require DOE Headquarters review and approval. A review template is provided in Appendix A to capture the basic activities a DOE customer should conduct in the review and approval of a contractor QAP.

The Office of Quality Assurance Programs is available for assistance with QAP assessments (see http://www.eh.doe.gov/qa/ for contact information).

Ensuring the adequacy and effectiveness of the quality management system is greatly enhanced by—

1. establishment of a robust assessment process (refer to Sections 4.9 and 4.10 of this Guide);
2. customer review and approval;
3. use of third-party assessments,
4. contract performance measures/incentives; and
5. use of regulatory and contract enforcement authority, including civil, criminal, and financial penalties.

A strong contractor quality management system is key to effective performance-based management, and it enables the optimizing of DOE oversight activities. The contractor needs to demonstrate to DOE the effectiveness of the quality management system. The use of a third-party team of "experts" can be an effective tool for evaluating the quality management system. To facilitate success, the contractor should work with the DOE customer as well as senior management in the selection of a third-party evaluation team. The team should be led by an individual who is truly independent from the assessed organization. The development of the criteria used for the evaluation should also include input and concurrence from the DOE customer.

4.2 Personnel Training and Qualification

4.2.1 Introduction

Qualification and training processes ensure that personnel achieve and maintain the required capabilities to perform their work.

4.2.2 Responsibilities

Management is responsible for committing resources to facilitate the training and qualification processes for personnel in their organizations and ensuring that personnel hired or transferred into positions meet the appropriate requirements. Each level of the organization should adequately describe its training and qualification needs. These descriptions should include requirements, interfaces, training methods, training responsibilities, and duties of line and training organizations.

4.2.3 Qualification of Personnel

Policies and procedures that describe personnel selection, training, and qualification requirements should be established for each function and follow Federal, State, and local guidelines, as applicable. These should include the minimum applicable requirements for education, experience, skill level, and physical condition. For example, DOE personnel responsible for oversight of QA at nuclear facilities are qualified to DOE M 426.1-1A. Likewise, the Contractor Requirements Documents of DOE O 420.1A, *Facility Safety,* dated 5-20-02, and DOE 5480.20A, *Personnel Selection, Qualification, and Training Requirements for DOE Nuclear Facilities,* dated 11-15-94, define requirements for contractor personnel with nuclear facility operation and system engineer responsibilities.

Before personnel are allowed to work independently, management should ensure those personnel have the necessary experience, knowledge, skills, and abilities. Personnel should be qualified based on factors such as—

- previous experience, education, and training;
- performance demonstrations or tests to verify previously acquired skills;
- completion of training or qualification programs; and/or
- on-the-job training.

4.2.4 Training

Training assists personnel in acquiring knowledge of the correct and current processes and methods to accomplish assigned tasks. It enables personnel to understand the fundamentals of the work, the associated hazards**,** the context within which the work is performed, and the reasons for any special work requirements. Initial training should prepare personnel to perform the job. Continuing training should maintain and promote improved job performance. Training can be grouped into three general categories: project-/task-specific, site-/facility-specific, and institutional.

1. Project-/task-specific training should impart the knowledge required for personnel to perform their assigned duties safely and successfully. This training may include project/task goals and schedules, implementing procedures, safety and hazard controls, methods, requirements, process metrics, and skills. Project/task-specific training requirements should be defined by project managers, and workers.

2. Site-/facility-specific training should convey the safety, emergency plans, security, and operations information necessary for personnel to prepare for and perform their assigned duties in the site/facility. Management is responsible for defining training requirements and ensuring that the training is administered.

3. Institutional training should convey general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

4.2.5 Training Plans

Training plans should be prepared for personnel responsible for managing, planning, performing, controlling, and overseeing work. Training plan content should also be based on current facility, site, or organization procedures; technical and professional references; and past organization/ industry experience. Training plans should consider changes in hazard conditions, technology, work methods, and job responsibilities. Training plans should also specify the type of training records to be maintained.

4.3 Quality Improvement

4.3.1 Introduction

Quality improvement is a disciplined management process based on the premise that all work can be planned, performed, measured, and improved. Management should ensure that the focus is on improving the quality of products, processes, and services by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating lessons learned, and resolving significant management issues and problems that hinder the organization from achieving its objectives. Management should balance safety and mission priorities (SMS Policy Principle 4) when considering improvement actions.

Management should encourage employees to plan, develop, explore and implement new ideas for improving products, processes, and services. Improvement processes are most effective when each employee participates and should not be delegated to a particular person or group. Management commitment can be demonstrated by empowering and encouraging employees to—

- identify problems,
- identify opportunities for improvement,
- identify "best management practices,"
- develop alternative approaches for addressing problems and recommend improvements (e.g., reducing process variability or cycle time),
- implement the approved solution,
- evaluate the improvement, and
- provide lessons learned to other organizations.

Quality problems and other quality-related information (i.e., both positive and negative) from various internal and external sources, should be reviewed and analyzed to identify improvement opportunities in the quality management system, processes, items, products, or services. Implemented improvements should be monitored and methods established to verify their effectiveness.

4.3.2 Improvement and Quality Problems

An effectively planned and implemented quality management system is one that—

- uses feedback information to improve items, services, and the processes that produce them;
- prevents or minimizes quality problems;
- corrects problems that occur; and
- uses performance measures that identify strengths and weaknesses.

Preventive action minimizes, through appropriate design, inspection, procurement, and other process controls and assessment activities, the occurrence of quality problems. DOE and contractor organizations should prioritize and focus their resources on preventive actions and on those quality problems that have the greatest potential for—

- posing adverse risks to the environment and human health,
- impacting the safety and reliability of operations and products, and
- affecting the ability to meet customer requirements.

As used in this Guide, a quality problem is a collective term that may be—

- a deficiency in an activity, product, service, item characteristic, or process parameter;
- a noncompliance to a requirement; or
- an indeterminate/substandard condition, or a suspect/counterfeit item (S/CI).

4.3.2.1 Quality Feedback

Work activities and management systems can be continuously improved through assessment and feedback processes. Effective feedback from multiple sources is the foundation for processes designed to prevent, identify, and correct problems. The least desirable form of feedback results from accidents or unplanned events that self-disclose the quality problem. The process should include the use of lessons learned from the local organization and other organizations. Identified improvement actions should also be shared with other organizations. Management should track the actions to closure and ensure the actions are effective in providing the anticipated improvements. Quality improvement processes will support SMS Policy feedback and improvement core function, and the Department's commitment to develop corrective action

plans for safety issues (findings) reported by the Office of Independent Oversight and Performance Assurance (OA), or for judgments of need resulting from Type A Accident Investigations. These findings will be tracked using the DOE Corrective Action Tracking System.

4.3.2.2 Identification of Quality Problems

Quality problems may be identified by internal organization sources (e.g., workers, customers, suppliers) or by an external source (customers/regulators). Once identified, quality problems should be evaluated to determine significance and documented. The method for determining the significance of a problem and the process for handling problems should be documented in the quality management system.

The causes of quality problems should be investigated and identified. Causes should be corrected to prevent recurrence of the problem. For straightforward problems, a simpler apparent cause process may be appropriate. For more serious or complex problems, a disciplined root cause analysis process should be applied.

Problems that are not significant and that cannot be readily corrected on the spot should be identified and documented (e.g., by logging) and handled in an expedient manner that may not follow the more formal processes for quality problem documentation (e.g., nonconformance report) and disposition.

Software quality problem reporting may be managed in a software specific process. However, a software specific process should include the same elements as the overall quality management process and should address the same quality problems listed in Section 4.3.2, including—

- deficiencies in an activity, product, service, item characteristic, or process parameter;
- deficiencies in a noncompliance with a legal, contractual, or other requirement; or
- the existence of substandard conditions.

4.3.2.3 Resolution of Quality Problems

A quality problem resolution process should consist of—

- identifying a condition adverse to quality,
- evaluating its significance and extent,
- analyzing the problem and determining its causes,
- reporting the planned actions to the organization identifying the problem,
- assigning responsibility for correcting the problem,
- taking prompt corrective (remedial) action and documenting that action,
- training or retraining on processes, procedures, or management systems,

- taking steps to prevent recurrence,
- replicating the actions where appropriate,
- verifying implementation,
- documenting closure, and
- determining effectiveness of the corrective and preventive actions for significant problems.

Quality problems identified by internal and external sources (e.g., DOE OA, judgments of need resulting from Type A Accident Investigations, DOE Office of Price-Anderson Enforcement, DOE Inspector General, or customers) should be tracked through resolution. Corrective action is the identification of cause and the effective resolution of a quality problem after its occurrence to prevent its recurrence. The Department's Corrective Action Tracking System (CATS) and Type A accident investigation judgments of need are used to report corrective actions and their status for Office of Oversight safety issues. Specific expectations for CATS and corrective action plans are defined in Attachment 4 of the QA Order and the CATS Web site at http://www.eh.doe.gov/camp/index.html.

Quality problem resolution typically involves—

- documenting dispositions for repairing, reworking, inspecting, or testing items;
- replacing or returning items to suppliers, scrapping the items, or using them as is;
- changing process parameters or procedures;
- eliminating substandard conditions; or
- changing the management system or methods for achieving compliance.

4.3.2.4 Quality Performance Analysis

Quality problems should be resolved individually as well as analyzed as a collection to identify systemic quality problems and opportunities for process improvement.

4.4 Documents and Records

4.4.1 Introduction

Documents and records are required to effectively manage, perform, and assess work. Documents and records should include applicable requirements to indicate that work (including safety) has been properly specified and accomplished. Management should identify any documents and records that must be developed and controlled. Management is responsible to provide the resources necessary to accomplish the document and record requirements.

4.4.2 Documents

A document control system should be in place to control the preparation, review, approval, issue, control, and revision of documents. Documents are required by organizations, projects, or programs to control policy and administrative and/or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data to be controlled from time to time for reference purposes. The document control system should be established to supply the documents necessary for personnel to safely and correctly perform their assigned responsibilities. Document control systems ensure that the mechanisms developed to implement the safety management functions of DOE P 450.4 are properly prepared, controlled, and available for use.

4.4.3 Records

A record contains information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions and provide evidence that work was correctly performed. Records may be in a variety of forms (e.g., electronic, written, or printed; microfilm; photographs; radiographs; or optical disks). Typical records include procedures, plans, and manuals; training and qualification results; acceptance test results; technical/ regulatory correspondence; operational records; design basis descriptions, design review results, design revisions, and configuration management data; and quality problem resolutions.

Records should be compiled in a records management system. The system should include provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records. Records retention, protection, preservation, change, traceability, accountability, and retrievability should also be specified. The records management system should have schedules for records retention and disposition consistent with the requirements of DOE O 200.1, *Information Management Program,* dated 9-30-96.

The hardware and software tools used to create and store records should be maintained to ensure that the records can be retrieved. The National Archives and Records Administration, 36 CFR Chapter XII, provides a recommended approach for maintenance of records, including electronic records management.

4.5 Work Processes

4.5.1 Introduction

Work is defined as the process of performing a defined task or activity. Work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls to achieve an end result.

4.5.2 Work Performance

Managers are responsible for ensuring that those under their supervision have the training, skills (including knowledge and understanding of the capabilities of the processes being used),

equipment, work process documents, and resources needed to accomplish their work. Line management and workers should cooperate to identify processes that can be improved based on feedback prior to and following implementation of the work process. Management should ensure that the following are clearly identified and conveyed to workers before they begin work:

- customer and data requirements for the work and final product;
- hazards associated with the work;
- safety, administrative, technical, environmental, and quality controls to be used during the work;
- technical standards applicable to the work and final product;
- acceptance criteria applicable to the work and final product; and
- procedures for verification of the completed work using established criteria.

Procedures, work instructions, or other appropriate means used to define work processes should be documented and controlled. The scope and detail of documentation should be commensurate with the complexity and importance of the work, the skills required to perform the work, the hazards and risks or consequences of quality problems in the product, process, or service, and the need to meet regulatory and contract requirements. Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented. This serves as the point of integration for ISM and QA into an integrated management approach. See DOE P 450.4 and DOE O 5480.19 as references for details and additional requirements.

Workers are responsible for the quality of their work. Workers should do their work correctly the first time, in accordance with established procedures and work instructions. Because workers are the best resource for contributing ideas for improving work processes, products, and services, they should be involved in work process design, process evaluation (pre-job briefing), and providing the feedback necessary for improvement.

4.5.3 Item Identification and Use Control

"Item" is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support system. A process for the identification and control of items should be established and implemented to—

- prevent the use of incorrect or defective items,
- identify and control S/CIs, and
- provide for the control and maintenance of items.

The identification and control process should apply from manufacture or receipt through delivery, installation, or use. The process should also provide for the identification and configuration control of installed or replacement items consistent with specified requirements.

Physical identification of items is preferred. Suitable identification information includes the unique part; lot; heat; model; version; or serial numbers on the item or in records traceable to the item, or both.

4.5.4 Item Protection

Work processes should be established and implemented to protect items in accordance with specified technical standards and administrative controls to prevent damage, loss, or deterioration. Work processes should specify protective methods for sensitive or perishable items, such as special handling, shipping, and storage controls for precision instrumentation and limited shelf life items, and for items requiring special protective environmental controls, such as temperature and humidity controls.

4.5.5 Equipment Control

Work processes should be established and implemented to ensure that equipment used for process monitoring and data collection is of the proper type, range, and accuracy. Such equipment should be calibrated according to technical standards and maintained to ensure continuing data quality and process capability. (See also Section 4.8.3.)

4.5.6 Software Control

Work process controls should be applied throughout the life cycle of software and the items it supports. References that describe these controls are included in Appendix B, References. Topics that are of particular interest to engineering, information technology, and quality assurance organizations are addressed below. Safety software used in nuclear facilities should be controlled consistent with DOE G 414.1-4, *Safety Software Guide,* dated 6-17-05. Additional resources are available at http://www.eh.doe.gov/sqa.

Software control processes should be established and implemented to ensure that computer programs used for applications such as developing or verifying designs, performing safety analyses, establishing safety envelopes, and performing safety management functions (e.g., tracking limiting conditions for operations or safety issue corrective actions, and controlling operating safety systems) perform as intended and cannot create a safety issue through failure or unexpected operational impacts.

4.6 Design

4.6.1 Introduction

A design process should be established that provides appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces. Design work should be based on sound engineering judgment, scientific principles, and applicable codes and standards. DOE O 420.1, *Facility Safety*, identifies some of the design requirements.

The design of SSCs, software, and processes should be subject to design process controls and verification requirements appropriate to the level of risk the items present to the public, the worker, the environment, and project success. For example, selection of the applicable design control requirements for a facility should be guided by safety analyses that establish—

- the identification and functions of safety (safety class and safety significant) SSCs;
- the significance to safety of functions performed by those SSCs; and
- the aspects critical to the performance, reliability, or programmatic requirements of the designed SSCs.

Designs should provide for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of the items. The designer should consider the expected use and life expectancy of the items to allow appropriate disassembly and disposal requirements to be addressed.

Design documentation should include a list of approved and controlled computer codes.

Design records should include documentation such as design inputs, calculations, and analyses; engineering reports; design outputs; design changes; design verification activities; and other documents that provide evidence that the design process was completed correctly.

4.6.2 Design Inputs

Design inputs should be based upon contractual requirements and customer expectations and should be technically correct and complete. Design inputs may include such information as design bases, health and safety considerations, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements.

4.6.3 Design Process

The design process should translate design inputs into design output documents that are technically correct and compliant with the end user's requirements. Aspects critical to the performance, safety, or reliability of the designed items should be identified during the design phase. Design output documents should be prepared to support other processes such as dose and risk assessments, procurement, manufacturing, assembly, construction, testing, operation, inspection, maintenance, and decommissioning.

Technical and administrative design interfaces should be identified and methods established for their control.

Computer software used to originate or analyze design solutions during the design process or analyze the potential accidents to be mitigated by the final design should be controlled using DOE Guide G 414.1-4, *Safety Software Guide,* dated 6-17-05. Software used to analyze designs or verify designs or that otherwise might have safety, operational, or programmatic consequences should be appropriately documented. Software used for designs should be validated for the

intended use; otherwise, status of the code validation should be identified and documented before use. The documentation should be sufficiently complete to allow a person technically qualified in the subject to review and understand it and verify the adequacy of the results without recourse to the originator. Reviewing and understanding an analysis may mean that a reviewer should be able to inspect the formulas executed by a computational program. Test cases should prove that the computations provide agreement with known and theoretical results.

Once tested, user-configurable files for computational programs should be placed under configuration control. As an alternative, the user-configurable file may be tested at each use to demonstrate that it produces correct results for the problem to which it is being applied. Software design should be maintained so that any changes are made under a documented configuration management process. The designer should also consider ease of enhancement to reflect hardware changes or migration to new platforms or operating systems. The design organization should perform design analyses and checks to ensure that design output documents meet design input requirements and that any changes have been approved and documented.

4.6.4 Design Output

The completed design should be recorded in design output documents such as drawings, specifications, test/inspection plans, maintenance requirements, and reports. As-built drawings and shop drawings should be maintained after production or construction to show actual configuration. The administrative interface process should clearly indicate responsibilities for design output documents, including the requirements for document control, configuration management, and records management.

4.6.5 Design Verification

Design verification is a documented process for ensuring that the design and the resulting items will comply with the project requirements. Design verification methods include, but are not limited to, design reviews, alternate calculations, qualification testing, and peer review of experimental design. When appropriate, the verification process may include consideration of previous verifications of similar designs or verifications of similar features of other designs.

Design verification should be performed by technically knowledgeable persons separate from those who performed the design. Interim verifications may occur at predetermined stages of design development. The extent of design verifications should be based on a graded approach depending on the designed product's complexity and importance to safety and project success.

Organizations rely on verified design output to support other work, such as procurement, manufacture, construction, testing, or experiments. When the verification cannot be achieved in time for these activities, unverified portions of the design should be identified and controlled. Design verifications should be completed before relying on the SSC to perform its function.

4.6.6 Design Changes

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. Temporary modifications should receive the same levels of control as the designs of permanent modifications.

4.6.7 Suspect/Counterfeit Items

DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, dated 11-3-04, provides design organization guidance to help avoid the procurement and use of S/CIs and ensure engineering involvement in disposition of any S/CIs discovered in items or systems. Additional guidance for evaluating S/CIs that may have been installed is provided at http://www.eh.doe.gov/sci/.

4.7 Procurement

4.7.1 Introduction

The procurement process should ensure that items and/or services provided by suppliers meet the requirements and expectations of the end user. The procurement process should be planned and controlled to ensure that—

- the end user's requirements are accurately, completely, and clearly communicated to the supplier;
- supplier, designer, and end-user requirements are met during the production phase; and
- the proper product is delivered on time and maintained until use.

Procurement processes should prevent introduction of S/CIs and provide a method to detect them before they are released for use (draft DOE G 414.1-3).

The selection of procurement requirements should be commensurate with the importance of the end use of the purchased item or service. Management controls exist for DOE procurement and subcontracts through applicable DOE Orders, the Department of Energy Acquisition Regulation (the DEAR) in 48 CFR subchapters A through H, and the Federal Acquisition Regulation (FAR), in 48 CFR 970 et. seq. The requirements in the QA Rule and Order should not be interpreted to require the development of redundant procurement management systems, but rather to ensure that existing procurement management systems adequately respond to end-user requirements.

The procurement process of DOE nuclear facility contractors must include a determination of the applicability of 10 CFR 830 to the supplier or subcontractor. [10 CFR 830.121 states "The QAP must: . . . c.(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of §830.122"]. If applicable, procurement

documents and contracts for items and services provided to facilities covered by 10 CFR 830 should include a statement informing the supplier or subcontractor that it is subject to 10 CFR 830 and of the potential for enforcement actions under 10 CFR 820. Suppliers and subcontractors are not required by 10 CFR 830 to submit their QAPs to DOE for review and approval; rather, it is left to the contractor to determine the methods for ensuring that procured items and services meet requirements and perform as expected.

4.7.2 Procurement Documents

Procurement documents should clearly state or reference requirements and acceptance criteria for purchased items and services. Procurement documents should include any specifications, standards, and other applicable documents referenced in the design documents. Critical parameters and requirements, such as document submittals, product related documentation, problem reporting, administrative documentation, personnel or materials qualifications, tests, inspections, performance expectations for services, and reviews, should be specified. When procuring safety-related SSCs or special processes, greater attention may be necessary based on their applications.

4.7.3 Supplier Qualification

The objective of evaluating suppliers is two-fold: 1) to verify the supplier has implemented a quality assurance program that conforms to contract requirements; and 2) to verify that the supplier is capable of providing the items or services identified in the contract. Prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements. An effective evaluation method is an assessment conducted at the supplier's facilities. The assessment may include personnel, technical and equipment capabilities, and processes. This method may be used in combination with—

- a review of the supplier's history of providing identical or similar items or services,
- a review of shared supplier quality information (e.g., DOE Consolidated Audit Program, DOE Laboratory Accreditation Program),
- an evaluation of certifications or registrations awarded by nationally accredited third parties, and
- an evaluation of documented qualitative and quantitative performance information provided by the supplier.

The method or combination of methods chosen is intended to provide adequate confidence that the supplied item or service will meet requirements.

Potential suppliers should be identified as early as possible in the design and procurement process in order to determine their capabilities.

4.7.4 Supplier Performance Monitoring

The qualified supplier's performance should be evaluated periodically during the life of the contract to confirm its continuing capabilities. Suppliers should be monitored to ensure that acceptable items or services are produced and schedule requirements are being met. Supplier monitoring of the work process should be performed to ensure conformance to those requirements that cannot be readily determined by inspection or test of the product. Monitoring may include—

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- surveillance of manufacturing processes and methods;
- processing and use of change information;
- review of internal assessments;
- review and disposition of nonconformances; and
- selection, qualification, and performance monitoring of subtier suppliers.

4.7.5 Inspection

The procurement process should provide for identifying inspections and tests to ensure conformance with purchase requirements. Design and procurement documents should specify critical or important acceptance parameters for inspection.

Inspections should include verification that specified documentation has been provided by the supplier and that items were not damaged during shipment. Inspection may include the following methods:

- inspections of materials or equipment at the supplier's plant,
- receipt inspection of the shipped items,
- review of objective evidence such as certifications and reports, and
- verification or testing of items before or following shipment.

4.7.6 Supplier Documentation

Supplier-generated documents should be accepted through the procurement system and controlled and processed by the end-user organization. These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformance documentation, corrective actions, approved changes, waivers, and deviations.

4.7.7 Procurement of Safety Grade Items for Nuclear Facilities/Activities

Items procured for safety applications in nuclear activities or SSCs should be either—

- purchased from a supplier whose quality assurance program has been evaluated and found acceptable or
- purchased as commercial-grade items for dedication to the safety service.

Commercial-grade items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards. Critical design characteristics should be identified by the design organization during item selection. Critical design characteristics and appropriateness of the item for use should be verified by—

- testing the item,
- inspecting the item, and/or
- evaluating the supplier's ability to consistently supply the item at a level of quality that meets the safety and reliability requirements for the item.

4.7.8 Multisite Procurement

Multisite procurement is becoming more common within the DOE complex and should be addressed in individual quality management systems and implementing procedures. For such procurements, interface among DOE and contractor organizations and a clear definition of the responsibilities of each organization with regard to quality requirements must be established and agreed to in writing.

4.8 Inspection and Acceptance Testing

4.8.1 Introduction

Inspections and tests are accomplished to verify that physical and functional aspects of items, services, and processes meet requirements and are fit for acceptance and use. Performance expectations, inspections and tests should be identified/considered early in the design process and/or specified in the design output and procurement documents.

Before beginning work, personnel should check items to ensure they are correct and suitable for their intended applications. Personnel should check their process output to verify that it meets or exceeds specified requirements.

4.8.2 Process

Inspection/test planning should be performed. Appropriate sections of approved codes or standards may be used for acceptance requirements and inspection/test methods. In planning for inspections/tests, personnel should consider provisions for the following—

- identification of characteristics to be examined;
- required qualifications of individuals who perform the examinations;
- descriptions of examination methods, including equipment and calibration requirements;
- acceptance and rejection criteria;

- suitable environmental conditions;
- shelf life and maintenance;
- required safety measures; and
- mandatory hold points, when applicable.

Inspections/tests should be performed by technically qualified personnel who have the authority to access appropriate information and facilities to verify acceptance. These qualified personnel should be independent of the activities being inspected/tested and should have the freedom to report the results of the inspections/tests. Inspection/test results should be evaluated and verified by qualified personnel of the design organization to document that requirements have been satisfied.

4.8.3 Software Testing

For software test planning, personnel should identify the activities necessary to show the acceptability of the software against the approved requirements and to verify the functionality of the software. Planning should address review and testing activities throughout the software life cycle.

Software tests should include evaluating whether the software adequately and correctly performs all intended functions (specified in the design requirements) and, as appropriate, whether the software properly handles abnormal conditions and events (and credible failures), does not perform adverse unintended functions, and does not degrade the system (either by itself or in combination with other functions). Safety software used in nuclear facilities should be tested consistent with DOE G 414.1-4.

Applications of commercially available computational software, which include spreadsheet and math programs, should be tested. The user-configurable files containing the mathematical model used to solve a problem should be tested and controlled for the type of problem and range of values for which a solution is being sought. The applications should be tested on the same platform and operating system, using the same build of the computational program that is used for the actual computation.

4.8.4 Records

Inspection and test records should, at a minimum, identify—

- item tested,
- date of test,
- test method,
- tester or data recorder,
- observations,

- results and acceptability, and
- action taken concerning problems noted.

As a result of the inspection/test process, the status of items, services, and processes requiring examination should be clearly and plainly denoted to ensure only those with acceptable inspection and test results are used. The process should provide for review and reinspection/retest of items whose inspection/test parameters have changed.

4.8.5 Control of Measuring and Test Equipment

Measuring and test equipment (M&TE) used for inspections, tests, monitoring, and data collection should be calibrated, maintained, and controlled using a documented process. M&TE should be checked before use to ensure that it is of the proper type, range, accuracy, and precision and that it is uniquely identified and traceable to its calibration data. Procedures should be established for testing, retesting, adjusting, and recalibrating M&TE. M&TE should be calibrated to standards traceable to the National Institute of Standards and Technology or other nationally recognized standards when appropriate. If no nationally recognized standard exists, the basis for calibration should be documented. When calibrating and/or checking M&TE for use, consideration should be given to computer programs that are part of the M&TE.

The use of each item of M&TE should be traceable and associated with the item of M&TE. This is because measurements and tests performed with the M&TE may need to be reevaluated if the item of M&TE is subsequently found to be out of its acceptable calibration range. Systems that rely on recording the identity of the M&TE in work packages are ineffective because it is usually almost impossible to review all work packages to identify each use of a particular item of M&TE.

4.9 Management Assessment

4.9.1 Introduction

Managers at every level should periodically assess their organizations and functions to determine how well they meet customer and performance expectations and mission objectives, identify strengths or improvement opportunities, and correct problems. Assessments should address the effective use of resources to achieve the organization's goals and objectives. Management assessments should determine whether an integrated management system exists and whether it focuses on meeting both customer and performance requirements and strategic goals. Management assessments conducted by line managers support implementation of DOE P 450.5, *Line Environment, Safety, and Health Oversight,* dated 6-26-97.

4.9.2 Responsibility

Managers are responsible for the conduct of management assessments. Direct participation by managers is essential to the success of the assessment process because they are in a position both to evaluate the organization as a total system and to effect change. Delegating management assessment to a consultant or internal audit group is inconsistent with the requirement and will

diminish its value to management. Personal involvement by management will yield the most meaningful information to be used in taking actions to maintain compliance and improve organizational performance.

4.9.3 Process

DOE has developed specific guidance on the conduct of management assessments that should be consulted for planning and performing management assessments. This guidance document is DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; and DOE P 450.5, Line ES&H Oversight Policy,* dated 5-31-01, and available at http://www.eh.doe.gov/qa/.

4.9.4 Third Party Assessment

A strong contractor assessment program is key to effective performance-based management, and it enables the optimizing of DOE oversight activities through the utilization of technical experts. The use of a third-party (agency, individual, or group of individuals) not associated with the DOE line management, or the contractor organization performing work who have adequate experience/qualifications is indicated where independently review/evaluate/assess/audit a contractor's validation of performance and verification that contractor supplied products and services are contractually compliant.

However, to facilitate success, before a third-party is commissioned to perform work, the contractor should consider the cost, determine the value, and consult with their DOE counterpart. DOE input and acknowledgement of concurrence should be obtained to ensure that the SOW, criteria used, and the results will be acknowledged/accepted by DOE.

4.10 Independent Assessment

4.10.1 Introduction

Senior management should establish and implement a process to obtain an independent assessment of the organization's programs, projects, contractors, and suppliers. The purpose of this type of assessment is to evaluate compliance performance of work processes with regard to requirements, expectations of customers, and efforts required to achieve the mission and goals of the organization. The results of independent assessments provide an objective form of feedback to senior management that is useful in confirming acceptable performance and should be used for identifying improvement opportunities. DOE has developed expanded guidance on this subject that should be consulted for planning and performing independent assessments (DOE G 414.1-1A, available at http://www.eh.doe.gov/qa/ or www.directives.doe.gov).

The independent assessment process includes both compliance- and performance-based approaches that focus on results. Compliance-based assessments focus on verification of adherence to established requirements. Performance-based assessments are conducted on activities and processes that relate directly to performance expectations and emphasize safety and reliability.

Independent assessments conducted by DOE and contractor line organizations support implementation of DOE P 450.5. DOE line organizations should apply the independent assessments to their work and the work of their contractors. Contractor line organizations should apply the independent assessments to their work and the work of their subcontractors.

4.10.2 Responsibility

Independent assessments provide senior management with information on the quality of items, services, and processes produced by or for the organization. Consequently, when conducting independent assessments, the assessment team should report to a sufficiently high level in the overall organization. This is to ensure organizational independence from the work and access to levels of management authority capable of directing subordinate levels to take actions in response to the assessment results.

Personnel performing independent assessments should have the necessary technical knowledge to accurately observe and evaluate the activities and processes being assessed. Personnel should be provided training, meet initial assessor qualification requirements, and maintain assessment skills by attending periodic training in assessment techniques and/or participating in independent assessments. Personnel performing independent assessments should have no direct responsibility for the work or organization they are assessing. The organization manager directly responsible for the work should be considered as a customer of the assessment product (e.g., feedback resulting from observations of performance).

Assessors' responsibilities include—

- evaluating work performance and process effectiveness,
- evaluating quality of work products,
- evaluating compliance to the management system requirements,
- identifying abnormal performance and potential problems,
- identifying opportunities for improvements, and
- documenting and reporting results.

The organization manager that is in receipt of the assessment report is responsible for verifying that corrective actions have been taken. After an appropriate implementation period, the organization manager is responsible for verifying satisfactory resolution of reported problems and the effectiveness of the corrective actions.

4.10.3 Process

Assessments should focus on effective implementation of established requirements as well as improving process effectiveness. Independent assessment personnel should base the evaluations on the approved system and not reinterpret or redefine the requirements. Assessments that are intended to evaluate the appropriateness of the approved system (or to interpret/define

requirements of the system) may be performed, but only with the direction of senior management.

Documented assessment results should be presented to management of the assessed organization and provided to other appropriate levels of management for review. Strengths and weaknesses affecting the quality of process outputs should be identified so that management can take meaningful action to improve quality.

Management should evaluate the assessment results to identify improvement actions and determine whether similar quality problems may exist elsewhere in the organization. Lessons learned from assessment results should be communicated to other organizations with similar activities or concerns.

The independent assessment process should include verification of the adequacy of effective corrective actions, including actions identified to prevent recurrence or to otherwise improve performance.

Independent assessments that confirm acceptable performance in areas of an organization may reduce frequency and depth of future assessments. Areas of poor or questionable performance should receive increased attention.

APPENDIX A. QUALITY MANAGEMENT SYSTEM REVIEW AND APPROVAL TEMPLATE

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?

APPENDIX B. REFERENCES

The following references provide requirements and acceptable methods for implementing many of the quality assurance (QA) requirements of 10 CFR 830 subpart A and DOE O 414.1C, *Quality Assurance,* dated 6-17-05. No single reference fully meets all the QA requirements. The principles, recommended approaches, and applications contained in these references may be used with the QA requirements to develop an effective management system to achieve quality.

Most of the documents listed here are accessible on-line. DOE Orders, Policies, Manuals, Guides, and Standards are available at www.directives.doe.gov; CFRs, OMB Circulars and Public Laws may be accessed at www.gpoaccess.gov; and NRC documents are available at www.nrc.gov. Additional QA resources are available at: http://www.eh.doe.gov/qa.

A. RELATED POLICIES, RULES, AND ORDERS

10 CFR 830, Nuclear Safety Management.

10 CFR 830 Subpart A, Quality Assurance Requirements.

36 CFR, Chapter XII, Subchapter B, Subpart A, Federal Archives and Records Administration.

48 CFR Parts 1–99, Federal Acquisition Regulation.

48 CFR 970, Department of Energy Acquisition Regulation (DEAR), DOE Management and Operating Contracts.

DOE O 414.1C, *Quality Assurance,* dated 6-17-05.

DOE O 420.1A, *Facility Safety,* dated 5-20-02.

DOE P 426.1, *Federal Technical Capability Policy for Defense Nuclear Facilities,* dated 12-10-98.

DOE P 450.4, *Safety Management System Policy,* dated 10-15-96.

DOE P 450.5, *Line Environment, Safety and Health Oversight,* dated 6-26-97.

DOE O 360.1B, *Training,* dated 10-11-01.

DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual,* dated 12-31-03.

DOE O 200.1, *Information Management Program,* dated 9-30-96.

DOE 5480.20A, *Personnel Selection, Qualification, and Training Requirements for DOE Nuclear Facilities,* dated 11-15-94.

Office of Management and Budget Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, dated 2-10-98.

Public Law 104-113, National Technology Transfer Act of 1995.

B. RELATED QUALITY MANAGEMENT SYSTEM GUIDES AND STANDARDS

DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; and DOE P 450.5, Line ES&H Oversight Policy,* dated 5-31-01.

DOE G 414.1-3 (formerly 440.1-6), *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance,* dated 11-03-04.

DOE G 414.1-4, *Safety Software Guide***,** dated 6-17-05.

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description.*

DOE/NNSA, *Weapon Quality Policy (QC-1)***,** Rev. 10, dated 2-10-04.

DOE G 450.3-3, *Tailoring for Integrated Safety Management Applications,* dated February 1997.

DOE G 450.4-1B, *Integrated Safety Management System Guide for Use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); the Functions, Responsibilities, and Authorities Manual; and the Department Of Energy Acquisition Regulation,* dated 3-1-01, Volume 1, "Guidance."

DOE-STD-1150-2002, *Department of Energy (DOE) Quality Assurance Functional Area Qualification Standard*, dated April 2002.

DOE-NE-STD-1004-92, *Root Cause Analysis Guidance Document,* dated February 1992.

American National Standards Institute (ANSI)/American Society for Quality (ASQ), Z 1.13-1999, Quality Systems Guide for Research, 1999.

ANSI/National Conference of Standards Laboratories, Z 540-1-1994, Calibration Laboratories and Measuring and Test Equipment—General Requirements, 1999.

ANSI/International Organization for Standardization (ISO)/American Society for Quality (ASQ) Q9001:2000, Quality Management Systems:—Requirements, 2000.

ANSI/ISO/ASQ Q9004:2000, Quality Management Systems:—Guidelines for Performance Improvements, 2001.

ANSI/ISO/ASQ QE19011S-2004, Guidelines for quality and/or environmental management systems auditing – U.S. Version with supplemental guidance added.

ANSI/ASQ E4-2004, Standard: Quality Systems for Environmental Data and Technology Programs-Requirements with Guidance for Use, 2004.

American Society of Mechanical Engineers NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications, Part 1-4, 2001.

International Atomic Energy Agency (IAEA) Safety Guide 50-SG-Q1, Establishing and Implementing a Quality Assurance Programme.

IAEA-TECDOC-1090, Quality Assurance within Regulatory Bodies, June 1999.

C. RELATED REFERENCES

American Society for Nondestructive Testing Recommended Practice SNT-TC-1A-2001.

DOE STD 3009-94, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses*, dated July 1994.

DOE-STD-1027-92, *Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports*, dated December 1992.

Electric Power Research Institute (EPRI) Guideline NP-5652, 1988 Revision, *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07),* June 1988.

EPRI Guideline TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items.*

ISO/IEC 17025, General Requirements for the Competence of Calibration and Testing Laboratories, 1999.

U.S. Nuclear Regulatory Commission (NRC) NUREG 0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management, 1983.

NRC NUREG/CR-5151, Performance-Based Inspections, June 1988.

NRC Regulatory Guide 1.28, Qualification and Training of Personnel for Nuclear Power Plants, Rev. 3, May 2003.

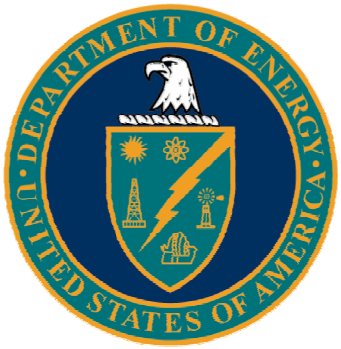
NRC Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation), Rev. 2, February 1978.

[QA Assessment Plan Template]

Quality Assurance Assessment Plan
For _____

Office of

_____



Department of Energy

Office of _____

Date: _____

CONTENTS

This assessment plan template is intended for use by the DOE for planning and assessing DOE Site Office QA implementation. It provides a broad based starting point for developing an assessment plan and lines of inquiries that must be supplemented by local requirements. Users are expected to limit the scope and focus the plan on the specific areas of interest for the given assessment. This template may be easily modified for use by DOE to plan and conduct assessments of contractor QAP implementation.

1. SCOPE

This assessment is considered a preliminary assessment of the implementation of QA policies and principles in _____ operations related to _____ activities. The areas of interest or activities to be assessed are identified in Section ___.

(1) Program – _____ ;
(2) Personnel Training and Qualification – _____ ;
(3) Quality Improvement – _____ ;
(4) Documents and Records – _____ ;
(5) Work Processes – _____ ;
(6) Design – _____ ;
(7) Procurement – _____ ;
(8) Inspections and Acceptance Testing – _____ ;
(9) Management Assessment – _____ ;
(10) Independent Assessment – _____ ;
(11) Software Quality Assurance – _____ ;
(12) Suspect/Counterfeit Items Prevention – _____ ;
(13) Corrective Action Management Program – _____ ;
(14) Integrated Safety Management – _____ ;

A follow-up assessment, pending the outcome of this assessment, is anticipated on or about _____.

2. OBJECTIVE

To provide feedback for continuous improvement: A process is established and effectively implemented to continuously improve safety and improve the efficiency and quality of operations. Procedures and mechanisms are in place to implement integrated safety management and quality assurance programs through approved program plans.

3. REQUIREMENTS

- DOE O 414.1C, *Quality Assurance*
- 10 CFR 830, Nuclear Safety Management
- DOE P 450.4, *Safety Management System Policy*
- Site-specific QA documentation
- Site-specific ISM documentation
- Organization or Site-specific FRAM/FRA

4. ASSESSMENT TEAM

The Assessment team will be composed of the following individuals:

_____ – Team Leader
_____
_____
_____ (Observer)

Brief biographical information for each team member is provided in Appendix 1-A.

5. ACTIVITIES TO BE ASSESSED

The Assessment Team will review the implementation of Quality Assurance (QA) and Integrated Safety Management Systems (ISMS) by evaluating some of the primary _____ functions and high-risk _____ activities. The Team will focus on _____ function(s) and a selected set of high-risk (hazard) activities. The Team will choose which activities to evaluate from a list of activities prioritized by risk provided by _____ prior to or at the initial briefing. For a chosen activity, the _____ topics will be evaluated by "drilling down" into the activity by lines of inquiry. Personnel interviews and observations may be utilized as determined by the Team while on-location.

As lines of inquiry are being pursued, the Team will also evaluate a number of general QA and ISMS topics, including _____. Spot-checks of QA and/or ISMS implementation in _____ may also be conducted during the assessment of the major activities.

The initial lines of inquiry listed below will be utilized during evaluation of specific work processes.

Review Area 1—Program

1. Review the organization and reporting chain (Criterion 1, DOE O 414.1C) to ensure clear lines of authority are established and utilized.

    - What is the organization structure of this activity?
    - Are functional responsibilities for QA defined and implemented for this activity?
    - What is the organization structure of the QA oversight of this activity?
    - Is the QA organization independent of the line management organizations?
    - What is the commitment of upper, middle, and lower management to the QA program and its implementation?
    - How is Quality policy promulgated and Quality improvement implemented throughout the organization associated with this activity?
    - Are QA audits, surveillances, and nonconformance reports part of the QA program?
    - What are the QA interface points with organizations that support this activity, and how is QA communicated to and implemented through them?
    - What is the process for determining the QA requirements for _____ and/or its contractors for this activity, and what is the review/approval/ implementation status of this process?
    - How are quality problems identified, documented, corrected, and prevented in the future for this activity?
    - How are Readiness Assessment and Operational Readiness Review results integrated with quality improvement and operational efficiency?
    - How are quality and efficiency improvements implemented, and how are lessons learned applied to this activity?

2. Review the graded approach and any criteria for determining what QA management requirements are implemented for various types of work.

    - What are the levels of risk associated with an activity?
    - What is the process for grading the application of QA requirements for activities? Does it identify consequences, requirements, and depth/extent/rigor necessary in application of those requirements?
    - What is the level of commitment of this activity's senior management to QA?
    - What are the greatest concerns regarding QA and ISMS implementation?
    - Are controls and verifications applied to this activity consistent with their importance to safety, cost, schedule, and success of this mission?
    - Are controls documented and communicated to personnel involved in this activity to ensure appropriate application and implementation?

3. Review and approval of contractor QAPs for selected high-risk activities.

    - What is the QA Plan?
    - Is the QA Plan approved? If not, when will it be approved?
    - What is the review process for the approval of the QAP for this activity?
    - What is the process for determining the QA requirements for _____ and its contractor(s) for this activity, and what is the review/approval/implementation status of this process?
    - What is/are the major contractor's QA Plan(s), and is it/are they implemented?

Review Area 2—Personnel Training and Qualification

Evaluate the status of implementation of a training and qualification program that ensures personnel are capable of performing their assigned work.

- What is the organization's documented training plan? Is it adequate and effective? How are training requirements established? What is the review and approval process?
- Does the organization have adequate resources, processes, and responsible elements 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?
- How are certifications and special qualifications (e.g., auditors, subject matter experts, nondestructive examination personnel, welders, etc.) established and maintained current?
- How is proficiency established and maintained for operational positions and/or functions?
- How is on-the-job training established and maintained?
- How is the required reading program established and maintained?

Review Area 3—Quality Improvement

1. Evaluate the status of implementation of a quality improvement process to detect and prevent quality problems.

    - Do established work processes and procedures adequately identify and report quality problems?
    - Does senior management policy encourage problem detection and prevention?
    - What are the existing processes for communicating lessons learned and performance information? Are they adequate? Are they effective?
    - How is the significance of quality problems categorized and prioritized?
    - Does this quality improvement process provide for the identification of the causes of problems? Does it require identification of actions to prevent recurrence? Are both of these required as part of the problem correction process? Is implementation effective?
    - How are cause, extent, and remedial and preventative actions for quality problems addressed?

2. Evaluate the approach to identification, control, and correction of items, services, and processes that do not meet established requirements (nonconforming).

    - What procedures determine which disciplines or functions evaluate and disposition the nonconforming item, service, or process? Are they adequate?
    - What procedures identify and control nonconforming items to prevent their inadvertent use? Are these procedures adequate?
    - How are quality problems associated with services and processes documented and corrected?

3. Evaluate the process to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

    - What quality performance analysis system is in place (e.g., six sigma, metrics and indicators, trending)? Is it adequate?
    - How does the performance analysis system provide for feedback to affected and related organizations or groups?

Review Area 4—Documents and Records

1. Evaluate the process for preparation, review, approval, issue, use, and revision of documents that prescribe processes, requirements, and design.

    - What is the approved and documented document control system providing the above functions? Is it documented? Does it clearly describe responsibilities and functions? Is it adequate?
    - Are key functions related to the quality criteria (e.g., design, procurement, work control, inspection, testing) described in reviewed and approved documents such as procedures?
    - Are key work processes and associated activities and functions in the FRA supported by documentation?

2. Evaluate the process for specification, preparation, review, approval, and maintenance of records.

    - What is the approved and documented records management system providing the above functions? Is it adequate?
    - Are the requirements of the National Archives and Records Administration addressed?
    - What is the quality records standard applied to the applicable contract(s), and is it fully implemented?

Review Area 5—Work Processes

Evaluate the implementation of quality management principles in work processes.

- Are the methods adequate for ensuring that work is performed consistent with technical standards, administrative controls, and other hazard controls?
- Are the core functions and guiding principles of ISM addressed in work processes?
- Do the approved instructions, procedures, and other appropriate means for the work processes meet regulatory or contract requirements?
- What are the methods that identify and control items to ensure their proper use? What are the methods that maintain items to prevent their damage, loss, or deterioration? Are these methods adequate? (See Review Area 3, items 2 and 3)
- What are the requirements for and methods of ensuring adequate calibration and maintenance for equipment used for process monitoring or data collection? Are they adequate?
- Is there an adequate system in place for use and control of software in accordance with DOE G 414.1-4?

Review Area 6—Design

Evaluate the implementation of quality management principles in design.

- How has this office determined whether it performs actual design work? If not, how is oversight of contractor design addressed and documented? How is the training and qualification of personnel carried out for this oversight of design?
- Are appropriate standards and sound engineering and scientific principles applied to design items and processes? How is this documented? Is the graded approach utilized properly?
- Is the use of software in the design and safety analysis process controlled in accordance 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?

- What is the process for design verification and/or validation for design products? Is it adequate? Are individuals other than those performing the design work utilized?
- Is the design work verified/validated before approval and implementation of design?
- What is the system for engineering involvement in the identification, analysis, and control of suspect/counterfeit items that could affect safety? Is it documented? Is it adequate?

Review Area 7—Procurement

1. Review contract List A/List B requirements for proper flowdown to contractors of DOE O 414.1C and/or 830 Subpart A requirements.

    - Review the list of contractors
    - Review _____ contract. (Team will select)
    - What is the schedule of assessments for this contractor?
    - For this contractor, how are quality problems identified, documented, reported, corrected, and prevented in the future?
    - How are past assessment results implemented?
    - How are flowdown requirements to subcontractors verified? Tracked?
    - How does _____ ensure that the QA Plan and ISM are implemented for all contractors?
    - How does the Field Office assessment program of this contractor continuously improve quality and efficiency of operations?
    - Review recent Customer Review Survey for activities of this contractor. How are feedbacks relayed to the contractor? What are the follow through activities?
    - How are contractor commitments tracked? Enforced?
    - How are new QA and ISM requirements incorporated into existing contracts?

2. Evaluate the process for review of proposals and selection of contractors, QA and ISMS requirements flow down, customer requirements flowdown

    - What is the contractor evaluation process used?
    - What is the process for determining customer requirements/specifications and how are these requirements captured and incorporated in the contract?
    - How are QA and ISMS requirements flowed down to the contractor and subcontractor?
    - How is the qualification of persons who evaluated the proposals determined? – compare with training and qualification records in CHRIS.
    - Review Contractor Records retained. Are the records complete?
    - How are new QA requirements incorporated into new contracts?

Review Area 8—Inspections and Acceptance Testing

Evaluate the process for inspections and acceptance testing of items, services, and processes.

- What is the method for specifying inspections and tests for items, services, and processes? Is it adequate?
- How are acceptance and performance criteria established and utilized? Is the graded approach applied satisfactorily?
- What is the process for inspecting, testing, and accepting software products? Is it adequate? What standards and requirements are invoked?
- Are inspections and acceptance tests planned and controlled? How?
- How are inspections and acceptance tests results documented?
- Is inspection and test equipment calibration established and maintained? How? How is traceability of calibration maintained? Is it adequate?

Review Area 9—Management Assessment

Evaluate the assigned responsibility for _____ implementation of Management Assessment (Criterion 9 DOE O 414.1C) for selected activities.

- What is the schedule of management assessments?
- How was the risk model utilized to determine assessment areas, schedule, and rigor?
- Does the management assessment program include all levels of management? If so, how?
- How are quality problems identified, documented, reported, corrected, and prevented in the future?
- How are past management assessment results implemented?
- How does the management assessment program continuously improve quality and efficiency of operations?
- How was result of the assessment incorporated in the lessons learned Program?

Review Area 10—Independent Assessment

Evaluate the assigned responsibility for _____ implementation of Independent Assessment (Criterion 10, DOE O 414.1C) for selected activities.

- What is the schedule of independent assessments for this activity?
- How was the risk model utilized to determine assessment areas, schedule, and rigor?
- Is the independent assessment program adequately defined and documented?
- By what criteria are assessors chosen for independent assessments?
- What is the process for reporting independent assessment results and required corrective actions to responsible management?
- How are past independent assessment results tracked through completion of corrective actions?
- How are past independent assessment results implemented?
- What performance parameters does the independent assessment program measure?

- How does the independent assessment program continuously improve quality and efficiency of operations?
- How was result of the assessment incorporated in the lessons learned Program?

Review Area 11—Software Quality Assurance

Evaluate the status of implementation of a software QA program.

- What safety-related software packages does the contractor use?
- What DOE SQA policies and requirements exist for these software packages? Are these incorporated into a formal QA program by the contractor?
- Is there anything specific in the contract with regard to DOE SQA policy and requirements?
- What are oversight processes/activities for SQA? Has there been any assessment to date either independently or as part of other QA or performance assessments?

Review Area 12—Suspect/Counterfeit Items Prevention

Review the oversight of the S/CI Prevention process implementation

- Does the contractor have S/CI program in place?
- What is the oversight process for this activity?
- What are the findings/observations of the most recent two assessment of this program?
- What are the corrective actions initiated to address any issues? How are these tracked?

Review Area 13—Corrective Action Management Program

Evaluate the Corrective Action Management Process and current status of corrective actions in tracking systems.

- Does the Field Office incorporate CAMP into its program?
- Has the Office assigned a responsible individual to manage this?
- How are CATS and CAMP reconciled? Is there a responsible individual assigned for CATS? How are corrective actions communicated to or coordinated with HQ?
- Obtain a couple of Nonconformance Records and review.

Review Area 14—Integrated Safety Management

Review the integration of ISMS into the overall quality assurance program for selected high risk activities.

- What is the management system utilized for implementing ISMS for this activity?
- What are the roles and responsibilities for ISMS implementation? Are they clearly defined/documented? Are they implemented?

- What is the process for feedback and continuous improvement in ISMS implementation?
- How are ISM lessons learned applied to this activity?
- Are ISMS line management responsibilities defined and implemented?
- What work controls are in place to ensure safety?
- What is the process for determining and grading the application of ISMS requirements?
- What is the commitment of upper, middle, and lower management to the ISM program and its implementation?
- How are Readiness Assessment and Operational Readiness Review results integrated with ISM and operational efficiency?
- What are the greatest concerns regarding ISM implementation?

6. ORGANIZATIONS TO BE NOTIFIED

____
____
____
____
____

7. APPLICABLE RECORDS, INTERVIEWS, OBSERVATIONS

The Assessment Team will require support from _____ to do an effective assessment. The Team has identified preliminary list of records, interviews, and observations of interest. It should be noted that additional ones may be identified as the assessment progresses. _____ should be prepared to provide the records and documents identified in advance and make the required individuals available for the interviews.

Record Review:

FRAM
Quality Assurance Plan
ISMS Description
Contract List A/List B requirements
Contractor QAP approval
List of current projects and activities
Management Assessment schedule
Independent Assessment schedule

For ISMS:

Oversight Assessment Plan for FY____
FY____ Safety Performance Objectives
Current _____ ISMS Description
Contractor ISMS Description
Contract Section I DEAR Clauses 970.5223-1 and 970.5204-2

Interviews:

AMEM (closeout)
Facility and Operations Team Leader
Quality and Safety Division Director
Quality Assurance and Process Management Team Leader
Quality Assurance Subject Matter Expert
Facility and Materials Disposition Division Acting Director
Waste Disposition Division Acting Director
Lead Facility Representative
Facility Engineers
Others as needed

Observations:

Any Management Assessment in progress
Any Independent Assessment in progress
Oversight or surveillance of contractor's S/CI program implementation
Corrective action status or planning meeting
Software QA activity
Performance measure status meeting
Effectiveness verification of any ISMS improvement action

8. SCHEDULE

Figure 1 lays out the proposed schedule for the assessment. The Assessment Team will arrive at the site on _____, _____. The briefing shown in Figure 1 below will commence as soon as the team arrives on site, which is expected to be _____.

The activities in the following _____ days will include interviews of key personnel and may include observations of activities. The Assessment Team Leader, in conjunction with _____ management will identify the individuals that need to be invited for discussions and the activities to be observed.

Figure 1: Proposed Assessment Schedule

Date: _____	
Time: _____	Travel to _____
Time: _____	• Briefing • Review list of current high-risk activities • Determine schedule for closeout meeting • Collect documents • Review documents
Date: _____	
Time: _____	• ISMS Integration into QA • Graded Approach definition, procedures, and implementation

Time: _____	• Contractor Lists A and B
	• Specific Contracts and Procurement
	• Contractor Oversight
	  o QAP review and approval
	  o S/CI Implementation
	  o CAMP
	  o Software QA
	  o Feed back and lessons learned

Date: _____	
Time: _____	Continue oversight elements

Time: _____	• New Contract(s) - Review Status
	  o QA Requirements flowdown
	  o Technical requirements flowdown
	  o Bidders questions

Date: _____	
Time: _____	Management Assessments Independent Assessment
	Additional Assessment Topics As Required
Time: _____	• Team meeting • Closeout meeting
Date: _____	
Time: _____	Travel back to DOE HQ

APPENDIX 1-A. ASSESSMENT TEAM MEMBERS' BIOGRAPHICAL INFORMATION

[Include the following information in the plan for the Team Leader and all members of the Assessment Team]

_____– Team Leader – Name & Title: _____

Experience:

Education:

Personal:

_____ - Team Member – Name & Title: _____

Experience:

Education:

Personal:

_____ - Team Member – Name & Title: _____

Experience:

Education:

Personal: