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 in order 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 830.120 and DOE O 414.1 (formerly DOE 5700.6C). We also evaluated the guidance in light of key policy initiatives, directive changes, and other changes that have occurred within DOE since the original Guide was issued April 1994. For example, the changes that address Integrated Safety Management (DOE P 450.4, DOE P 450.5, 48 CFR 970.1001, 49 CFR 970.5204-2, and DOE M 411.1-1) were evaluated to ensure the guide compliments and supports this safety initiative.

The Quality and Safety Management Special Interest Group (QSM SIG) participated in the development of this Guide with DOE leadership. DOE sponsors the QSM SIG to support implementation of the quality Order and rule. The QSM SIG operates as a peer networking resource and is available to DOE and contractor personnel for sharing lessons learned, advancing the quality of our products and services, and obtaining advice or assistance with quality management system development and implementation. The QSM SIG coordinator can be contacted at 423-576-3316 or www.orau.gov/qsm.

From our evaluation and coordination with user groups, specific major improvements have been made 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 830.120.

- Included discussion on implementing quality and safety management (ISM) systems in an integrated manner with the SAFETY MANAGEMENT SYSTEM POLICY, DOE P 450.4, and the LINE MANAGEMENT ENVIRONMENT, SAFETY, AND HEALTH OVERSIGHT POLICY, DOE P 450.5.

- Discussed the use of a single management system or work process for similar requirements.

- Identified links to the expanded guidance for management and independent assessments (DOE G 414.1-1).

- Discussed the flow-down of quality requirements from 10 CFR 830.120 and DOE O 414.1 to suppliers/subcontractors.

- Added 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.

- Added guidance on procurement processes for nuclear safety applications.

- Relocated all the references, standards, and requirements documents to the rear of the guide.

Recommended Actions for Implementing DOE G 414.1-2

The Office of Nuclear Safety Policy and Standards (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 in conjunction with the INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE, DOE G 450.4-1. This is especially important where a single process is used to satisfy the QA and SMS expectations.

The DOE and contractor quality management systems should be reviewed to verify–

- they are integrated with the Safety Management System established by DOE P 450.4;

- appropriate national/international standards have been adopted and identified to implement the QAP;

- processes for implementing the Quality Improvement criteria to adequately address steps for response, tracking, correction/resolution, reporting, and closure of findings from all sources, including those from external sources (e.g., the DOE Office of Oversight, EH-2, and Federal/State regulators) as required by the Department's Implementation Plan for DNFSB Recommendation 98-1;

- the senior management position responsible for the QAP is identified; and,

- that the QA criteria have been adequately applied to the radiation protection programs developed for 10 CFR 835.

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DOE G 414.1-2
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QUALITY ASSURANCE MANAGEMENT SYSTEM GUIDE for use with 10 CFR 830.120 and DOE O 414.1

U.S. Department of Energy
Washington, D.C. 20585

FOREWORD

This Department of Energy (DOE) Guide is approved by the Office of Nuclear Safety Policy and Standards (EH-31), 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 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.

Guides are used to identify government and non-government standards that DOE finds acceptable for implementing its 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 Explorer System at the following address: http://www.explorer.doe.gov:1776/htmls/

ACKNOWLEDGMENTS

This Guide was prepared by a working group under the policy direction of the DOE Office of Nuclear Safety Policy and Standards. Contributions to this Guide were also made by other DOE personnel, including members of the Quality and Safety Management Special Interest Group and the Quality Assurance Working Group. The following individuals were directly and substantively involved in the development of this Guide:

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CONTENTS

CONTENTS (continued)

QUALITY MANAGEMENT SYSTEM GUIDE for use with 10 CFR 830.120 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 830.120, *Quality Assurance*, and DOE O 414.1, QUALITY ASSURANCE (formerly DOE Order 5700.6C, QUALITY ASSURANCE), are used to provide a quality management system for accomplishing and assessing DOE's work in accordance with all requirements. The system is compliant with and integrated with the safety management system (ISMS) required by DOE P 450.4, SAFETY MANAGEMENT SYSTEM POLICY. The quality management system provides processes and tools for ensuring that the ISMS achieves its objectives. 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.

II. APPLICATION

2.1 Quality

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 830.120 and DOE O 414.1, henceforth referred to as the rule and Order. This Guide also describes the relationship of quality assurance to other processes that aid compliance with ISMS requirements. This Guide will also assist the user in obtaining customer concurrence on the QAP.

The quality requirements described in this Guide are interrelated and include criteria for managing, achieving, and assessing work. Implementing the quality requirements will contribute to improved safety, management, and the reliability of DOE products and services. This interrelationship precludes an organization from implementing only selected requirements and ensures the integrated approach required 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.

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. An organization may select alternative methods to document and implement its management system as long as the requirements of the rule and Order are satisfied. Ultimately, the content of the management system must be based on an organization’s unique set of overall responsibilities and customer expectations.

2.2 Integrated Safety Management System (ISMS)

Effective implementation of the rule and Order quality requirements will also provide processes and tools to support principles and functions of the Safety Management System Policy (DOE P 450.4) and related 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.

III. DISCUSSION

The quality attained in a product or service is described by 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 all entities that supply to or 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 requirements of 10 CFR 830.120 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.

The concept of developing a management system to simultaneously satisfy the requirements of a nuclear safety rule, those of an integrated management systems policy and regulation, and an overall quality management system for items and services produced by an organization may at first appear inconsistent or unworkable. Experience has shown, however, that designing a system to a minimum performance level will inevitably result in less than minimum results. The development and implementation of a quality management system, integrated throughout the organization, will improve performance and provide assurance that the requirements of DOE O 414.1, Nuclear Safety Management Rules (10 CFR 830 and 835), and the DOE Safety Management System Policy /Acquisition Regulation (DOE P 450.4, 48 CFR 970.5204-2, and 970.1001) are being satisfied.

IV. GUIDANCE

4.1 Program

4.1.1 Introduction

The principal factor representing the performance of an organization 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. 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 support and function with the Department's ISMS.

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, which addresses the organizational structure, functional responsibilities, levels of authority, and interfaces.

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.

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. In many cases, the particular standards to be adopted are specified by the customer. Organizations with multiple customers must often develop their management system using several standards. Clearly defined standards will also support Safety Management System Policy Principle 5, *Identification of Safety Standards and Requirements.*

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.

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 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 by–

- establishing task assignments;
- identifying lines of communication;
- determining and providing the necessary resources and environment to accomplish the required activities;
- ensuring employees are trained appropriately and are capable of performing task assignments;
- obtaining timely, objective feedback on the effectiveness of planning and work to meet performance measures; and
- involving all employees to ensure that improvements are identified and implemented to enhance performance.

4.1.3 Graded Approach

The scope, depth, and rigor of the management system's application of requirements to a specific activity should be determined by the use of a grading process. 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 10 CFR 830.120 or DOE O 414.1.

The grading process should be used to evaluate hazards or risks and to determine the appropriate controls to address those hazards or risks. This process is accomplished by deliberate quality planning and is based on facility-specific or activity-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;
- impact/consequences on 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;
- complexity of products or services involved; and
- history of problems at a site or facility.

The varying degrees of the controls applied should be dependent upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations. Risk is a fundamental consideration in determining to what extent controls should be applied. 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 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 (ref. DOE-STD-3009-94) 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.

The first step in the grading process is to identify the consequences and probability of a failure. 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 procedures 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.

4.2 Personnel Training and Qualification

4.2.1 Introduction

A fundamental requirement for effective accomplishment of any mission is that all personnel be capable of performing their assigned tasks. Qualification and training processes ensure that personnel achieve and maintain the required capabilities. Principle 3 of the SMS Policy contains a similar expectation for personnel to possess the experience, skills, and abilities commensurate with their responsibilities.

4.2.2 Responsibilities

Management should commit resources to facilitate the training and qualification processes for personnel in their organizations, and to ensure 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. These should include the minimum applicable requirements for education, experience, skill level, and physical condition. For example, the

OSHA terms “competent, qualified, certified, and designated” each have pre-requisites based in approved standards. Physical condition used in this context means such human attributes as visual acuity and hearing, which are necessary to properly perform the job.

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

- previous experience, education, and training;
- a performance demonstration or test to verify previously acquired skills;
- completion of a training or qualification program; and/or
- on-the-job training.

4.2.4 Training

Training should help personnel acquire knowledge of the correct and current processes and methods to accomplish assigned tasks. It should also enable 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.

Training goals, lesson plans, and other training materials should be consistently developed, reviewed by experienced personnel, approved by management, and used to effectively deliver training. Training materials should be controlled to ensure that the latest approved versions are used. Instructors may be training providers or qualified members of the organization. Instructors should possess technical knowledge, experience, and training development and instructional skills. Instructor training should be based, in part, on the results of instructor evaluations and training on new methods and equipment.

Training effectiveness should be monitored. Worker performance should be evaluated to ensure that the training program conveys all required knowledge and skills. Feedback from personnel performance, former trainees and supervisors, accidents, and assessments should be used to determine effectiveness of training. The results of these evaluations should be used as the basis for improving the training program and is an example of the SMS Policy feedback and improvement function.

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 all functions, including those personnel responsible for managing, planning, and controlling work. Initial training should prepare personnel to perform the job. Continuing training should maintain and promote improved job performance. Training plans can contribute to employee satisfaction and an interest in self-enhancement, thereby motivating personnel to develop enhanced technical, managerial, or other skills capabilities, and to track and document such development.

Managers and workers should consider all types of available training when preparing their training plans. 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

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; and
- when necessary, corrects problems that occur.

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 non-compliance with a legal, contractual, or other requirement; or
- the existence of a substandard condition or a suspect/counterfeit item.

Quality problems may be identified by the organization or by an external source (customer/regulator). Corrective action is the identification of cause and the resolution of a quality problem after its occurrence to prevent its recurrence. Preventive action ensures, through appropriate design, inspection, procurement, and other process controls and assessment activities, that a quality problem does not occur. 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.

Quality improvement is a management process that is carried out to improve an item, service, product, or process. All aspects of work activities and the management system are subject to continuous improvement through an assessment and feedback process. Feedback originates from workers, customers, and suppliers. 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 ensure they are providing the anticipated improvements. Quality improvement processes will support SMS Policy feedback and improvement Core Function 5, Line Management ES&H Oversight Policy, and the Department's commitment to develop corrective action plans for safety issues reported by the Office of Oversight (EH-2). [Also see sections 4.3.4, 4.9, and 4.10]

4.3.2 Identification of Quality Problems

A quality problem should be identified, documented, and evaluated to determine significance. Usually, identification of a problem comes in the form of feedback from workers and from internal and external customers. 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. If the quality problem is likely to affect safety or mission significantly, the impacted items or processes should be controlled to prevent their further use. Problems that are not likely to be 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 dispositioning. The method for determining the significance of a problem and the process for handling problems should be documented in the quality management system.

The QAP or other documentation should define the conditions governing the issuance and removal of stop work orders

4.3.3 Resolution of Quality Problems

A quality problem resolution process should consist of–

- identifying a condition adverse to quality,
- evaluating its significance,
- analyzing the problem and determining its causes,
- reporting the planned actions to the organization identifying 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.

Management should be involved in approving corrective/preventive actions for significant quality problems and following them through to closure**.**

Quality problems identified by internal and external sources (e.g., DOE Office of Oversight, 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. Specific expectations for CATS and corrective action plans will be available shortly after publication of this guide on the Office of Environment, Safety, and Health website at: http://tis.eh.doe.gov/ism/. The planned corrective/preventive actions and progress through to closure should be reported to the identifying organization when requested.

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.

4.3.4 Quality Improvement

Improvement in quality 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 develop and explore new ideas for improving products, processes, and services. Effective improvement processes require each employee to participate and cannot be delegated to a particular person or group. Management commitment can be demonstrated by empowering workers to–

- identify process problems,
- develop alternative approaches for addressing problems (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, 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.

4.4. 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 should commit the resources necessary to accomplish the document and record requirements.

4.4.2 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. A document control system should be established to supply such documents necessary for personnel to safely and correctly perform their assigned responsibilities. Document systems ensure that the mechanisms developed to implement the safety management functions of DOE P 450.4 are properly prepared, controlled, and available for managers and the workers.

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. Records may be in a variety of forms (e.g., electronic, written or printed, microfilm, photographs, radiographs, or optical disks). Records are compiled into a records management system that ensures appropriate records are maintained. The system should include provisions for records retention, protection, preservation, change, traceability, accountability, and retrievability. While in storage, records should be protected from damage, loss, and deterioration.

The hardware and software required to ensure retrievability and usability of archived records should be maintained.

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

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.

4.5.2 Work Performance

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 (ISMS Core Function 1);
- acceptance criteria applicable to work and final product (ISMS Core Function 1);
- hazards associated with the work (ISMS Core Function 2);
- technical standards applicable to work and final product (ISMS Core Function 1and 3); and
- safety, administrative, technical, and environmental controls to be employed during the work (ISMS Core Function 3).

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).

Procedures, work instructions, or other 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, and the hazards and risks or consequences of quality problems in the product, process, or service (ISMS Guiding Principle 6). Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented (ISMS Guiding Principle 5, Core Function 3).

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 (ISMS Core Function 4). 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, and providing the feedback necessary for improvement (ISMS Core Function 5).

4.5.3 Item Identification and Use Control

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 suspect/counterfeit items, and
- provide for the control and maintenance of items.

“Item” is a collective term that may include hardware, samples, software, or data. 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.

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 their 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 are 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.)

4.6 Design

4.6.1 Introduction

A formal design process should be established that provides control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces appropriate to the importance of the design. Design work should be based on sound engineering judgement, scientific principles, and applicable codes and standards.

The design of items, such as structures, systems, and components that involve a higher-than-normal level of risk (including those items important to safety), should be subject to more definitive design process control and verification requirements. 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 inspection, testing, and maintenance 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 records should include documentation of design input, calculations and analyses, engineering reports, design output, design changes, and design verification activities.

4.6.2 Design Input

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

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, 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.

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: as-built mark-up and updating during construction and operation phases, and the requirements for document control and records management.

4.6.5 Design Verification

Design verification is a formal, documented process for ensuring that the resulting items will comply with the requirements. Design verification methods include, but are not limited to, technical reviews, peer reviews, alternate calculations, and qualification testing. When appropriate, the verification process may consider 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 and number of design verifications should be based on a graded approach and should depend 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, or experiment. 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

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 440.1-6 , Section 4.3, 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.

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.

The selection of procurement requirements should be commensurate with the importance of the purchased items or services. 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. The requirements in 10 CFR 830.120(c)(2)(iii) and Criterion 7 of DOE O 414.1 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 should include a determination of the applicability of 10 CFR 830.120 to the supplier or subcontractor. If applicable, procurement documents and contracts for items and services provided to facilities covered by 10 CFR 830.120

should include a statement informing the supplier or subcontractor that they are subject to 10 CFR 830.120 and the enforcement actions under 10 CFR 820. Suppliers and subcontractors are not required by 10 CFR 830.120 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 test/inspection requirements and acceptance criteria for purchased items and services. Procurement documents should include any specifications, standards, and other documents referenced in the design documents. Critical parameters and requirements, such as submittal, product related documentation, problem reporting, administrative documentation, personnel or materials qualifications, tests, inspections, and reviews, should be specified.

4.7.3 Supplier Qualification

Potential suppliers should be identified early in the design and procurement process in order to determine their capabilities. Prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements. An effective evaluation method is an assessment of personnel and processes conducted at the supplier's facilities (a quality assurance program evaluation). This method may be used in combination with–

- a review of the supplier's history for providing identical or similar items or services;
- a review of shared supplier quality information;
- an evaluation of certifications or registrations awarded by nationally accredited third parties; and
- an evaluation of documented qualitative and quantitative information provided by the supplier.

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

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. Monitoring may include–

- surveillance of work activities,
- inspection of facilities and processes,

- review of plans and progress reports,
- processing of change information,
- review and disposition of nonconformances, and
- selection, qualification, and performance monitoring of sub-tier suppliers.

4.7.5 Inspection

The procurement process should provide for identifying the need for inspections and tests. Requirements for inspections and tests should be obtained from design documents. Inspections should be adequate to ensure conformance with purchase requirements, including verification that specified documentation has been provided by the supplier. The inspection should verify 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 prior to or following shipment.

Critical or important acceptance parameters and other requirements, such as inspection/test equipment or qualified inspection/test personnel, should be specified in design documentation. In addition, the risks associated with the possibility of obtaining suspect/counterfeit items should be evaluated and, if appropriate, measures implemented to identify them. DOE G 440.1-6 provides additional guidance on this subject.

4.7.6 Supplier Documentation

Supplier-generated documents should be accepted through the procurement system and controlled and processed by the end-user organization according to the provisions of Criterion 4 of DOE O 414.1 (Documents and Records). These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and deviations.

4.7.7 Suspect/Counterfeit Items

The selection of suppliers and the purchase of commercial-grade materials should be evaluated to prevent the procurement of suspect/counterfeit items and to detect them before they are released for use. Information in DOE G 440.1-6, Section 4.1, should be used to minimize the possibility of procuring suspect/counterfeit items.

4.7.8 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
- 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.

4.8 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 use and acceptance. Inspections and tests should be identified early in the design process and specified in the design output documents.

The type of item and the length of time it is expected to remain in storage should be considered during inspection planning.

Personnel should check items prior to their use to ensure that the items are correct and suitable for their intended application. 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. Inspection/test planning should contain provisions for at least the following:

- 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;
- 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 authorized personnel to document that all requirements have been satisfied. Final acceptance should be verified and documented by the organization having final responsibility for the item or process.

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

- item tested,
- date of test,
- tester or data recorder,
- observations,
- results and acceptability, and
- action taken concerning quality problems noted.

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.

Final inspections are usually distinct from inspections conducted during the work process. Final inspection confirms the item, service, or process is ready for acceptance testing and/or operation. As such, it includes completeness, cleanliness, identification/markings, calibration, alignment/adjustment, adequate records, or other characteristics indicating conformance to requirements.

4.8.3 Control of Measuring and Test Equipment

Measuring and Test Equipment (M&TE) used for inspection, tests, and monitoring or data collection should be calibrated and maintained using a documented process. M&TE should also be checked prior to its use to ensure that it is of the proper type, range, accuracy, 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 available and appropriate. If no nationally recognized standards exist, the bases for calibration should be documented.

4.9 Management Assessment

4.9.1 Introduction

Managers at every level should periodically assess the performance of their organizations and functions to determine how well it meets customer requirements and expectations, and mission objectives, so that improvements can be made. This assessment should address the use of human and material resources to achieve the organization's goals and objectives. The management assessment should also include an introspective evaluation to determine if an integrated management program exists and if it focuses on meeting both customer requirements and strategic goals (ISMS Core Function 5). Management assessments conducted by DOE and contractor "line" managers support implementation of DOE P 450.5, LINE ENVIRONMENT, SAFETY, AND HEALTH OVERSIGHT.

DOE has developed expanded guidance on this subject that should be consulted for planning and performance of management assessments (ref. DOE G 414.1-1).

4.9.2 Responsibility

Managers perform 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 the manager. Personal involvement by the manager will naturally yield the most meaningful information for that manager to use in taking actions to improve organizational performance.

4.9.3 Process

Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve processes. Those areas that present the greatest consequences of failure and the greatest benefit from improvements if implemented should receive particular emphasis. Management assessments should focus on identifying and resolving both singular and systemic management issues and problems that may prevent customer requirements and expectations from being met. For example, senior managers may use the process to determine the degree to which the ISMS is achieving the Department's safety objective. Criteria set forth in the Presidential Award for Quality or the Malcolm Baldrige National Quality Award is another example of broad management issues that may be used for

management assessments. Results from internal or external (e.g., Office of Oversight or Office of Enforcement and Investigation) independent assessments should be used as input to the management assessment. These independent assessments often contain indicators of potential management issues.

Managers should assess their processes for planning; organizational interfaces (internal and external to the organization); integration of management systems (e.g., safety, quality, project); use of performance metrics; training and qualifications; and supervisory oversight and support. Effective management assessments include an evaluation of such conditions as the state of employee knowledge, motivation, and morale; communication among workers; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.

Direct observation of work is an effective, preferred assessment method that will make the manager aware of interactions at a work location. Other methods that are useful when combined with observation include worker and customer interviews, safety and performance documentation reviews, and drills or exercises.

Performance measurement is an effective way to integrate assessment methods into daily operations and strengthen the alignment of purpose between management and workers. Performance measurement should be based on objective standards, clearly defined goals, results-oriented metrics, and meaningful review and feedback processes.

4.9.4 Results

Management assessment results should be documented and used as input to the organization's improvement process. Periodic review of performance metrics at appropriate management levels and with customers is effective in validating organizational performance.

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 the 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 (ISMS Core Function 5).

The independent assessment process should use a performance-based approach to focus on results. Performance-based assessments are conducted on activities that–

- relate directly to final objectives,
- emphasize safety and reliability, and
- measure item or service performance.

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.

Separately, the Secretary of Energy has established the Office of Oversight to conduct independent assessments of DOE and contractor safety performance. DOE and contractor organizations should not consider the Office of Oversight function as satisfying the QA rule/Order requirements for independent assessment.

DOE has developed expanded guidance on this subject that should be consulted for planning and performing independent assessments (DOE G 414.1-1).

4.10.2 Performing Organization

Independent assessments advise senior management on the quality of items, services, and processes produced by or for the organization. Consequently, the persons or organization conducting independent assessments 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.

In addition, personnel performing independent assessments should have the necessary technical knowledge to accurately observe and evaluate activities being assessed. They should have no direct responsibility for the work or organization they are assessing. The manager directly responsible for the work should be considered as a customer of the assessment product (e.g., feedback resulting from observations of performance).

4.10.3 Process

The type and frequency of independent assessments should be based on the status, complexity, risk, and importance of the activities or processes being assessed. The criteria used for assessments should describe acceptable work performance and should promote improvement of the process or activity. Assessments should also address management processes that affect work performance, such as planning, program support, training, and the performance of SMS Policy Core Safety Functions.

Independent assessments may include methods such as monitoring operations, inspections, peer and technical reviews, audits, surveillances, customer interviews, or combinations thereof.

The assessment should focus on improving output quality and process effectiveness by emphasizing improvement methods. Independent assessment personnel should base the evaluation 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.

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;
- documenting and reporting results; and
- verifying satisfactory resolutions of reported problems.

The independent assessment process should include verification of the adequacy of 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.

4.10.4 Results

Documented assessment results should be presented to the organization that was assessed and provided to the 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.

Management should track improvement actions until a resolution has been implemented and verified as completed.

REFERENCES

The following references provide acceptable methods for implementing many of the requirements of 10 CFR 830.120 and DOE O 414.1. No single reference fully meets all the requirements. The principles, recommended approaches, and applications contained in these references may be used with 10 CFR 830.120 and DOE O 414.1 to develop an effective management system to achieve quality. The latest date of the reference is provided; however, the QAP developer may use any issue of the reference appropriate to the QAP work.

A. RELATED POLICIES, RULES AND ORDERS

10 CFR Part 830, Nuclear Safety Management

10 CFR 830.120, 4-5-94, Quality Assurance Requirements

48 CFR Part 46, Quality Assurance (note: part 46 is part of the FAR)

48 CFR Parts 1-99, Federal Acquisitions Regulations System

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

DOE O 414.1, QUALITY ASSURANCE, dated 11-24-98

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 360.1, TRAINING, dated 5-31-95

DOE O 200.1, INFORMATION MANAGEMENT PROGRAM, dated 9-30-96

B. RELATED QUALITY MANAGEMENT SYSTEM STANDARDS

DOE G 414.1-1, IMPLEMENTATION GUIDE FOR USE WITH INDEPENDENT AND MANAGEMENT ASSESSMENT REQUIREMENTS OF 10 CFR 830.120 AND DOE ORDER 5700.6C QUALITY ASSURANCE, dated August 1996

DOE G 440.1-6, IMPLEMENTATION GUIDE FOR USE WITH SUSPECT/COUNTERFEIT ITEMS REQUIREMENTS OF DOE 440.1 WORKER PROTECTION MANAGEMENT, 10 CFR PART 830.120; AND DOE 5700.6C QUALITY ASSURANCE, dated June 1997

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ANSI/NCSL Z540-1-1997, Calibration Laboratories and Measuring and Test Equipment, General Requirements

ASME NQA-1-1997, Quality Assurance Program Requirements for Nuclear Facilities, Part 1, Requirements and Part 3, Nonmandatory Appendices

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DOE-ER-STD-6001-92, June 1992, *Implementation Guide for Quality Assurance Programs for Basic and Applied Research* (to be superseded by ANSI/ASQ Z1.13-1999)

International Atomic Energy Agency (IAEA) Safety Guide 50-SG-Q1, 1995, Establishing and Implementing a Quality Assurance Programme

C. RELATED REFERENCES

American Society for Nondestructive Testing Standard SNT-TC-1A

ANSI/ISO/ASQC Q10011-1-1994, Guidelines for Auditing Quality Systems - Auditing

ANSI/ISO/ASQC Q10011-2-1994, Guidelines for Auditing Quality Systems - Qualifications Criteria for Quality Systems Audits

ANSI/ISO/ASQC Q10011-3-1994, Guidelines for Auditing Quality Systems - Management of Audit Programs

ANSI/ISO/ASQC Q10012-1-1992, Quality Assurance Requirements for Measuring Equipment, Part 1: Meteorological Confirmation System for Measuring Equipment

ANSI/ISO/ASQC-14001-1996, Environmental Management Systems - Specification with Guidance for Use

ANSI/ISO/ASQC-14004-1996, Environmental Management Systems - General Guidelines on Principles, Systems, and Supporting Techniques

ANSI/ISO/ASQC-14010-1996, Guidelines for Environmental Auditing - General Principles

ANSI/ISO/ASQC-14011-1996, Guidelines for Environmental Auditing - Audit Procedures - Auditing of Environmental Management Systems

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DOE G 450.4-1, INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE FOR USE WITH DOE 450.4 SAFETY MANAGEMENT SYSTEM POLICY, AND DEAR SAFETY MANAGEMENT SYSTEM CONTRACT CLAUSE, Volumes 1 and 2, dated November 1997

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USNRC Regulatory Guide 1.33, Rev. 2, February 1978, Quality Assurance Program Requirements (Operations).