Preamble to DOE G 414.1-2, Quality Assurance Management System Guide

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 and that support the Safety Management System Policy, DOE P 450.4.

The revised Quality Assurance Management System Guide includes enhancements arising from experience with implementing the DOE QA Rule 10 CFR 830 Subpart A and DOE O 414.1A. 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.
- Strengthened the use of a single management system or work process for similar requirements.
- Incorporated review guidance for use by DOE in evaluating contractor Quality Management Systems.
- 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/CI) 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.
- 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 414.1-2

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The Office of Quality Assurance Programs (EH-31) 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 (ISMS). The Guide should also be made available to employees responsible for implementation of these systems.

- Use the Guide to review new and existing DOE and contractor quality management systems.

The 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; radiation protection programs developed for 10 CFR 835; and, safeguards and security work;

- integration with the Safety Management System is established by DOE P 450.4;

- appropriate national/international standards have been adopted from the established requirements set and identified to implement the QAP; and,

- the senior management position responsible for the quality management system is identified.

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FOREWORD

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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.

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

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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. Applicable standards and a list of references providing other sources of information are included at the end of this document.

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

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The revisions to this Guide were prepared by a working group under the policy direction of the DOE Office of Quality Assurance. Contributions to this Guide were also made by DOE personnel, DOE contractors, and members of national standards bodies during the review and comment process. The following individuals were directly and substantively involved in the development of this Guide:

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QUALITY MANAGEMENT SYSTEM GUIDE for use with 10 CFR 830 Subpart A and DOE O 414.1

I. INTRODUCTION

To accomplish the 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 the 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. The criteria of 10 CFR 830 Subpart A, *Quality Assurance*, and DOE Order O 414.1, QUALITY ASSURANCE, are used to provide a quality management system for accomplishing and assessing DOE's work in accordance with requirements.

II. 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) in accordance with the requirements of 10 CFR 830 Subpart A and DOE O 414.1, hereafter referred to as the Rule and Order.

This Guide may also be usedby a contractor to assist in obtaining QAP approval from their DOE Customer.

This guidance is interrelated and includes methods for managing, achieving, 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 Rule and Order. Use of this guide in conjunction with appropriate standards will facilitate development and approval of a QAP compliant with the Rule and Order. An organization may select alternative methods to document and implement its quality management system as long as the requirements of the 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, and customer expectations.

III. DISCUSSION

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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, public, contractors, suppliers, and employees. The attainment of quality is the responsibility of each member of an organization. The quality criteria of 10 CFR 830 Subpart A (the nuclear safety management QA rule) and DOE O 414.1 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.

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The Department's objective is to simultaneously satisfy requirements of the nuclear safety management QA rule, safety management system policy and regulation, 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.

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IV. GUIDANCE

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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 QA program, hereafter referred to as a quality management system or QAP. 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, and assessing the adequacy of work, including work assigned to parties outside the organization. The quality management system is intended to compliment the Department's ISMS.

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The quality management system should focus on 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.

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4.1.2 Responsibilities

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.

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The QA rule and Order and the Safety Management System Policy emphasize that management should promote effective achievement of performance objectives through implementation of the SMS Policy Guiding Principles

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4.1.3 GRADED APPROACH

The Graded Approach must be implemented without compromising the safety of the public, employees or facilities; adversely impacting the environment; or failing to comply with U.S. Department of Energy (DOE) requirements, rules, and regulations. The graded application of facility/activity requirements is dependent on the 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 prior to performing the activity. The purpose of grading is to select the

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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 10 CFR 830 Subpart A or DOE O 414.1. [hyper-links]

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

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- 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; and,
- performance history of a facility or activity.

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

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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 relative risk.

Risk is a quantitative or qualitative expression of possible impacts or loss (e.g., project, financial, safety) that considers both the probability of an event causing harm or loss and the consequences

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of the event. Determination (or estimation) of the probability or likelihood of the occurrence should be a part of the risk expression. For example, procurement of nuclear safety class items would require more rigorous supplier controls to meet procurement requirements, than that needed for facility area lighting fixtures. Estimates and qualitative expressions are useful for management issues where quantitative data is unavailable. Process systems, repetitive activities, and hardware are typically more suitable for quantitative expressions of risk.

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The first step in the grading process is to identify the consequences and probability of a failure prior to the work being performed. The second step is to identify the specific requirements to be applied. The third step is to determine the depth, extent, and degree of rigor necessary in the application of requirements. The final step is to communicate and implement the selected requirements and 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.

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The graded approach must not be used to "grade to zero" which has the affect of eliminating a 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.

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4.1.4 Integrating the Safety Management System and Quality Management System

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The quality management system complements and is integrated with the safety management system (SMS) described in DOE P 450.4, SAFETY MANAGEMENT SYSTEM POLICY 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 the ISMS achieves its objectives.

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DOE P 450.4 expresses a fundamental expectation that all work 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 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. The DOE Quality and Safety requirements share a management systems approach to achieving their objectives. As such, they offer many opportunities for sharing a single document (QAP or ISMS description) to describe how the organization intends to implement the requirements. Likewise, a single process (e.g., procedures and plans) that satisfies quality and safety requirements should be employed. Shared attributes of Quality and Safety Management Systems include–

- expectations for implementation (DEAR 970.5204-2 (c)),
- documentation of the Management System (ISMS Principle 7 Operations Authorization),
- clear roles and responsibilities (ISMS Principle 2),
- balanced priorities (resources) (ISMS Principle 4),
- feedback and improvement (ISMS Core Function 5),

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- line management responsibility (ISMS Principle 1),
- competence and qualifications (ISMS Principle 3),
- standards and controls for work (ISMS Principle 5 and Core Function 4), and
- graded and tailored controls (ISMS Principle 6).

The INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE, DOE G 450.4-1, 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 Technology Transfer Act of 1995 (PL 104-113) and OMB Circular A-119. The Rule and Order requirements are stated as performance expectations and do not specify methods for achieving the desired performance. Consequently, organizations should identify, document, and use appropriate standards to develop and implement the management system. Clearly defined standards will also support Safety Management System Policy Principle 5, Identification of Safety Standards and Requirements.

Current appropriate standards include:

ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications (for nuclear-related activities);
ANSI/ISO/ASQ Q 9001-2000, Quality Management System -Requirements (for non-nuclear activities); and,
ANSI/ASQ Z 1.13, Quality Guidelines for Research, 1999, (for non-nuclear 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 system using several standards. For example, a single facility may adopt ISO 9001 for corporate reasons, ASME NQA-1 for an EPA/NRC regulation, and "QC-1" for nuclear weapons activities. The standards selected should suit the products and services of the organization and its customers.

4.1.6 Quality Management System Review and Approval

The quality management system requires review for compliance with the Rule and Order, and DOE approval. A review template is provided in Appendix 1 to capture the basic activities a DOE customer should conduct in the review and approval of a contractor QAP.

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Ensuring the adequacy and effectiveness of the quality management system is greatly enhanced by: the establishment of a robust assessment process (refer to section 4.9 and 4.10) ; customer review and approval; and, the use of third-party assessments.

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 local DOE.

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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 des cribe 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 personal responsible for oversight of QA at nuclear facilities are qualified to DOE M 426.1-1. 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;
- a performance demonstration or test to verify previously acquired skills;
- completion of a training or qualification program; and/or

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- 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, and controlling 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.

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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.

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Management should encourage employees to develop and explore 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–

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- 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
- utilizes 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–

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- 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;

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- a non-compliance to a requirement; or
- an indeterminate/substandard condition, or a suspect/counterfeit item.

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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 Judgements of Need resulting from Type A Accident Investigations.

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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 (customer/regulator). 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.

If the quality problem is likely to affect safety or mission significantly, the impacted items or processes should be controlled with respect to their further use. Conditions governing the issuance and removal of stop work orders should be documented.

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;
- A non-compliance with a legal, contractual, or other requirement; or
- The existence of a substandard condition.

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4.3.3.3 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,
- 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 Office of Independent Oversight and Performance Assurance (OA), or for Judgements of Need resulting from Type A Accident Investigations, DOE Office of Enforcement and Investigation, or customers) should be tracked through resolution. The Department's Corrective Action Tracking System (CATS) is used to report corrective actions and their status for Office of Oversight safety issues. Corrective action is the identification of cause and the effective resolution of a quality problem after its occurrence to prevent its recurrence. Specific expectations for CATS and corrective action plans are defined in Attachment 4 of the QA Order and the CATS website at: http**********

Quality problem resolution typically involves–

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

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4.3.3.4 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.

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4.4. Documents and Records

4.4.1 Introduction

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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.

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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, 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 such 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.

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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 documents that define the design basis, review, and revision; procedures, plans, and manuals; test results; correspondence; operational records; and training records.

Records should be compiled in a records management system. The system should include provisions for specifying, preparing, reviewing, approving, dispositioning, 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 in accordance with the requirements of DOE O 200.1, INFORMATION MANAGEMENT PROGRAM.
The hardware and software tools used to create and store records should be maintained to ensure that the records can be retrieved. NARA Code of Federal Regulations ###, Subchapter B, Subpart A, [add to references] which addresses electronic records management provides a recommended approach for maintenance of records.

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The records management system should have schedules for records retention and disposition in accordance with the requirements of DOE O 200.1, INFORMATION MANAGEMENT PROGRAM.¶

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 and instructions and equipment under administrative, technical, and environmental controls to achieve an end result.

4.5.2 Work Performance

Management is responsible to ensure 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. Management should ensure that the following are clearly identified and conveyed to workers prior to beginning work:

- Customer and data requirements for the work and final product;
- Safety, administrative, technical, environmental, and, quality, controls to be employed during the work;
- Acceptance criteria applicable to work and final product;
- Hazards associated with the work;
- Technical standards applicable to work and final product; and
-

Procedures, work instructions, or other appropriate means used to define work processes should be documented. 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 to meet regulatory and contract requirements. Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented.
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. Since 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,

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subsystem, system, unit, or support systems. A process for the identification and control of items should be established and implemented to:

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- prevent the use of incorrect or defective items,
- identify and control suspect/counterfeit items, 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 in accordance with specified requirements.

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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.

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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.

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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.)

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4.5.6 Software Control

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Work process controls should be applied throughout the life-cycle of software and the items it support. Resources that describe these controls are included in the References. Topics that are of particular interest to engineering, information technology, and quality assurance organizations are addressed below.

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Software control processes should be established and implemented to ensure that computer programs used for applications such as developing or verifying designs, performing safety analysis, establishing safety envelopes, performing safety management functions (e.g., tracking limiting conditions for operations or safety issue corrective actions, and controlling operating safety systems.)

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Software design should be maintained so that any changes are made under a documented configuration management process. The design should also consider ease of enhancement to reflect hardware changes or migration to new platforms or operating systems. Computations used to analyze designs, verify designs, or that otherwise might have safety, operational, or programmatic consequences should be appropriately documented. 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.

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.

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.

4.5.7 Software Testing

Software test planning 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 lifecycle.

Software test planning should consider that the software adequately and correctly performs all intended functions (specified in the design requirements), and as appropriate that the software; properly handles abnormal conditions and events (and credible failures), does not perform advers unintended functions, and does not degrade the system (either by itself or in combination with other functions).

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.

The design of structures, systems, components, software, and processes should be subject to design process controls and verification requirements appropriate to the level of risk the items

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presents 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) structures, systems, and components and
- the significance to safety of functions performed by those structures, systems, and components.

Designs should provide for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of the items. The design should consider the expected use and life expectancy of the items in order 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 output, design changes, and design verification activities and other documents that provide evidence that the design process was completed correctly.

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4.6.2 Design Input

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Design input should be based upon contractual requirements and customer expectations, and should be technically correct and complete. Design input 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

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The design process should translate design input 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 should be validated for the intended use; otherwise, status of the code validation should be identified and documented prior to use.

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.

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4.6.4 Design Output

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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.

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4.6.5 Design Verification

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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 consider previous verifications of similar designs or verifications of similar features of other designs.

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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 system, structure, or component to perform its function and before installation becomes irreversible.

4.6.6 Design Changes

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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, [NUMBER CHANGE ADD TO REF.] provides design organization guidance to help avoid the procurement and use of suspect/counterfeit items. Additional guidance is provided for evaluating suspect/counterfeit items that may have been installed. [Add Hyperlink to guide and website].

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4.7 Procurement

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4.7.1 Introduction

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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 suspect/counterfeit items and provide a method to detect them before they are released for use (DOE G 414.1-3).

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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 Part 9, and Federal Acquisition Regulations (FAR) in 48 CFR Parts 1 to 99 [check #]. The requirements in the 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.

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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 they are subject to 10 CFR 830 and 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

Comment: ;

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 its application.

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4.7.3 Supplier Qualification

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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 capability, processes. This method may be used in combination with–

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- a review of the supplier's history for 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.

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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

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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 assure conformance to those requirements that cannot be readily determined by inspection or test of the product. Monitoring may include–

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- surveillance of work activities,
- inspection of facilities and processes,
- review of plans and progress reports,
- 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 sub-tier suppliers.

4.7.5 Inspection

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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.

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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:

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- 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 prior to or following shipment.

4.7.6 Supplier Documentation

Comment: ;

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.

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4.7.7 Procurement of Safety Grade Items for Nuclear Facilities/Activities

Items procured for safety applications in nuclear activities, structures, systems, or components 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 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 Multi-Site Procurement

Multi-Site 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

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4.8 Inspection and Acceptance Testing

4.8.1 Introduction

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

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

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4.8.2 Process

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Inspection/test planning should be performed. Appropriate sections of approved codes or standards may be used for acceptance requirements and inspection/test methods. Inspection/test planning should consider provisions for the following:

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- identification of characteristics to be examined;
- required qualifications of individuals who perform the examination;
- a description 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 in order 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 to document that requirements have been satisfied.

4.8.3 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.

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The inspection/test process should identify the status of items, services, and processes requiring examination to ensure only those with acceptable inspection and test results are used. The process should provide for review and reinspection/retest of changed inspection/test parameters.

4.8.4 Control of Measuring and Test Equipment

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Measuring and Test Equipment (M&TE) used for inspection, tests, monitoring, and data collection should be calibrated and maintained using a documented process. M&TE should be checked prior to its use to ensure that it is of the proper type, range, accuracy, precision, and that it is uniquely identified and traceable to its calibration data. Procedures should be established for testing, retesting, adjusting, and recalibrating the M&TE. M&TE should be calibrated to standards traceable to the National Institute of Standards and Technology (NIST) or other nationally recognized standards when appropriate. If no nationally recognized standard exist, the bases 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.

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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 to correct problems. Assessments should address the effective use of resources to achieve the organization's goals and objectives. Management assessments should determine if an integrated management system exists and if 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.

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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.

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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 and can be accessed at www.directives.doe.gov . This guidance document is DOE G 414.1-1 *(need hyperlink)*.

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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. The contractor needs to demonstrate to DOE the quality of their assessment program. The use of a third-party team of "experts" can be an effective tool for evaluating the quality of the contractors' assessment programs. To facilitate success, the contractor should work with the DOE customer as well as senior management in the selection of the evaluation team. The team should be led by an outside party (individual) who is truly independent from both the assessed organization as well as the local DOE. The development of the criteria used for the evaluation should also include input and concurrence from the local DOE.

4.10 Independent Assessment

4.10.1 Introduction

Senior management should establish and implement a process to obtain an independent assessment of the organizations' 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.

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.

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Independent assessments conducted by DOE and contractor line organizations support implementation of DOE Policy P 450.5, LINE ENVIRONMENT, SAFETY, AND HEALTH OVERSIGHT. 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 advise senior management 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.

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Personnel performing independent assessments should have the necessary technical knowledge to accurately observe and evaluate 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 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 to verify that corrective actions have been taken. After an appropriate implementation period, the organization manager is responsible to verify satisfactory resolution of reported problems and the effectiveness of the corrective actions.

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<#>verifying satisfactory resolutions of reported problems.¶

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 the 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.

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DOE has developed expanded guidance on this subject that should be consulted for planning and performing independent assessments (DOE G 414.1-1). This document can be accessed at www.directives.doe.gov.

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QUALITY MANAGEMENT SYSTEM REVIEW & APPROVAL TEMPLATE

I. Qualification

Federal personnel assigned to lead the review team and recommend approval of contractor quality management systems should have completed, at a minimum, the DOE Quality Assurance Functional Area qualification standard in accordance with the Federal Technical Capabilities Manual, DOE M 426.1-1. 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.

II. Quality Management System Review

What requirements apply to the quality management system?
Template not mandatory, guide used by DOE to ensure minimum nuclear safety quality requirements are addressed in quality management systems.
Applicable to nuclear and radiological facilities only (where Rule applies).
Not just safety related.
Responsibilities for review and approval of initial submittals and revisions.
Implementation?
Can be used by contractors in their assessment program.
Frequency

III. General Requirements

Contract requirements and expectations – identified?
Safety SSCs identified and discussed?
Appropriate standards selected (e.g., NQA-1, ISO 9001, etc.)
Integrated with other management system and quality requirements (e.g., ISM, QC-1, etc.)?
How so?

IV. Checklist

4.1 Program

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

- 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?

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- Are there organizations excluded from the scope of the QAP? 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, calibration, etc.?

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

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 it applies to?
- Are the requirements for qualification and/or certification of personnel for specific functional areas (e.g., auditors, subject matter experts, nondestructive examination, etc.) established?

Is the methodology described for providing continuing training to personnel to maintain their job proficiency?

4.3 Quality Improvement

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

- Do work processes, procedures, etc. call for identification and reporting of quality problems?
- Does senior management policy support 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 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?
- Does the QMS address documentation and correction of quality problems associated with services and processes?

Does the quality management system provide for the identification of the causes of problems and work to prevent recurrence as a part of correcting the problem?

- Does the QMS describe methods for addressing cause, extent, 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, etc.)?
- 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 processes, specify requirements, or establish design?

- Is there a document control system that provides these functions?

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 NARA addressed?

4.5 Work Processes

Does the quality management system provide methods ensuring work is performed consistent with technical standards, administrative controls, and other hazard controls?

Do the approved 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?

Is the method to maintain items to prevent their damage, loss, or deterioration adequately described? Does this method address the requirements of DOE O 433.1?

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

4.6 Design

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Do design items and processes use sound engineering/scientific principles and appropriate standards?

What method is used to incorporate applicable requirements and design bases in design work and design changes?

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 there verification and/or validation of work before approval and implementation of the design?

4.7 Procurement

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How are the requirements for the procurement of items and services established? Do the requirements include performance specifications and expectations?

Is there a system to evaluate and select prospective suppliers on the basis of specified criteria?

How does the quality management system establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services?

4.8 Inspection and Acceptance Testing

How are inspections and tests specified for items, services, and processes? How are acceptance and performance criteria established and used?

Is inspection and test equipment calibrated and maintained?

4.9 Management Assessment

Does the quality management system describe how managers, at all levels, assess their management processes?

Does the quality management system provide for the identification and correction of problems that hinder the organization from achieving its objectives?

4.10 Independent Assessment

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?

Are the persons conducting independent assessments technically qualified and/or knowledgeable in the areas to be assessed?

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The system is compliant with and integrated with the safety management system (ISMS) required described in by DOE P 450.4, SAFETY MANAGEMENT SYSTEM POLICY. The quality management system provides processes and tools for ensuring that the ISMS achieves its objectivess. A comprehensive management system will result from the integrated quality and safety management expectations so that the DOE mission is accomplished safely and DOE/contractor performance can be objectively assessed.

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This Guide also describes the relationship of quality assurance to other processes thatthat aid the implementation of compliance with the ISMS requirements.

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This interrelationship precludes an organization from implementing only selected requirements and ensures the integrated approach required described in by DOE P 450.4, SAFETY MANAGEMENT SYSTEM POLICY. A selective approach to implementing the criteria would create an incomplete system and could lead to quality failures (i.e., a failure to meet customer requirements and mission objectives). Similarly, a quality management system limited in scope to "nuclear safety class" or "hazard category 1" items could fail by ignoring the related activities necessary to accomplishing the mission and their effect on the safety and health of the public, workers, and the environment.

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2.2 Integrated Safety Management System (ISMS)

Effective implementation of the rRule and Order quality criteriarequirements will also provide processes and tools to support the principles and functions of the Safety Management System Policy (DOE P 450.4) and related portions of the portions of the DOE Acquisition Regulation (DEAR, 48 CFR 970.5204-2). The quality rule and Order and the Safety Management System Policy, DOE P 450.4, have been selected as DOE management systems. DOE P 450.4 expresses a fundamental expectation that all work 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 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. The DOE Quality and Safety requirements share a management systems approach to achieving their objectives. As such, they offer many opportunities for sharing a single document (QAP or ISMS description) to describe how the organization intends to implement the requirements. Likewise, a single process (e.g., procedures and plans) that satisfies quality and safety requirements should be employed. Shared attributes of Quality and Safety Management Systems include–

expectations for implementation (DEAR 970.5204-2 (c)),

documentation of the Management System (ISMS Principle 7 Operations Authorization),
clear roles and responsibilities (ISMS Principle 2),
balanced priorities (resources) (ISMS Principle 4),
feedback and improvement (ISMS Core Function 5),
line management responsibility (ISMS Principle 1),
competence and qualifications (ISMS Principle 3),
standards and controls for work (ISMS Principle 5 and Core Function 4), and
graded and tailored controls (ISMS Principle 6).

The quality management system also supports implementation of DOE P 450.5, LINE ENVIRONMENT, SAFETY AND HEALTH OVERSIGHT POLICY. The Quality Improvement, Procurement, and Assessment criteria offer processes to ensure that DOE oversight of its contractors is effectively planned and implemented and that it achieves the desired results.

THE INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE, DOE G 450.4-1, contains more information on safety management principles, supporting attributes, and references on the subject.

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[COMMENT]**Section III, DISCUSSION**

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Ensuring the adequacy and effectiveness of the quality management system is greatly enhanced by the establishment of a robust assessment process that includes the use of third party assessments. A strong contractor self-assessment program is key to effective performance based management, and it enables the optimizing of DOE oversight activities. The contractor needs to demonstrate to DOE the quality of their self-assessment program. The use of a third party team of "experts" can be an effective tool for evaluating the quality of the contractors self-assessment program. The key to success, however, is working with your DOE field office as well as your senior management in the selection of the evaluation team. The team should not consist of representatives from your organization or your DOE field office. The team may consist of a high level DOE person so that your local office will respect the results of the evaluation. The team should be lead by an outside party (individual) who is truly independent from both your organization as well as DOE. The development of the criteria used for the evaluation should also include input and concurrence from your local DOE.

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DOE Orders and other requirements documents prescribe a variety of management systems to assist DOE offices and contractors in achieving their missions and goals. A formal management system that has been established for a facility or activity should be compared to the criteria of the rule and Order to ensure that the appropriate requirements have been addressed. [This paragraph does not make sense.}

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adopted are specified by the customer. Organizations with multiple customers must often develop their management system using several standards. For example, a single facility may adopt ISO 9001 for corporate reasons, ASME NQA-1 for an EPA/NRC regulation, and "QC-1" for nuclear weapons activities. DOE has a process for "tailoring" standards to fit the work and associated hazards described in DOE G 450.3-3, TAILORING FOR ISM APPLICATIONS. The user is cautioned that tailoring may not be used to circumvent requirements of the QA rule or DOE P 450.4. The standards ultimately selected should suit the products and services of the organization and its customers. Several of these standards are included in the references.

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Ensuring the adequacy and effectiveness of the quality management system is greatly enhanced by: the establishment of a robust assessment process; customer review and approval; and, the use of third-party assessments.

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and maintenance; inspection and testing; safeguards and security; data collection and analysis; assessment and oversight. Each w

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All work should be regarded as a process. Each work process consists of a series of actions planned and carried out by qualified workers using specified work processes and equipment under administrative, technical, and environmental controls established by management to achieve an end result.

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should ensure that those under their supervision have the

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safety, administrative, technical, and environmental controls to be employed during the work (ISMS Core Function 3).

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Management should ensure that those under their supervision have the 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 (ISMS Guiding Principles 1 and 3).

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(ISMS Guiding Principle 5, Core Function 3).