National Nuclear Security Administration

Quality Assurance

Qualification Standard
Reference Guide

NOVEMBER 2006

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PURPOSE

The purpose of this reference guide is to provide a document that contains the information required for a National Nuclear Security Administration (NNSA) technical employee to successfully complete the Quality Assurance Functional Area Qualification Standard. In some cases, information essential to meeting the qualification requirements is provided. Some competency statements require extensive knowledge or skill development. Reproducing all the required information for those statements in this document is not practical. In those instances, references are included to guide the candidate to additional resources.

SCOPE

This reference guide has been developed to address the competency statements in the April 2002 edition of DOE-STD-1150-2002, Quality Assurance Functional Area Qualification Standard. Competency statements and supporting knowledge and/or skill statements from the qualification standard are shown in contrasting bold type, while the corresponding information associated with each statement is provided below it. The qualification standard for quality assurance (QA) contains 24 competency statements. This reference guide will address all the statements; however performance-based skills and abilities within those competencies will not be covered.

Every effort has been made to provide the most current information and references available as of November 2006. However, the candidate is advised to verify the applicability of the information provided.

Please direct your questions or comments related to this document to Mark Alsdorf, TQP Manager, Learning and Career Development Department, NNSA Service Center, 505-845-6448.

TECHNICAL COMPETENCIES

A. QA Program Management

1. QA personnel should demonstrate a working-level of knowledge of Department of Energy (DOE) QA policy, programs, processes, and regulatory requirements contained in:

- **DOE O 414.1C, Quality Assurance**
- **10 CFR 830, Subpart A, Quality Assurance**
- **Office of Price-Anderson Enforcement Procedures and Guidance**
- **10 CFR 820, Procedural Rules for DOE Nuclear Activities**

a) Discuss the purpose and scope of the Price-Anderson Amendments Act (PAAA) and its applicability to the DOE's QA activities.

The PAAA provides indemnification to DOE contractors who manage and conduct nuclear activities in the DOE complex. In a general sense, the Government acts as an insurer for these contractors against any findings of liability arising from the nuclear activities of the contractor within the scope of its contract.

In 1988, the PAAA was signed into law to extend the Government insurance program which was about to expire. It differed from the original act in two principal ways. First, it made Price-Anderson coverage mandatory for all management and operating (M&O) contractors, subcontractors, and suppliers conducting nuclear activities for DOE (for the purposes of the statute, "nuclear" includes "radiological"). Second, Congress mandated that DOE change its methods of managing nuclear activities at those sites by requiring DOE to undertake enforcement actions against indemnified contractors for violations of nuclear safety requirements. Thus, indemnification risks would be minimized by minimizing the risk to workers and the public. The benefit of indemnification is accompanied by the availability of sanctions to assure compliance with nuclear safety rules.

For all M&O contractors, subcontractors, and suppliers thereto, DOE has the authority to issue notices of violation when non-compliances with nuclear safety requirements are identified. In addition, for cases involving for-profit contractors, DOE has the authority to issue fines for violations of nuclear safety rules up to $100,000 per day per occurrence. Civil penalties are not applicable to individual employees or to contractors specifically exempted by section 234A (d) of the Atomic Energy Act of 1954 (as amended).

Title 10 CFR 820 establishes the legal framework for implementing DOE's Nuclear Safety Enforcement Program. The responsibility for program development and implementation has been assigned to the Enforcement and Investigation Staff in the Office of Health, Safety, and Security. Early in the process of developing the Enforcement Program, it was recognized that significant integration with other DOE organizations and programs, such as the Quality Assurance Program, would be necessary and appropriate. This integration or matrix approach would best use the existing DOE programs and technical resources to ensure that the enforcement process properly considers the actual or potential safety significance of a violation when determining an appropriate enforcement sanction.

The DOE Quality Assurance Rule (QA Rule) is part of the Nuclear Safety Management Rule, 10 CFR 830, and is covered by the PAAA. Title 10 CFR 830, subpart A, establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities.

b) Discuss the purpose, interrelationships, and importance of DOE Policy 450.4, Safety Management System Policy, DOE Policy 450.5, Line Environment, Safety and Health Oversight, DOE O 414.1C, Quality Assurance, and 10 CFR 830, Subpart A, Quality Assurance.

DOE Policy 450.4, Safety Management System Policy
Safety management systems provide a formal, organized process whereby people plan, perform, assess, and improve the safe conduct of work. The safety management system is institutionalized through DOE directives and contracts to establish the Department-wide safety management objectives, guiding principles, and functions.

The system encompasses all levels of activities and documentation related to safety management throughout the DOE complex.

DOE Policy 450.5, Line Environment, Safety, and Health Oversight
This Policy has been canceled.

DOE O 414.1C, Quality Assurance
The objectives of this Order are to ensure that DOE, including NNSA, products and services meet or exceed customers' expectations, and to achieve QA for all work based on the following principles:

- That quality is assured and maintained through a single, integrated, effective QA program (i.e., management system)
- That management support for planning, organization, resources, direction, and control is essential to QA
- That performance and quality improvement require thorough, rigorous assessment and corrective action
- That workers are responsible for achieving and maintaining quality
- That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products

One additional objective is to establish quality process requirements to be implemented under a QA program (QAP) for the control of suspect/counterfeit items (S/CIs), corrective actions, and nuclear facility safety software.

10 CFR 830, Subpart A, Quality Assurance
This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services that affect, or may affect, the nuclear safety of DOE nuclear facilities.

c) Discuss the DOE and contractor requirements and responsibilities for development, review, approval, and implementation of QAPs.

DOE O 414.1C, attachment 2, Contractor Requirements Document states that a contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that

- implements QA criteria, S/CI prevention requirements, and safety software using a graded approach and describing how the QA criteria and graded approach are applied.
- uses the appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include the
    - American Society of Mechanical Engineers (ASME) NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications (for nuclear-related activities);
    - American National Standards Institute/International Organization for Standardization/American Society for Quality (ANSI/ISO/ASQ) Q 9001-2000, Quality Management System: Requirements (for non-nuclear activities);
    - ANSI/ASQ Z 1.13, 1999, Quality Guidelines for Research (for non-nuclear research activities).
- applies additional standards, where practicable and consistent with contractual or regulatory requirements and 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). (Note: These standards are sometimes referred to as "voluntary standards." However, once the practicable standard[s] is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.)
- integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements, the S/CI prevention process, and safety software quality requirements with other quality or management system requirements in DOE directives and external requirements, including as applicable
    - DOE P 450.4, Safety Management System Policy, dated October 15, 1996;
    - NNSA Quality Management Policy, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities);
    - DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description.

The contractor must

- submit a QAP to DOE for approval before beginning work under a DOE contract;
- implement the QAP as approved and modified by DOE;
- indicate in the submittal any third-party certification affecting the QAP;
- revise an existing QAP that was approved in accordance with previous versions of the CRD to DOE O 414.1C, Quality Assurance, to address enhancements;
- regard a QAP as approved by DOE 90 calendar days after DOE receipt, unless approved or rejected by DOE at an earlier date, and include any modification made or directed by DOE;
- submit QAP changes made the previous year annually to DOE for review and approval. In the submittal, identify the changes, the reason for the changes, and the

basis for concluding that the revised QAP continues to satisfy the current requirements.

d) Discuss the process for obtaining an exemption to DOE O 414.1C, Quality Assurance, and 10 CFR 830, Subpart A, Quality Assurance.

DOE/NNSA may grant temporary or permanent exemptions to its directives provided such exemptions are not prohibited by law and do not present an undue risk to public health and safety, the environment, or facility workers.

Completed exemption requests are to be submitted to the Site Office Manager, NNSA. Exemption requests should include the following information:

- A citation of the regulation to be exempted
- A detailed description of the proposed exemption
- A statement to outline the basis for the exemption

e) Discuss the requirements of DOE O 414.1C, Quality Assurance, and 10 CFR 830, Subpart A, Quality Assurance.

DOE O 414.1C and 10 CFR 830, subpart A contain may of the same requirements through the following 10 basic criteria. The QAP must address the following management, performance, and assessment criteria.

(1) Management/Criterion 1—Program.

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

(2) Management/Criterion 2—Personnel Training and Qualification.

(a) Train and qualify personnel to be capable of performing assigned work.
(b) Provide continuing training to personnel to maintain job proficiency.

(3) Management/Criterion 3—Quality Improvement.

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

(4) Management/Criterion 4—Documents and Records.

(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
(b) Specify, prepare, review, approve, and maintain records.

(5) Performance/Criterion 5—Work Processes.

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

(6) Performance/Criterion 6—Design.

(a) Design items and processes using sound engineering/scientific principles and appropriate standards.
(b) Incorporate applicable requirements and design bases in design work and design changes.
(c) Identify and control design interfaces.
(d) Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
(e) Verify/validate work before approval and implementation of the design.

(7) Performance/Criterion 7—Procurement.

(a) Procure items and services that meet established requirements and perform as specified.
(b) Evaluate and select prospective suppliers on the basis of specified criteria.
(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(8) Performance/Criterion 8—Inspection and Acceptance Testing.

(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.
(b) Calibrate and maintain equipment used for inspections and tests.

(9) Assessment/Criterion 9—Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(10) Assessment/Criterion 10—Independent Assessment.

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

f) Referring to DOE G 414.1-2A, Quality Assurance Management System Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance, discuss the implementation of an effective QAP.

DOE G 414.1-2A provides information on principles, requirements, and practices used to establish and implement an effective QAP or quality management system consistent with the requirements of 10 CFR 830 Subpart A and DOE O 414.1C. The guide may also be used by a contractor to assist in obtaining QAP approval from its DOE customer.

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

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

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

system's scope. The scope also describes the organizational structure, functional responsibilities, levels of authority, and interfaces.

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

A graded approach that doesn't compromise public, employee, or facility safety or adversely impact the environment, and which complies with requirements, rules, and regulations, must be used to implement the QAP.

g) Referring to DOE G 414.1-2A, discuss the shared attributes of quality and safety management systems and the methods for integrating the implementation of the DOE Safety Management System and QAP.

The quality management system complements and is integrated with the SMS, described in DOE P 450.4, Safety Management System Policy, dated October 15, 1996, and DOE Acquisition Regulation 48 CFR 970.5204-2 (i.e., the DEAR ISMS clause). The quality management system provides processes and tools for ensuring that ISMS objectives are achieved. DOE P 450.4 expresses a fundamental expectation that all work will be performed safely. The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the quality management system ensures compliance with the approved safety standards set, so that the expectation for safe work within controls is met. This also ensures that workers, the environment, and the public are reasonably protected from harm.

At the organizational or institutional level, the DOE quality and safety requirements share a management systems approach to achieve their objectives. As such, the required system documentation for each (ISM system description and QAP) may be integrated into a single document to describe how the organization intends to implement the requirements. In some cases, the local DOE office (site office or field element) and the contractor may determine that it is expedient to maintain both the ISM system description and the QAP. In these cases, at a minimum, the implementing mechanisms that are described in each should be integrated to the maximum extent practical, and the system description and QAP should cross-reference these procedures as applicable. For example, the processes and procedures for conducting management assessments should be referenced in the QAP and the ISM system description. Likewise, a single process (e.g., procedures and plans) that satisfies quality and safety requirements at the facility level and the activity level should be used.

h) Discuss the purpose, benefits, and restrictions of the graded approach in the implementation of DOE quality assurance requirements.

DOE G 414.1-2A states that a graded approach that doesn't compromise public, employee, or facility safety or adversely impact the environment, and which complies with requirements, rules, and regulations, must be used to implement the QAP. The graded application of

facility/activity requirements is dependent on the hazards and/or level of risk associated with the activity or structures, systems, and components (SSCs) under consideration. The scope, depth, and rigor of the quality management system's application of requirements should be determined by the use of a grading process before performing the activity. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and the success of the program.

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

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

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- the 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;
- the adequacy of existing safety documentation;
- the relative importance of radiological and non-radiological hazards;
- the complexity of products or services involved;
- the performance history of a facility or activity;
- any other relevant factors.

The first step in the grading process is to identify the hazards, and for the facility level, their consequences and the probability of a failure, before work begins. The second step is to identify the specific requirements and controls to be applied. The third step is to determine the depth, extent, and degree of rigor necessary in the application of the requirements and controls. The final step is to communicate and implement the selected requirements and controls and their degree of rigor by means of documented work processes (procedures, instructions, specifications, and controls). The logic, method of implementation, and basis for grading should be documented in the quality management system, periodically reviewed in light of changes that may have occurred, and if appropriate, revised to reflect those changes.

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

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

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

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

i) Referring to DOE G 450.4-1 discuss the objectives, requirements, and implementation of DOE O 414.1A, Attachment 2, "Safety Issue Corrective Action Process," for reporting, tracking, and resolution of quality problems.

DOE G 414.1-5, Corrective Action Program guide was approved on March 2, 2006. The following is an excerpt from that document.

Corrective action programs should meet the basic criteria of the generalized process for feedback and improvement within the DOE ISMS. This generalized process includes the following steps.

Identify and Report Problem Findings
Identifying and reporting problem findings from a variety of sources to include a specific operational event, internal or external assessment or investigation, observation during daily work performance, and worker safety concern is the first generalized step for the feedback and improvement core safety function. All workers should be encouraged to evaluate performance and safety of workers, products, services, and processes; identify potential and actual problems (i.e., deficiencies, incidents, malfunctions, weaknesses, failures, etc.) at the earliest possible time before they become more significant; and immediately report these problems. This first step should be formally defined and fully integrated with the site/organization continuous performance and safety improvement strategy. This step is further explained in paragraph 4 of the Guide.

Evaluate Each Problem Finding snd Develop Appropriate Corrective Actions and Corrective Action Plans

The second generalized step provides the framework for defining a problem by collecting and evaluating relevant information to determine the facts and causal factors, including root causes. The site/organization responsible for the function/activity where the problem finding was identified should have a clear understanding and description of the finding supported by the facts and causal factors in order to develop the most appropriate, timely corrective actions to resolve the finding and prevent recurrence. These corrective actions are then incorporated into the corrective action plan (CAP). Other considerations in corrective action planning should include determining the actual and potential significance, complexity, and impact of the problem finding on the safety, reliability and mission performance of the site/organization and the workers. This second generalized step is considered the cornerstone

of the feedback and improvement process core safety function and oftentimes the most difficult and least understood. This step is further explained in paragraph 5 of the guide.

Close and Implement Corrective Actions and Resolve Each Problem Finding
The third generalized step in the feedback and improvement core safety function includes closing and implementing corrective actions to resolve the findings delineated in the CAP. Completion and implementation status is tracked and reported to ensure timely and adequate resolution of each finding. The completion and implementation of the CAP can be a tedious process with potential for ineffectiveness in the corrective action process. Although the findings have been identified and detailed plans to correct the findings have been developed, the often long and weary process of actively completing and implementing all of the corrective actions for each finding in the CAP has the propensity to receive less attention as emphasis is shifted to other more immediate initiatives, crises, and requirements. It is important that closure and implementation of the CAP receive continuous management attention, progress monitored and updated, and status periodically reported. This step is further explained in paragraph 6 of the guide.

Close Each Problem Finding and Determine Effectiveness of Corrective Actions

The fourth generalized step in the feedback and improvement core safety function includes completion of all corrective actions for the findings listed in the CAP and an independent followup assessment by the responsible site/organization to verify closure and review the effectiveness of the corrective actions in resolving each finding and preventing recurrence. This followup step is paramount to the success of the feedback and improvement core safety function and corrective action program. The resources (funding, personnel, and time) expended to identify the finding and implement the corrective actions will be fruitless if the causal factors involved in the finding has not been effectively resolved or the same or similar findings recur. There may also be financial costs based on repeat violations and civil penalties associated with the failure to resolve the finding effectively. Most importantly, the potential adverse impact of an unresolved finding to the mission and safety of workers would remain for unsuspecting managers and workers who implemented the corrective actions and presumed the finding was resolved. This step is further explained in paragraph 7 of the guide.

2. QA personnel should have a working-level knowledge of the QAP requirements identified in their organization and the contractor's QA documents.

a) Describe the purpose and elements of an effective QAP.

Refer to element "f" of competency A1 for a description of the purpose and elements of an effective QAP.

b) Discuss line management's responsibilities for the QAP.

Site manager and program manager responsibilities for the QAP are to

- develop and implement approved QAPs governing the work under their purview, including software development/use, in accordance with requirements defined in

paragraph 4 of DOE O 414.1C, S/CI prevention requirements (attachment 3), CAMP requirements (attachment 4), and Safety Software Quality requirements (attachment 5).

- identify the senior management position assigned this responsibility.
- submit QAPs to the appropriate SOs for review, resolution of differences of opinion, and approval.
- review and, where delegated authority to do so, approve new and revised QAPs for contractors within their purview. (Note: The scope and rigor of review must be graded based on the status of the contractor's prior quality performance [e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification]. QAPs must be reviewed and approved or rejected within 90 calendar days of receipt.)
- perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness. (Note: The frequency and scope of assessments must be graded based on the status of prior quality performance and any third-party QAP certification. Other suitable methods may be used in combination with independent assessments.)
- periodically report management assessment results to their organizations' SOs describing the effectiveness of field element and contractor QA implementation.
- prepare and implement a CAP to address all findings in the CAMP assessment report, and enter, track, and report the status of the CAP in CATS.
- complete the CAP and conduct a follow-up review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings.
- approve the effectiveness review report and follow-up report recommendations.

c) Describe the graded approach for application of quality requirements.

Refer to element "h" of competency A1 for a description of the graded approach.

d) Discuss stop work authority as it relates to:

- **Origin of stop work authority**
- **Intended purpose**
- **Legal implications**

DOE O 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, section 4g, provides workers with the authority to stop work.

> Implement procedures to allow workers, through their supervisors, to stop work when they discover employee exposures to imminent danger conditions or other serious hazards. The procedure should ensure that any stop work authority is exercised in a justifiable and responsible manner.

Stop work is a DOE requirement to ensure all employees are provided the responsibility and authority to stop work practices in their immediate area that are imminently dangerous.

A work practice is considered to be imminently dangerous if serious injury to employees or the public or damage to the environment may occur if the practice continues.

Any stop work authority must be exercised in a justifiable and responsible manner. All workers, supervisors, managers, and safety professionals are responsible for being cognizant

of the conditions in their workplaces and for being prepared to stop work if conditions pose a serious threat to health or safety, or a detriment to the environment. Hazards analyses and hazard prevention/abatement processes result in routine hazards being controlled. The stop work requirement is intended to address extraordinary or unanticipated circumstances and situations where there is a breakdown in controls. When a reasonable person views the circumstances as having the potential to cause injury, serious impairment, harmful health effects, or serious damage to the environment, a stop work order is to be issued. However, the full implications of what will occur must be recognized. Any work stoppage must alleviate the hazard without creating unintended consequences that are worse than the hazard. Whenever workers see a need to stop work, they are to advise their supervisors. Before a stop work order is issued, the person issuing it needs to ensure the work stoppage itself will not negatively impact workers or public health and safety or the environment.

3. QA personnel should have a working-level knowledge of the application of appropriate regulations, codes, and consensus standards to DOE QAP implementation.

a) Discuss the applicability of Nuclear Regulatory Commission (NRC) and Environmental Protection Agency (EPA) QA regulations to the organization's activities.

Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, to 10 CFR 50, Licensing of Production and Utilization Facilities, establishes quality assurance requirements for the operation of nuclear lower plant safety-related structures, systems, and components. NRC Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants.

EPA uses its quality system to manage the quality of its environmental data collection, generation, and use. The primary goal of the quality system is to ensure that environmental data are of sufficient quantity and quality to support the data's intended use. Under the EPA quality system, organizations develop and implement supporting quality systems.

Title 48 CFR 46 allows federal agencies to select a national consensus standard as a basis for their quality specifications. EPA has selected ANSI/ASQC E4 as the basis for its quality specifications and, through tailoring language to 48 CFR 46, requires that applicants/ contractors submit a quality management plan (or equivalent) and a quality assurance project plan (or equivalent) to demonstrate conformance to the standard.

b) Describe the general relationship and applicability of the following documents (or the latest version) to DOE QA requirements:

- **American Society for Quality ASQ-E4, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs**
- **ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications**
- **ASQ Q9001, Quality Management Systems — Requirements**
- **DOE/RW/0333P, Quality Assurance Requirements and Description**

- **ISO 14001, Environmental Management System**
- **DOE Nuclear Weapons QA Requirements QC-1**

ASQ-E4, Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use
Note: The title of this document has been changed to "Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use." The document specifies requirements for a quality system to enable an organization to formulate policies and procedures to plan and implement sufficient and adequate quality management practices for environmental programs. This standard is applicable to any organization that wishes to

- implement, maintain, and improve a quality system for environmental programs;
- specify quality requirements when contracting for work;
- assure itself of its conformance with its stated quality policy;
- demonstrate such conformance to others.

All the requirements in this standard are intended to be incorporated into quality systems supporting environmental programs involving environmental data and environmental technology. The extent of the application will depend on the environmental policy of the organization, the nature of its environmental programs, and the conditions under which it operates.

ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications
This standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity.

ASQ Q9001, Quality Management Systems — Requirements
The term ISO 9000 refers to a set of quality management standards. ISO 9000 currently includes three quality standards: ISO 9000:2000, ISO 9001:2000, and ISO 9004:2000. ISO 9001:2000 presents requirements, while ISO 9000:2000 and ISO 9004:2000 present guidelines. All of these are process standards (not product standards).

ISO first published its quality standards in 1987, revised them in 1994, and then republished an updated version in 2000. These new standards are referred to as the ISO 9000 2000 Standards.

ISO's purpose is to facilitate international trade by providing a single set of standards that people everywhere would recognize and respect.

The ISO 9000 2000 standards apply to all kinds of organizations in all kinds of areas. Some of these areas include manufacturing, processing, servicing and so on.

How does ISO 9000 Work?
Here's how it works. You decide that you need to develop a quality management system that meets the new quality standard. That is your mission. You choose to follow this path

because you feel the need to control or improve the quality of your products and services, to reduce the costs associated with poor quality, or to become more competitive. Or, you choose this path simply because your customers expect you to do so or because a governmental body has made it mandatory. You then develop a quality management system that meets the requirements specified by ISO 9001:2000.'

In the course of doing so, you may also wish to consult the ISO 9000:2000 and ISO 9004:2000 guidelines. However, please remember that your quality management system must meet ISO's requirements, not its guidelines.

Once your quality management system has been fully developed and implemented, you carry out an internal audit to ensure that you have met every single ISO 9001 2000 requirement.

When you're ready, you ask a registrar to audit the effectiveness of your quality management system. If your auditors like what they see, they will certify that your quality system has met ISO's requirements. They will then issue an official certificate to you and they will record your achievement in their registry.

You can then announce to the world that the quality of your products and services is managed, controlled, and assured by a registered ISO 9001 Quality Management System!

Why is ISO 9000 Important?
ISO 9000 is important because of its orientation. While the content itself is useful and important, the content alone does not account for its widespread appeal.

ISO 9000 is important because of its international orientation. Currently, ISO 9000 is supported by national standards bodies from more than 120 countries. This makes it the logical choice for any organization that does business internationally or that serves customers who demand an international standard of quality.

DOE/RW/0333P, Quality Assurance Requirements and Description
The quality assurance requirements and description (QARD) is the principal QA document for the DOE Office of Civilian Radioactive Waste Management Program. It establishes the minimum requirements for the QA program. The QARD contains regulatory requirements and program commitments necessary for the development of an effective QA program. Implementing documents must be based on, and be consistent with, the QARD.

The QARD applies to the following:

- Acceptance of spent nuclear fuel and high-level waste
- Transport of spent nuclear fuel and high-level waste
- Storage of spent nuclear fuel through receipt of storage cask certification or a facility operating license
- The Mined Geologic Disposal System, including the site characterization activities (Exploratory Studies Facility and surface based testing), through receipt of an operating license
- High-level waste form development through qualification, production, and acceptance

- Characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel

ISO 14001, Environmental Management System
ISO 14001:2004 specifies requirements for an environmental management system to enable an organization to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organization subscribes, and information about significant environmental aspects. It applies to those environmental aspects that the organization identifies as those which it can control and those which it can influence. It does not itself state specific environmental performance criteria.

ISO 14001:2004 is applicable to any organization that wishes to establish, implement, maintain, and improve an environmental management system; to assure itself of conformity with its stated environmental policy; and to demonstrate conformity with ISO 14001:2004 through one of the following actions:

- Making a self-determination and self-declaration
- Seeking confirmation of its conformance by parties having an interest in the organization, such as customers
- Seeking confirmation of its self-declaration by a party external to the organization
- Seeking certification/registration of its environmental management system by an external organization

All the requirements in ISO 14001:2004 are intended to be incorporated into any environmental management system. The extent of the application will depend on factors such as the environmental policy of the organization; the nature of its activities, products and services; and the location where and the conditions in which it functions.

DOE Nuclear Weapons QA Requirements QC-1
The purpose of this document, Weapon Quality Policy (QC-1), is to establish the quality management system requirements for weapon activities of the NNSA and its contractors, and to ensure compliance with other applicable orders and regulations such as 10 CFR 830 and DOE O 414.1C and with DOE Integrated Safety Management (ISM) requirements.

c) Describe the relationship of consensus standards adopted by DOE and contractor organizations to the DOE quality requirements and any enhancements to the standards that are necessary to meet DOE requirements.

DOE requirements only provide general "whats." Standards can be used to provide specifics and to show how DOE requirements are implemented. Voluntary consensus standards are technical standards that are developed by experts recognized by national and international professional and technical societies, using a structured and formal consensus process. Their technical adequacy is established through expert review and, in many cases, has been proven through years of use. These standards extend through technical, management, and procurement areas. Examples include standards developed by standards development organizations (SDOs) such as the American Nuclear Society (ANS), ASME, the American Society for Testing and Materials (ASTM), and the Institute of Electrical and Electronics Engineers (IEEE). Consistent with the policy in OMB A-119, voluntary consensus standards are the technical standards of choice for DOE facilities, projects, and programs.

4. **QA personnel should have familiarity-level knowledge of the DOE Regulations, Orders, and Standards generally applicable to DOE contracts, programs, and projects that affect QA. For example:**
   - **10 CFR 970, DOE Acquisition Regulations (DEAR), DOE Management and Operating Contracts**
   - **DOE O 430.1, Life-Cycle Asset Management**
   - **DOE O 413.3A, Program and Project Management for the Acquisition of Capital Assets**
   - **DOE 0 200.1, Information Management Program**
   - **DOE N 203.1, Software Quality Assurance**
   - **DOE O 250.1, Directives System Order**
   - **DOE O 360.1B, Federal Employee Training**
   - **DOE O 425.1C, Startup and Restart of Nuclear Facilities**
   - **DOE O 5480.19, Conduct of Operations for DOE Facilities**
   - **DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities**
   - **DOE-STD-1073-2003, Configuration Management Program**
   - **DOE O 435.1, Radioactive Waste Management**
   - **DOE O 451.1B, National Environmental Policy Act Compliance Program**
   - **DOE O 460.2A, Departmental Materials Transportation and Packaging Management**
   - **DOE O 470.1, Safeguards and Security Program**
   - **DOE O 151.1C, Comprehensive Emergency Management System**
   - **DOE O 442.1A, Department of Energy Employee Concerns Program**
   - **DOE O 225.1A, Accident Investigation**
   - **DOE O 232.1, Occurrence Reporting and Processing of Operations Information**
   - **DOE O 210.1, Performance Indicators and Analysis of Operations Information**
   - **DOE Guide 430.1-2, Implementation Guide for Surveillance and Maintenance During Facility Transition and Disposition**
   - **DOE Guide 430.1-3, Deactivation Implementation Guide**
   - **DOE Guide 430.1-4, Decommissioning Implementation Guide**
   - **DOE N 221.6, Reporting Fraud, Waste, and Abuse**
   - **DOE-STD-1082-94, Preparation, Review, and Approval of Nuclear Safety Requirements**
   - **DOE-STD-1083-95, Requesting and Granting Exemptions to Nuclear Safety Rules**
   - **DOE-STD-7501-99, The DOE Corporate Lessons Learned Programs Supporting Knowledge and/or Skills**

   a) **Discuss the applicability, purpose, scope, and impact of the above DOE Regulations, Orders, and Standards.**

10 CFR 970, DOE Acquisition Regulations (DEAR), DOE Management and Operating Contracts
Note: The correct regulation is 48 CFR 970, DOE Management and Operating Contracts. The following information is from that regulation.

This part provides Departmental policies, procedures, provisions, and clauses that implement and supplement the Federal Acquisition Regulation (FAR) and other parts of the DEAR for the award and administration of the Department's management and operating contracts. The FAR and other parts of the DEAR apply to management and operating contracts. See 48 CFR 970.5200 for guidance regarding which provisions and clauses (from FAR, DEAR Part 970, or other parts of the DEAR) to include in management and operating contracts.

DOE O 430.1, Life-Cycle Asset Management
This Order has been replaced by DOE O 430.1B, Real Property Asset Management. DOE O 430.1B establishes an integrated corporate-level, performance-based approach to the life-cycle management of DOE's real property assets. It links real property asset planning, programming, budgeting, and evaluation to the Department's multi-faceted missions. Successful implementation of this Order will enable the Department to carry out its stewardship responsibilities, and will ensure that facilities and infrastructure are properly sized and in a condition to meet DOE's mission requirements today and in the future.

DOE O 413.3A, Program and Project Management for the Acquisition of Capital Assets
The Order provides DOE/NNSA project management direction for the acquisition of capital assets that are delivered on schedule, within budget, and fully capable of meeting mission performance and environmental safety and health standards.

DOE O 200.1, Information Management Program
The objectives of this Order are to

- ensure Departmental missions and goals, information, information resources, and information technology investment decisions will be made based on programmatic need, using performance-based measures tied to the budget, using sound business practices, and complying with applicable laws and regulations;
- treat information, information resources, and information technology as corporate assets integrated with programmatic planning and budgeting;
- provide a framework for managing information, information resources, and information technology investment that supports the operating elements of the Department in the accomplishment of its missions and functions in an efficient and effective manner and in accordance with Departmental policy.

DOE N 203.1, Software Quality Assurance
The objectives of this notice are to define requirements and responsibilities for software quality assurance (SQA) within DOE to ensure that

- all software owned or maintained by DOE is subjected to formal quality assurance;
- all DOE software engineering follows identified standards and best practices throughout the project and product lifecycle;
- due to the spectrum of requirements, the degree of SQA is risk-based;
- personnel are capable of correctly developing, using, and managing software.

DOE O 250.1, Directives System Order
The correct number for this Order is DOE O 251.1B. The DOE Directives System is the means by which DOE policies, requirements, and responsibilities are developed and communicated throughout the Department. Directives are used to inform, direct, and guide employees in the performance of their jobs, and to enable employees to work effectively within the Department and with agencies, contractors, and the public.

DOE O 360.1B, Federal Employee Training
The objective of this Order is to plan and establish requirements and assign responsibilities for DOE Federal employee training, education, and development under the Government Employees Training Act of 1958.

DOE O 425.1C, Startup and Restart of Nuclear Facilities
The objective of this Order is to establish the requirements for DOE/NNSA for startup of new nuclear facilities and for the restart of existing nuclear facilities that have been shut down. Nuclear facilities are activities or operations that involve radioactive and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists to the employees or the general public. The requirements specify a readiness review process that must, in all cases, demonstrate that it is safe to start (or restart) the applicable facility.

DOE Order 5480.19, Conduct of Operations for DOE Facilities
The objective of this Order is to provide requirements and guidelines for DOE/NNSA to use in developing directives, plans, and/or procedures relating to the conduct of operations at DOE facilities. The implementation of these requirements and guidelines should result in improved quality and uniformity of operation.

DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities
The objective of this Order is to define the program for the management of cost-effective maintenance of DOE nuclear facilities. Guidance for compliance with this Order is contained in DOE G 433.1-1, Nuclear Facility Maintenance Management Program Guide for Use with DOE O 433.1, which references federal regulations, DOE directives, and industry best practices using a graded approach to clarify requirements and guidance for maintaining DOE-owned Government property.

DOE-STD-1073-2003, Configuration Management
Note: The title of this document has been changed from Configuration Management Program to Configuration Management.

The purpose of this standard is to define the objectives of a configuration management process for DOE nuclear facilities (including activities and operations), and to provide detailed examples and supplementary guidance on methods of achieving those objectives. Configuration management is a disciplined process that involves both management and technical direction to establish and document the design requirements and the physical configuration of the nuclear facility, and to ensure that they remain consistent with each other and the documentation.

DOE O 435.1, Radioactive Waste Management
The objective of this Order is to ensure that all DOE radioactive waste is managed in a manner that is protective of worker and public health and safety, and the environment.

DOE O 451.1B, National Environmental Policy Act Compliance Program
The purpose of this Order is to establish DOE internal requirements and responsibilities for implementing the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality Regulations Implementing the Procedural Provisions of NEPA (40 CFR 1500-1508), and the DOE NEPA Implementing Procedures (10 CFR 1021).

DOE O 460.2A, Departmental Materials Transportation and Packaging Management
The objectives of this Order are to establish requirements and responsibilities for management of DOE/NNSA materials transportation and packaging, and to ensure the safe, secure, and efficient packaging and transportation of hazardous and non-hazardous materials.

DOE O 470.1, Safeguards and Security Program
This Order has been replaced by DOE O 470.4, Safeguards and Security Program. The objective for DOE O 470.4 is to establish the roles and responsibilities for the DOE Safeguards and Security (S&S) Program. The DOE S&S Program consists of six key elements: (1) Program Planning and Management, (2) Physical Protection, (3) Protective Force, (4) Information Security, (5) Personnel Security, and (6) Nuclear Material Control and Accountability.

DOE O 151.1C, Comprehensive Emergency Management System
The objectives of this Order are

- to establish policy and to assign and describe roles and responsibilities for the DOE Emergency Management System, which provides the framework for development, coordination, control, and direction of all emergency planning, preparedness, readiness assurance, response, and recovery actions. The Emergency Management System applies to DOE/NNSA.
- to establish requirements for comprehensive planning, preparedness, response, and recovery activities of emergency management programs or for organizations requiring DOE/NNSA assistance.
- to describe an approach to effectively integrate planning, preparedness, response, and recovery activities for a comprehensive, all-emergency management concept.

DOE O 442.1A, Department of Energy Employee Concerns Program
As a service to all Departmental elements, the purpose of this Order is to establish a DOE Employee Concerns Program (ECP) that ensures employee concerns related to such issues as the environment, safety, health, and management of DOE/NNSA programs and facilities are addressed through

- prompt identification, reporting, and resolution of employee concerns regarding DOE facilities or operations in a manner that provides the highest degree of safe operations;
- free and open expression of employee concerns that results in an independent, objective evaluation;
- supplementation of existing processes with an independent avenue for reporting concerns.

DOE O 225.1A, Accident Investigation
The objective of this Order is to prescribe requirements for conducting investigations of certain accidents occurring at DOE/NNSA operations and sites; to prevent the recurrence of such accidents; and to contribute to improved environmental protection and safety and health of DOE/NNSA employees, contractors, and the public.

DOE O 232.1, Occurrence Reporting and Processing of Operations Information
This Order has been canceled and replaced by DOE M 231.1-2. DOE M 231.1-2 and DOE O 231.1A, Environment, Safety, and Health Reporting, set forth the minimum set of occurrence reporting requirements for DOE/NNSA and contractors responsible for the management and operation of DOE-owned and DOE-leased facilities, including NNSA facilities. These requirements include categorizing occurrences related to safety, environment, health, or operations; notifying DOE of these occurrences; and developing and submitting documented follow-up reports.

DOE O 210.1, Performance Indicators and Analysis of Operations Information
This Order has been canceled.

DOE G 430.1-2, Implementation Guide for Surveillance and Maintenance During Facility Transition and Disposition
This guide was prepared to provide guidance on surveillance and maintenance (S&M) activities conducted as part of facility transition and disposition activities for DOE/NNSA facilities that have been declared or are forecast to be excess to any current or future mission requirements. It is one of four guides developed to provide guidance for facility transition and disposition activities.

DOE G 430.1-3, Deactivation Implementation Guide
This guide was prepared to aid in the development, planning, and implementation of deactivation requirements and activities at DOE/NNSA facilities that have been declared excess to any future mission requirements. It is one of four guides developed to provide guidance for facility transition and disposition activities.

DOE G 430.1-4, Decommissioning Implementation Guide
This guide was prepared to aid in the planning and implementation of decommissioning activities at DOE/NNSA facilities that have been declared excess to any future mission requirements. It is one of four guides that have been developed to provide guidance for facility transition and disposition activities.

DOE N 221.6, Reporting Fraud, Waste, and Abuse
This Order has been canceled.

DOE-STD-1082-94, Preparation, Review, and Approval of Nuclear Safety Requirements
This standard has been canceled.

DOE-STD-1083-95, Requesting and Granting Exemptions to Nuclear Safety Rules
DOE may grant temporary or permanent exemptions to its nuclear safety rules provided that the provisions of 10 CFR 820, subpart E, Exemption Relief, are met. The provisions of 10 CFR 820 state that the Secretarial Officer should utilize any procedures deemed necessary and appropriate to comply with the exemption responsibilities. This standard establishes an acceptable procedure to be used to request and grant exemptions to DOE nuclear safety rules in accordance with 10 CFR 820.

This standard is intended for use by all DOE elements and their contractors when requesting or granting exemptions to the following rules and their subparts:

- 10 CFR 830, Nuclear Safety Management
- 10 CFR 834, Radiation Protection of the Public and the Environment (proposed)
- 10 CFR 835, Occupational Radiation Protection or any other rule in 10 CFR which DOE has adopted and determined to be related to nuclear safety

DOE-STD-7501-99, The DOE Corporate Lessons Learned Programs Supporting Knowledge and/or Skills
This technical standard provides management expectations and a framework for the DOE Corporate Lessons Learned Program. The framework is intended to support development

and implementation of a DOE-wide lessons learned infrastructure that supports and promotes the identification and communication of lessons learned by DOE and contractor personnel in the performance of DOE missions. This technical standard was prepared with the involvement and input of line managers, technical specialists, and individuals involved with lessons learned programs from the DOE and its contractor community.

b) Discuss the authorities, roles, and responsibilities of QA personnel with regard to the above documents.

The following responsibilities are from DOE 414.1C, attachment 2, Contractor Requirements Document (CRD).

Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance.

Uses the appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include the following.

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

Applies additional standards, where practicable and consistent with contractual or regulatory requirements and 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). [Note: These standards are sometimes referred to as "voluntary standards." However, once the practicable standard(s) is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.]

Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this CRD, the S/CI prevention process (Paragraph 4) and Safety Software Quality Requirements (Paragraph 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable -

- DOE P 450.4, Safety Management System Policy, dated 10-15-96
- DOE P 450.5, Line Environment, Safety and Health Oversight, dated 06-26-97
- NNSA Quality Management Policy, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities)
- DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description
- DOE/CBFO-94-1012, DOE Carlsbad Field Office, Quality Assurance Program Description, (for the Waste Isolation Pilot Plant and related activities)

Quality assurance personnel should periodically review and assess operation performance. These reviews can assist line managers and supervisors in identifying and correcting problems.

5. QA personnel should have a working-level knowledge of channels to maintain communication with Headquarters, field elements, and the public.

a) Identify the various internal and external groups with whom quality assurance personnel must interface in the performance of their duties.

Quality assurance personnel must interface with a variety of people, including contractor personnel, fissile operating personnel, safety personnel, all levels of management, professional societies, DOE management, and the public.

b) Describe DOE's organization and discuss DOE's procedures for communicating between organizational elements.

Secretary Bodman's top priority is the health, safety, and security of the DOE)workforce and the communities that service our nation-wide complex of laboratories, facilities, and cleanup sites. Since becoming Secretary of Energy, he has continually emphasized the need for the Department to have a safe and secure work environment for all federal and contractor employees. The Secretary has also stressed the importance of delineating clear roles and responsibilities and line management accountability to advance this priority.

In reviewing the worker health and safety functions within DOE, and the various DOE Program Offices that have a role in advising the Secretary and Deputy Secretary on the worker health and safety posture of the Department, it was determined that change was necessary to clarify those roles by providing a more focused and integrated organizational approach. A major factor in this decision was how best to maximize the very important core functions being carried out by the current safety and security organizations. It was determined that the strengthening of worker health, safety, and security is best accomplished through the creation of a new office, the Office of Health, Safety, and Security. Responsibility for effective implementation of health, safety and security programs will continue to reside, as it has in the past, with the Department's line managers. However, the new office will enhance the effectiveness and efficiency of health, safety, environmental protection, and security programs across the complex by providing line managers and their sites with more effective and consistent policy, assistance, enforcement, and independent oversight. Combining health, safety, security, enforcement, and independent oversight responsibilities into the Office of Health, Safety and Security creates one unified office that will result in improved coordination among these important functions, including an integrated approach to managing risks involving safety and security considerations.

The Secretary's commitment to worker health and safety has led him to conclude that it is necessary to implement this plan to strengthen and enhance the worker health and safety programs within DOE. The creation of the Office of Health, Safety and Security will ensure that all health and safety functions currently managed by the Office of Environment, Safety and Health will continue in a more integrated and effective manner to improve the protections afforded our workers and the public. Additionally, all safety and security

functions currently managed by the Office of Security and Safety Performance Assurance will continue to be effectively implemented. These changes will be enhanced by the added benefits of an integrated management approach for safety and security, where both disciplines will benefit from increased coordination and cooperation.

Through discussions with senior officials throughout DOE and in discussions with external stakeholders, the Department has determined that the following factors are key to improving the health, safety, and security functions of the Department:

Serve as a direct report to the Office of the Secretary
Consistent with the Department's efforts to instill an integrated management approach with clear responsibilities and accountability, the Office of Health, Safety and Security will support the Secretary and the Deputy Secretary in their efforts to ensure improved protection of the workforce, the public, and the environment from hazards associated with Department sites and operations, as well as provide the policy, assistance, and oversight to assist line management secure our national security assets from all internal and external threats. Therefore, the office will report directly to the Office of the Secretary, maintain independence from the line organizations, and have unencumbered access to senior program managers.

Better alignment of health, safety and security responsibilities
The Office of Health, Safety and Security will be organized along functional responsibilities to provide line managers with the assistance and tools necessary to ensure the effectiveness of programs that are important to worker health and safety, the environment, and national security. This includes existing programs and functions such as the Voluntary Protection Program, current and former worker health studies and surveillance, support for the Energy Employees Occupational Illness Compensation Program, and safety-related quality assurance.

Continuity of professional leadership
The Department's Office of Health, Safety and Security must maintain institutional stability, continuity, and impartiality in meeting the Department's mission across the complex. The Secretary will appoint a career Federal professional as the Chief Health, Safety, and Security Officer to lead this office who possesses an extensive understanding of Departmental operations and who will sustain focus on worker health, safety and security programs through changes in Administrations. This position will be personally accountable to the Secretary/Deputy Secretary.

Better alignment of separate responsibilities outside of safety and security to other DOE Offices
The current safety and security organizations include certain functions that are more appropriate for a line organization such as management of a laboratory or facility and providing staff augmentation to line management in development of authorization basis documentation or facility design. The Department is moving these responsibilities to the appropriate functional office so that the Office of Health, Safety, and Security can work exclusively on health, safety, and security policies, and issues and programs, including providing independent oversight and enforcement.

Strengthened line management accountability
Closer coupling of the independent oversight function of the Office of Security and Safety Performance Assurance (SSA) and the analysis function of the Office of Environment, Safety, and Health (EH) will result in improved reporting on performance to the Secretary and support his need to hold line managers accountable for performance. Additionally, enhanced capability to identify Department-wide worker health, safety, environmental, and security issues will assist line management (program offices and the field) in addressing those significant issues.

Increased collaboration
There are opportunities for increased coordination among several health, safety, and security functions, such as training, policy development, technical assistance, independent oversight, and enforcement. For example, the National Training Center has the proper infrastructure to design and sustain training activities for both safety and security. Additionally, by moving the Office of the Departmental Representative (DR) to the Defense Nuclear Facilities Safety Board (DNFSB) into the new office, there will be significant opportunities for enhanced collaboration between the DNFSB and the primary office functions (e.g., safety and oversight) with which they work. This new office will work closely, on a continuing basis, with key stakeholders such as unions and workers in addition to line management. Changes in the organizational structure of environment, safety, and health policy as well as health studies and surveillance will facilitate opportunities for collaboration and provide opportunities for improvement.

Strengthened corporate training for both safety and security professionals
The new office will establish a unified center for DOE training support in the safety and security areas which will provide a comprehensive and coordinated approach for enhancing and maintaining the expertise, knowledge and skills for all safety and security professionals within the Department. This is essential to address the human capital concerns associated with an aging workforce and to strengthen our efforts to attract and retain the future workforce the Department needs. To further enhance the technical expertise of the health and safety professionals, the new office will coordinate the Federal Technical Capabilities Program, the Technical Qualification Program, Nuclear Executive Leadership Training, and Human Performance Improvement training activities at the corporate level for the entire Department.

Strengthened capability to address Department-wide issues
A high priority of the new office will be to establish a dedicated group to focus on assisting line organizations to resolve issues utilizing a structured approach to identify and address causes to prevent recurrence of safety incidents throughout the Department. Closer coupling of DR with the worker safety and health policy, technical assistance and independent oversight functions will facilitate improvements in addressing issues identified by external sources. Further benefits will be gained through the integration of the safety and security functions such as developing a coordinated effort to evaluate new security technology being considered to meet the Design Basis Threat. The Department has already seen the benefit of a similar effort involving security policy, technical assistance, and independent oversight.

Other organizations associated with quality assurance personnel are the International Atomic Energy Agency (IAEA) and the Defense Nuclear Facilities Safety Board DNFSB). DOE O

142.2, Safeguards Agreement and Protocol With the International Atomic Energy Agency, was approved on January 7, 2004 to ensure that DOE complies with the Agreement Between the United States of America and the IAEA for the Application of Safeguards in the United States, the Protocol to the Agreement, and the subsidiary arrangements to the Agreement and to prescribe policies and responsibilities for DOE to ensure compliance with the Agreement, Protocol, and subsidiary arrangement.

DOE M 140.1-1B, Interface with the Defense Nuclear Facilities Safety Board was approved on March 30, 2001 to present the process DOE will use to interface with the Defense Nuclear Facilities Safety Board (Board) and its staff.

c) Describe DOE's procedures and policies for communicating with regulatory agencies and other stakeholders.

The extensive and varied alliances that quality assurance personnel are required to cultivate require equally extensive and varied approaches. The information below provides suggested approaches, but is not all-inclusive.

DOE P 141.2, Public Participation and Community Relations, provides guidance on building alliances. This DOE policy states that public participation is open, ongoing, two-way communication, both formal and informal, between the DOE and its stakeholders concerning DOE's missions and activities. Effective public participation is at the core of good community relations, which is essential for DOE facilities to achieve their missions. Regular, interactive communication enables all parties to learn about and better understand each other's views and positions.

DOE P 141.2 also provides a mechanism for bringing a broad range of stakeholder viewpoints and community values into DOE's decision making early in the process. This early involvement enables DOE to make more informed decisions and build mutual understanding and trust between DOE, the public it serves, and the communities that host its facilities.

Effective public participation and good community relations both rest on a foundation of positive personal relationships; DOE managers and staff are encouraged to seek to build and nurture such relationships.

The methods used to encourage public participation will vary widely in nature and scope and may include, but are not limited to, informal conversations, written and electronic communication, scheduled meetings and workshops, legally required hearings, and federal-state-local-tribal meetings. Under DOE P 141.2, DOE actively seeks, considers, and responds in a timely manner to the views of its stakeholders, thereby providing them an opportunity to influence decisions.

The goals of the DOE Public Participation and Community Relations Policy are as follows:

- DOE will actively seek to identify stakeholders, consider public input, and incorporate or otherwise respond to the views of its stakeholders in making its decisions.
- The public will be informed in a timely manner and empowered to participate at appropriate stages in DOE's decision-making processes. Such processes will be

open, understandable, and consistently followed. Managers will define clear access points for public input from the earliest stages of a decision process and will provide adequate time for stakeholders to participate.

- Credible, effective public participation processes, including active community outreach, will be consistently incorporated into DOE program operations, planning activities, and decision-making processes at Headquarters and in the field. Employees within the DOE complex will share responsibility for promoting and improving public participation and community relations.
- DOE will conduct periodic reviews of its public participation and community relations efforts.

Alliances are often highly visible during emergencies. DOE G 151.1-1, volume 4-5, Emergency Facilities and Equipment, states that the ability to provide the public, media, and DOE employees with accurate and timely information is based on an effective Emergency Public Information (EPI) program. To be effective, emergency public information should be coordinated with onsite and offsite federal, state, local, and tribal emergency response organizations. The EPI program provides the means for a facility to coordinate the timely exchange of information among representatives from DOE and other organizations. This coordination is critical to prevent dissemination of confusing, conflicting, and erroneous information.

Quality assurance personnel's interaction with Congress is often dependent on circumstances. However, DOE M 135.1-1A, Department of Energy Budget Execution Funds Distribution and Control Manual, provides some insight on congressional alliances.

Congressional notifications are intended to ensure that the appropriate committees are promptly and fully informed of changes in program activities. Information may be conveyed in written correspondence or through informal discussion with the appropriate committees.

When events or conditions in the fiscal year necessitate changes to the approved budget, proposals must be communicated to the congressional committees responsible for those appropriations. Processes are in place to address changes for reprogramming, restructuring, appropriation transfer, notification, and deferral and rescission proposals.

When changes do not require formal or internal/limited reprogramming procedures, but may affect areas known to be of interest or concern to Congress, DOE will notify the appropriate committees of changes in program activities to ensure they are promptly and fully informed.

In these cases, DOE may elect to notify the appropriate committees through less formal procedures. The Office of the Chief Financial Officer's informal discussions with the appropriate committee, or a Secretarial Officer's correspondence with the appropriate committee, serves as sufficient notification of the impending actions.

6. QA personnel should demonstrate the ability to effectively communicate (both orally and in writing) with the contractor, stakeholders, and other internal and external organizations.

a) Demonstrate written communication skills as applicable in the development of

- **Assessment reports**

- **Technical reports**
- **Technical papers**
- **QAP**
- **Work process documents (e.g., procedures)**

The following information may be helpful in developing the listed documents.

Assessment Reports
Assessment reports are required to communicate the issues identified during an assessment. Assessment team leaders have the overall responsibility for preparing the report and obtaining approval for its release from their senior management. The assessment report may be formal or informal, depending on the level of assessment performed, but should provide a clear picture of the results in terms of the programs, systems, and processes assessed. The report should be clear and easy to understand and should include only facts that directly relate to assessment observations and results. It should include sufficient information to enable the assessed organization to check the report for accuracy (if such a check was not done during the assessment) and to develop and implement appropriate improvement plans. Every effort should be made to ensure assessment reports are concise, accurate, and understandable.

For example, summary information may be clearer or more easily understood if presented graphically. In preparing the report, authors should also remember that many people who will read the report have had no active role in the assessment and the report may be their only source of information regarding its conduct and results. A recognized good practice is to provide a draft copy of the report to the assessed organization to allow the staff to comment on the factual accuracy (if a draft for this purpose was not presented at the post-assessment meeting); however, the review is only to confirm factual accuracy, not to contest or argue the assessment team's conclusions.

Specific report formats may vary considerably from one organization to the next. In developing a report format, the assessment organization should solicit input from report recipients to ensure the report meets their needs. An independent assessment report usually includes an executive summary, observation section, results section, and attachments that provide supplementary information to validate the assessment and its methodology.

Technical Reports
Scientific/technical reports and products provide the results of scientific and technical studies and investigations that relate to research, development, demonstration, and other specialized areas such as environmental and health protection and waste management. Technical reports document the findings of the funded research and development project. Commercially published books, copyrighted papers, or journal reprints cannot be disseminated by DOE. If these products are identified as deliverables, citations should be provided showing the publisher availability. Project status reports or other status reports, including project management, financial, or budget reports, administrative information, or those reports generated by support service contractors performing non-technical tasks are considered to be management reports.

Technical Papers
The typical format of a technical paper is organized as follows:

- Abstract. Typically, the abstract is not more than 100–150 words long.
- Introduction. The author should introduce the problem and outline the solution. The statement of the problem should include a clear statement as to why the problem is important.
- Related work. In cases where information is taken from a journal or magazine, the author should cite anything relevant from the last 2–3 years.

The body of the paper should address the following:

- The problem
- The approach and architecture
- The results

The body should contain sufficient motivation, with at least one example scenario (preferably two) with illustrating figures, followed by a concise generic problem statement model, i.e., functionality, particularly emphasizing new functionality. Additional sections include

- the architecture of the proposed system(s) to achieve the model, which should be more generic than your own peculiar implementation. Always include at least one figure.
- realization, which contains actual implementation details when implementing architecture isn't totally straightforward. Briefly mention the implementation language, the platform, the location, dependencies on other packages, and minimum resource usage, if pertinent.
- an evaluation: How does it really work in practice? Provide real or simulated performance metrics and end-user studies, mention external technology adaptors, if any, etc.
- related work.
- summary and future work.
- acknowledgements.
- a bibliography.
- an appendix.

It is recommended that you write the approach and results sections first, which go together. Then write the problem section, if it is separate from the introduction, followed by the conclusions and the introduction. Write the introduction last since it glosses the conclusions in one of the last paragraphs. Finally, write the abstract. Last, give your paper a title.

QAP

Refer to competency 2, element "a" for a discussion of the QAP.

Work Process Documents

Managers are responsible for ensuring that those under their supervision have the training, skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work. Line management and workers should cooperate to identify processes that can be improved based on feedback prior to and following implementation of the work process. Management should ensure that the following are clearly identified and conveyed to workers before they begin work:

- Customer and data requirements for the work and final product
- Hazards associated with the work

- Safety, administrative, technical, environmental, and quality controls to be used during the work
- Technical standards applicable to the work and final product
- Acceptance criteria applicable to the work and final product
- Procedures for verification of the completed work using established criteria

Procedures, work instructions, or other appropriate means used to define work processes should be documented and controlled. The scope and detail of documentation should be commensurate with the complexity and importance of the work; the skills required to perform the work; the hazards and risks or consequences of quality problems in the product, process, or service; and the need to meet regulatory and contract requirements.

b) Demonstrate effective and appropriate communications skills during interactions with contractors.

This is a performance-based competency. The qualifying official will evaluate the completion of this competency.

7. QA personnel should demonstrate a working-level knowledge of control of documents and records.

a) Describe the role of documents for prescribing processes, the specification of requirements, and the establishment of design.

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

A process shall be established for approving, issuing, and distributing design information, including changes. Design information transmitted across organization interfaces shall identify the status of information provided and any incomplete items that require further evaluation, review, or approval.

b) Define and explain the control of documents and records.

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

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 files, written or printed documentation, microfilm, photographs, radiographs, or optical disks). Typical records include procedures, plans, and manuals; training and qualification results; acceptance test results; technical/regulatory correspondence; operational records; design basis descriptions, design review results, design revisions, and configuration management data; and quality problem resolutions.

Records should be compiled in a records management system. The system should include provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records. Record retention, protection, preservation, change, traceability, accountability, and retrievability should also be specified. The records management system should have schedules for records retention and disposition consistent with the requirements of DOE O 200.1, Information Management Program, dated September 30, 1996.

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

c) Describe implementation techniques and/or procedures for the development and control of documents and records.

Documents should be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. A documented process should be established and maintained to control documents, including models and data.

The process should define responsibility for preparing, reviewing, approving, issuing, and distributing documents that are adequate, complete, and correct. The process should ensure that

- controlled documents are identified;
- individuals responsible for the preparation, review, approval, and distribution of controlled documents are identified;
- controlled documents are reviewed for completeness, and are approved prior to distribution;
- the correct documents are used;
- documents specify effectivity;
- documents are released, distributed, and implemented in a timely manner.

A process should be established and documented for records management. Records should be specified, prepared, reviewed, approved, and maintained to demonstrate achievement of quality requirements and effective operation of the quality management system.

Procedures should be established and implemented for the identification, collection, organization, filing, storage, maintenance, retrieval, distribution, retention, and disposition of records. Records should be maintained to furnish objective evidence that items or activities meet specified requirements.

A record should be identifiable as a record; completely and accurately reflect the work accomplished or information required; be legible; and be traceable to associated requirements, items, and activities.

Records may be originals, copies, or electronic. Records should be authenticated and dated by authorized personnel. Acceptable methods of authentication include statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensure traceability to a specific authenticating individual and organization and to an authentication date.

d) Discuss methods of record storage and retrieval requirements.

Records should be stored such that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.

e) Discuss the definitions of "temporary records," "lifetime records," and "permanent records." Identify the sources of requirements and describe how different types of records are maintained.

Temporary Records
Temporary records are those records determined by the Archivist of the United States to have insufficient value (on the basis of current standards) to warrant preservation by the National Archives and Records Administration (NARA). This determination may take the form of one of the following:

- An Agency records disposition schedule approved by NARA (Standard Form 115, Request for Records Disposition Authority)
- A general records schedule issued by NARA

Lifetime Records
Lifetime records are those records that must be maintained for the duration of the project.

Permanent Records
Permanent records are those records that NARA has determined to have sufficient value to warrant preservation in the National Archives. Permanent records include all records accessioned by NARA's Office of the National Archives and later increments of the same records, and records for which the disposition is "permanent" on Standard Form 115, Request for Records Disposition Authority, approved by NARA on or after May 14, 1973.

f) Discuss the management requirements contained in DOE O 200.1, Information Management Program.

Heads of Departmental elements are responsible for

- promoting the use of sound business practices in information management and information technology activities consistent with applicable laws and regulations;
- ensuring that the policy and objectives of this directive are incorporated into their program planning, management, contract administration, and performance evaluation activities;
- ensuring that requirements and procedures detailed in the policies and manuals associated with information management are implemented, and that individual

information systems under their cognizance are effectively managed throughout their life cycle.

B. General Technical Performance

1. QA personnel should demonstrate a working-level knowledge of the processes for performing work to established technical standards, administrative controls, and other hazard controls to meet regulatory or DOE requirements.

a) Describe the methods used to identify work to be performed and the associated hazards (e.g., FEOSH).

Managers are responsible for ensuring that those under their supervision have the training, skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work. Line management and workers should cooperate to identify processes that can be improved based on feedback prior to and following implementation of the work process. Management should ensure that the following are clearly identified and conveyed to workers before they begin work:

- Customer and data requirements for the work and final product
- Hazards associated with the work
- Safety, administrative, technical, environmental, and quality controls to be used during the work
- Technical standards applicable to the work and final product
- Acceptance criteria applicable to the work and final product
- Procedures for verification of the completed work using established criteria

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

b) Describe the methods for approving work process controls, such as procedures or instructions.

To be approved, work processes must be developed and implemented using available S/CI information and must include

- engineering involvement in the development of procurement specifications, during inspection and testing, and when replacing, maintaining, or modifying equipment.
- procurement processes that prevent introduction of S/CIs by
    - identifying technical and QA requirements in procurement specifications;

    - accepting only those items that comply with the procurement specifications consensus standards and commonly accepted industry practices;
    - inspecting inventory and storage areas to identify, control, and disposition S/CIs.
- inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards.
- engineering evaluations and disposition of S/CIs installed in safety applications/ systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and workers and the cost/benefit impact, and must include a schedule for replacement (if required).
- processes to ensure that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.
- contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.
- testing procured or installed S/CIs as necessary using approved engineering test methods.
- reporting S/CIs as per DOE O 231.1A, change 1, Environment, Safety, and Health Reporting, dated June 3, 2004, and DOE O 221.1, Reporting Fraud, Waste, and Abuse, dated March 22, 2001, to
    - the responsible DOE/NNSA line management offices;
    - the Office of Environment, Safety and Health;
    - the Office of the Inspector General.
- Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

c) Discuss the use of approved work process controls to conduct work.

Work should be performed according to written safety procedures and approved work process controls. Work should be directed by a supervisor who is qualified by training and experience in the applicable safety-related work practices.

Workers should report any hazards to their immediate supervisor. The supervisor should take all corrective actions necessary to address an employee's concerns.

Instructions should be based on a thorough analysis of the job and its hazards. If the same task is repeated, it may be performed under specific work rules that are based on such analyses.

2. QA personnel shall demonstrate a working-level knowledge of the processes for identification, marking, and control of items.

a) Discuss methods of identifying and controlling items that have been procured and accepted.

A process shall be established and documented so that items are identified and controlled to ensure proper use, and maintained to prevent damage, loss, or deterioration.

Physical identification shall be used where possible. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Where practical, markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden unless other means of identification are substituted. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

Markings, authorized stamps, tags, labels, routing cards, physical location, or other suitable means shall identify the status of items from the initial receipt and fabrication of items up to and including use. When required, traceability of an item shall ensure applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records.

The process shall provide for maintenance or replacement of markings and identification records due to damage from handling or aging, as well as protection of identifications on items subject to excessive deterioration due to environmental exposure.

b) Discuss methods for the control of items during handling, storage, and shipping.

Handling, storage, packaging, and delivery shall be controlled to prevent damage, loss, deterioration, or substitution, and the process to control handling, storage, packaging, and delivery shall be documented. These activities shall be conducted in accordance with specifications, instructions, procedures, and drawings.

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested according to established criteria to ensure performance.

c) Describe methods for assuring that items remain properly identified throughout their life cycle.

Refer to element "a" of this competency for a discussion of proper item identification.

3. QA personnel shall have familiarity-level knowledge of maintenance management practices. Reference DOE O 433.1, Maintenance Management Program for DOE Nuclear Facilities.

a) Define each of the following maintenance-related terms and explain their relationship to each other:
- **Corrective**
- **Planned**
- **Preventive**
- **Reliability-centered**
- **Predictive**

Corrective
Corrective maintenance consists of all those actions performed to restore failed or malfunctioning equipment to service per the current authorization basis. Corrective

maintenance activities should ensure that the condition that caused the failure is identified, corrected, and documented. Analysis should be performed to determine the root cause of failure and the corrective action that should be taken, including feedback into the preventive and predictive maintenance programs and maintenance training and qualification programs. The establishment of priorities for corrective maintenance should be based on plant objectives and the relative importance of the equipment.

Corrective maintenance is performed to accomplish timely repair of failed or malfunctioning equipment, systems, or facilities in order to restore their intended function or design condition. A program for identification and timely repair of improperly operating or failed equipment, systems, or facilities should be established based on a detailed master list of safety-related and non-safety-related facility features. There should be established criteria and responsibilities in use to review and approve maintenance work requests, and only approved procedures should be used to perform routine or emergency maintenance actions.

Planned

Planned maintenance consists of preventive or seasonal maintenance activities performed before SSC failure that may be initiated by predictive or periodic maintenance results, through vendor recommendations, or by experience/lessons learned. These include actions such as scheduled cold weather protection, valve repacking, replacement of bearings as indicated from vibration analysis, major or minor overhauls based on experience factors or vendor recommendations, and replacement of known life-span components. For example, repacking a valve because of packing leakage would be corrective maintenance, but scheduled repacking before leakage would be planned maintenance.

Preventive

Preventive maintenance (PM) includes all those planned, systematic, periodic, and seasonal maintenance actions taken to prevent SSC or facility failures, to maintain designed-in operating conditions, and to extend operating life. The PM process takes into account the inevitability of failures in any simple or complex piece of equipment, although the consequences of failures can be controlled by careful design and effective maintenance. The reason for the failure incident can be apparent if basic differences between expected behaviors and the actual behaviors of SSCs are considered. These differences can be translated into possible failure modes. PM identifies any differences between actual and expected behavior of SSCs. Generally, regulatory and code requirements, DOE technical safety requirements for surveillances, in-service inspection and testing, vendor recommendations, and other forms of maintenance action and frequency selection based on engineering judgment or analytical methods are the pursuit of proactive planned maintenance.

Reliability-Centered

Reliability-centered maintenance is a proactive systematic decision logic tree approach to identify or revise preventive maintenance tasks or plans to preserve or promptly restore operability, reliability, and availability of facility SSCs, or to prevent failures and reduce risk through types of maintenance action and frequency selection to ensure high performance.

Reliability-centered maintenance is the performance of scheduled maintenance for complex equipment, quantified by the relationship of preventive maintenance to reliability and the benefits of reliability to safety and cost reduction through the optimization of maintenance

task/frequency intervals. The concept relies on empirical maintenance task/frequency intervals to make determinations about real applicable data suggesting an effective interval for task accomplishment. The approach taken to establish a logical path for each functional failure is that each functional failure, failure effect, and failure cause be processed through the logic so that a judgment can be made as to the necessity of the task, and includes (1) reporting preventive maintenance activities, plans, and schedules; (2) optimizing/ calculating the preventive maintenance interval by balancing availability, reliability, and cost; (3) ranking preventive maintenance tasks; (4) accessing preventive maintenance information from piping and instrumentation drawings (P&IDs); (5) accessing preventive maintenance and other maintenance data; (6) listing recurring failure modes/parts, including failure to start and failure to run; (7) calculating and monitoring SSC availability; (8) accessing preventive maintenance procedures; and (9) keeping track of preventive maintenance cost.

Predictive

Predictive maintenance includes the actions necessary to monitor, find trends in, and analyze parameters, properties, and performance characteristics or signatures associated with SSCs, facilities, or pieces of equipment to discern whether a state or condition may be approaching that is indicative of deteriorating performance or impending failure that could compromise the intended function of SSCs, facilities, or equipment. Predictive maintenance activities involve continuous or periodic monitoring and diagnosis to forecast component degradation so that as-needed planned maintenance can be initiated before failure. Not all SSC, facility, or equipment conditions and failure modes can be monitored and diagnosed in advance; therefore, predictive maintenance should be selectively applied. To the extent that predictive maintenance can be relied on without large uncertainties, it is normally preferable to activities such as periodic internal inspection or equipment overhauls.

b) Describe the elements of an effective work control program and the documentation used to control maintenance.

A work-control program based on the requirements of DOE O 433.1, Maintenance Management Program for Nuclear Facilities, should be integrated with the planning system.

The implementation of this program should ensure that the maintenance activities in nuclear facilities are conducted in a manner that preserves and restores the availability and operability of the SSCs important to safe and reliable facility operation. The work-control program should include a work order system, job planning and estimating, time standards, a priority system, procedures and documentation, scheduling, post-maintenance testing, backlog work management, equipment repair history and vendor information, training and qualifications, an ISMS, lockouts/tagouts, work performance standards, human factors, and engineering.

c) Discuss the relationship between maintenance and Conduct of Operations, QA, and Configuration Management.

Several DOE enforcement actions have illustrated the need to take a comprehensive, graded approach to the establishment and implementation of maintenance work controls that is commensurate with the hazard and risk to workers and the public, as well as other factors.

There is a definite need to apply QA, safety management, configuration management, human factors engineering, conduct of operations, and other operational programs in an integrated fashion to control work at a nuclear facility, with a focus beyond the work involving equipment referenced in the documented safety analysis or technical safety requirements. However, some contractors operating DOE nuclear facilities have narrowly construed nuclear safety to require a direct nexus between the regulated activity and public health and safety such that a violation of the requirements would be the immediate cause of a health or safety impact. This nexus is not so direct, and the definition is not so narrow. The nexus might be as broad as the requirement to implement a QAP that relates to nuclear activities. Violation of a QA requirement may not result in a direct or potential immediate threat to health or safety, but it could be an important link in a sequence of activities that could lead to a nuclear accident or radiological exposure.

d) Discuss the storage and maintenance requirements for parts, materials, and equipment.

Methods should be provided for storage, issuance, and maintenance of an adequate and readily available supply of tools and equipment, and for the development of special tools and equipment needed in the maintenance program.

Tools and equipment of the proper type, quality, and quantity should be available for issue and use when needed by the maintenance crafts persons. Adequate tool and equipment control in the facility contributes to worker efficiency, and it also is needed to limit the number of tools introduced into potentially contaminated areas, to minimize the spread of radioactive contamination, and to reduce volumes of solid radioactive wastes. A dedicated supply of tools and equipment should be established for exclusive use within the facility's radiological areas (RAs). A controlled supply of tools and equipment should be provided to ensure that an adequate quantity is available to avoid delays in maintenance work activities. Good tool control should minimize the risks of personnel contaminations and the inadvertent release to RAs of such potentially contaminated items. Personnel accountability is essential to an effective tool and equipment control program.

A program for storing, issuing, and maintaining tools and equipment is needed to accomplish maintenance activities effectively and efficiently. The process of providing tools and equipment should include proper storage and issuance controls. Crafts persons should be readily able to obtain the tools and equipment they need to perform maintenance and then return them as soon as practicable after completing the work. Tools and equipment should be kept in a state of readiness, some by inclusion in the PM program. Proper PM can also result in improved personnel safety and extended life of tools and equipment.

A system should exist that provides for tool and equipment control within the maintenance organization. This system should include unique identification of controlled items, and documentation of their issue and return. Also, the system should provide for storing, issuing, and maintaining tools and equipment in a manner so as to enhance efficient and effective maintenance activities.

Crafts persons should be provided an initial issue of tools of the trade for day-to-day use. On the basis of need, special tools should be drawn from controlled storage and returned as soon as reasonable after completion of the task.

All worn or damaged tools should be repaired or replaced. Tools should be regularly inspected and serviced on the basis of recall program controls to ensure they

- remain safe to use
- are in a high state of readiness for use
- do not prematurely require replacement

The process should provide the supervisor with opportunities to exercise an active role in encouraging individual innovation when new and/or special tool and equipment needs exist.

A program for the development of new or special tools and equipment should specify formal criteria covering safety, identification, availability for future use, and cost-effectiveness.

Supervisors should have an active role in identifying and approving tool and equipment improvements that make maintenance more effective and efficient. These improvements can result in improved safety for personnel and equipment, improved work quality, and improved facility reliability.

The maintenance organization should assign responsibility for the proper storage and issuance of both stationary and portable tools and equipment. Permanent issuance of tools to individuals or groups of crafts persons who use them daily and who are responsible for maintaining them contributes to worker efficiency. Tools and equipment used less often should be available on an as-needed basis. For these, proper storage facilities should be central to shops and normal work areas and should be readily accessible to crafts persons to promote efficiency. Controls, such as sign-out sheets and tool crib attendants, should be used in tool storage areas to provide accountability for and availability of tools. A policy should be established for the storage, issuance, decontamination, and reuse of contaminated tools and equipment.

Worn, defective, or otherwise unusable tools should be segregated so that only safe, usable tools are available. Un-repairable tools should be disposed of in a timely manner.

Policies governing the control of tools and equipment should be clearly established. Policies and procedures should emphasize personnel accountability and item traceability. These policies should address all aspects of tool control including inventory, issue, tracking, use, and return.

An inventory system should be established for tools and equipment. This inventory should be computer-based, compatible with existing facility inventory systems, and adaptable to daily supply changes.

Worn, defective, or otherwise unusable tools should be removed from work areas as soon as possible to prevent inadvertent use.

The replenishment of tool supplies should be performed only by the responsible coordinating department on the basis of past usage and expected needs. The uncontrolled introduction into the RA of tools and equipment should be prohibited.

Tools and equipment that need inspection, calibration, or refurbishment by personnel in specific work groups or by vendors may require shipment to special locations elsewhere on-site or off-site. When those transfers are necessary, the control coordinator should have records of location and status.

An inventory of all maintenance tools and equipment should be performed at least annually and after major planned outages. The quantities of tools and equipment should be compared to previous inventories and significant changes should be investigated. The inventory list should include equipment items such as chain falls, lifting rigs, and scaffolding, as well as all tools. This inventory should be maintained by a single organization which is also responsible for the storage, issuance, and control of tools and equipment.

The following items, at a minimum, should be addressed in the storage and issuance process:

- Potentially contaminated and contaminated items should remain within the RA until verified by the appropriate authority to be clean and safe to remove.
- A job-planning process goal should be to ensure that the proper items are available in the quantities required to support scheduled maintenance requirements.
- Instrument/motor/pump pools should maintain a supply of critical items for designated applications.
- Reuse of repaired items should be encouraged on the basis of maintaining them in a high state of clean, safe, and reliable readiness.
- Specialty tools should be identified and stored for ready retrieval.
- Unusable items should be segregated from normal items for dispositioning and to prevent inadvertent issue for use.
- Instructions should be developed to define responsibility and accountability for the proper storage and issuance of controlled items.
- The system should provide for storage areas that segregate items to prevent cross-contamination or wrong selection for issue.
- The system should provide for designating and controlling storage, laydown, and staging areas.
- A method should be established which provides for inventory listings of specialty and controlled tools and equipment and which may be used to communicate applicable information to potential users.

e) Describe the difference between temporary and permanent repairs/work and the requirements and controls to prevent inadvertent modifications.

Temporary repairs are temporary modifications to the facility that allow equipment to remain in or be returned to service in a condition that is not the same as the original design specification. Prior to implementation, temporary repairs should receive a safety review in accordance with the facility temporary modification program to ensure the adequacy of the repairs and their effect on personnel and equipment safety and reliability. Temporary repairs should be tracked after their completion for consideration of permanent repairs. Permanent corrective action should be taken as soon as practicable.

4. QA personnel shall demonstrate a familiarity-level knowledge of the processes for design and engineering practices.

a) Describe methods of identifying and controlling design inputs, design processes, and design outputs.

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

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

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

Design Outputs
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.

b) Discuss different methods of design analysis and design changes, and state how they are documented and controlled.

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 and documentation as the designs of permanent modifications.

c) Identify the methods of design verification and describe their relative advantages and disadvantages.

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

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

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

d) Discuss the controls for computer software used to originate design solutions and design verification.

Computer software used to originate or analyze design solutions during the design process, or to analyze the potential accidents to be mitigated by the final design, should be controlled using DOE G 414.1-4, Safety Software Guide, dated June 17, 2005. Software used to analyze designs or verify designs or that otherwise might have safety, operational, or programmatic consequences should be appropriately documented. Software used for designs should be validated for the intended use; otherwise, status of the code validation should be identified and documented before use. The documentation should be sufficiently complete to allow a person technically qualified in the subject to review and understand it, and to verify the adequacy of the results without recourse to the originator. Reviewing and understanding an analysis may mean that a reviewer should be able to inspect the formulas executed by a computational program. Test cases should prove that the computations provide agreement with known and theoretical results.

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

5. QA personnel shall demonstrate a familiarity-level knowledge of the computer software quality assurance.

a) Discuss the objectives, applicability, requirements, and responsibilities prescribed in DOE Notice 203.1, Software Quality Assurance.

Objectives
The objectives of DOE N 203.1 are to define requirements and responsibilities for software quality assurance (SQA) to ensure that

- all software owned or maintained by DOE is subjected to formal quality assurance;
- all DOE software engineering follows identified standards and best practices throughout the project and product lifecycle;

- due to the spectrum of requirements, the degree of SQA is risk-based;
- personnel are capable of correctly developing, using, and managing software.

Applicability
This directive applies to Departmental elements that acquire, develop, modify, or maintain computer software.

The Contractor Requirements Document, attachment 1, sets forth the requirements to be applied to all management and operating and other contracts that require the acquisition, development, modification, or maintenance of computer software, as provided by contract and as implemented by the appropriate contracting officer. Compliance with the Contractor Requirements Document will be required to the extent set forth in the contract.

The provisions of this Notice apply to all DOE software or software customized for DOE use, proposed for use, under development, or being maintained and used, whether that software was developed in-house, licensed from a commercial vendor for customized use, obtained from another organization, or otherwise acquired. The type of software includes, but is not limited to, (a) administrative/business-oriented software, (b) scientific/engineering software, (c) manufacturing-oriented software, and (d) process control (e.g., Programmable Logic Control instructions).

The requirements of this Notice are not mandatory for basic scientific research and development activities conducted to support the Office of Science mission unless those activities are governed by the requirements in 10 CFR 830.

However, line management is encouraged to consider all or part of the Notice requirements in meeting its responsibilities to ensure the quality of the software developed for basic research. Business systems that support basic research are not exempted from the Notice requirements.

Executive Order 12344 (set forth in Public Law 106-65 of October 5, 1999 [50 U.S.C. 2406]) establishes the responsibilities and authority of the director, Naval Nuclear Propulsion Program, for all facilities and work that comprise the program, which is a joint Navy/DOE organization. The director's responsibilities include the operating practices and procedures applicable to naval nuclear propulsion plants. The director must establish the quality assurance requirements implemented within the Program. Accordingly, this Notice does not apply to the Naval Reactors Program.

Requirements
SQA Program. Each Departmental element shall develop, document, and implement an SQA program. Each SQA program will consist of an identified focal point of contact, defined authorities, policies, procedures, training, adopted standards, and conventions tailored to local needs. Each program will treat SQA initiatives appropriately, commensurate with their size, complexity, cost, degree of external impact, degree of customization, functions performed, and other factors important to local management. The SQA program will describe how project SQA plans are to be developed and implemented.

Risk-Based, Graded Approach. All software owned or maintained by DOE must be subjected to a degree of formal SQA commensurate with the safety, security, and risk involved in developing and using the software. This approach allows all software, including software that may be categorized as research and development, to be assessed for and receive an appropriate and commensurate amount of SQA.

Lifecycle-Based SQA Processes and Procedures. The SQA processes and procedures used must be software product and project lifecycle based; documented to provide a baseline for auditing; and applied in a consistent, repeatable, and predictable manner. The adequacy of selected processes and practices, as well as their oversight, is the responsibility of each individual Departmental element.

Project SQA Plans. Project SQA plans will be developed and will address testing (e.g., unit, integration, system, acceptance), verification and validation, structured walkthroughs, peer reviews, inspections, audits and any other requirements specified for an application (e.g., by contract). Each plan should be commensurate with the level of the size, complexity, and scope of the software project.

Oversight. Each Departmental element will conduct systematic reviews to ensure that the requirements of this directive and DOE O 414.1C are met, and to determine the need to update its own SQA program. Relative to software, these reviews should also ensure that appropriate safety and security controls are in place, are effective, and reflect currently accepted industry practices. For line management assessment of an SQA program, the principles and guidelines in DOE P 450.5 will apply and should be followed.

Training. Sites are responsible for ensuring the adequacy of training programs to meet current and future personnel skill needs in the areas of SQA, software engineering, and software user training.

Integration. Sites must integrate the SQA program planning process with the strategic planning, Safety Management System, and budget process, as appropriate, to ensure that SQA program decisions are made, adequately funded, and executed to support DOE organizational and site missions and priorities.

Responsibilities

The requirements for Departmental elements are listed below. Additional responsibilities are available in DOE N 203.1.

Departmental elements should implement the appropriate level of management effort and assume responsibility, accountability, and oversight for continued SQA management process compliance within their respective program areas. Specifically, Departmental elements should

- establish and document SQA programs;
- identify a focal point of contact;
- ensure that the SQA programs conduct risk assessments and determine the level of SQA to be applied;
- ensure that the level of SQA is tailored to the site needs;
- oversee development and implementation of SQA processes and procedures;

- ensure the production and delivery of quality software products;
- ensure that SQA programs are reviewed;
- ensure that SQA plans are approved;
- relative to software, ensure that appropriate safety and security controls are in place, are effective, and reflect currently accepted industry practices;
- ensure the adequacy of training programs for SQA, software engineering, and software user training;
- ensure that any SQA program related to safety is developed and implemented in a manner that is consistent with DOE P 450.4, and associated standards and manuals;
- ensure that any nuclear software program related to safety is developed and integrated with existing nuclear safety policies and standards;
- ensure that all SQA programs are developed and implemented in a manner that is consistent with applicable classified and/or unclassified policy.

6. QA personnel shall demonstrate a familiarity-level knowledge of procurement processes.

a) Discuss the relationship between the organization with technical authority over the procurement (engineering) and: the organization that negotiates and executes the purchase (buyer); environment, safety, and health and quality organizations; and the receiving/storage organization.

The procurement process begins with a procurement request and acquisition planning. Acquisition planning establishes requirements for items needed, and establishes special procurement requirements that may be added to standard boilerplate terms and conditions. The enforcement of the terms and conditions by cognizant organization and procurement officials is necessary so that contractual requirements are not waived or relaxed by acquiescence.

A key element of the procurement process is the specification. The specification should be developed by engineering and should establish the technical and quality requirements, including applicable codes and standards that the item must meet. A graded approach is applied based on the specific application and the potential impact of failure of the item on the health and safety of the public, workers, or the environment, resulting in the determination of specific quality controls and verification methods, such as quality assurance audits and/or source surveillance at the supplier's facility, receipt inspection, and post-installation inspection and testing.

Items intended for use in safety systems and mission critical facilities should be procured from suppliers whose quality assurance programs have been evaluated by the purchaser, other DOE contractors, or third party certification agencies. Items procured for use in non-safety systems that are subsequently upgraded for use in safety systems should be subjected to the same controls and verification (including the use of qualified suppliers, and inspection and acceptance testing) applied to safety systems and mission critical facilities. Items procured through surplus or other uncontrollable channels for use in safety systems and mission critical facilities should be supported by documentation of their conformance that has been validated by the purchaser or, in the absence of such documentation, verified for acceptability by inspection or acceptance testing. Specifications for commercial grade items

intended for use in safety systems and mission critical facilities should identify the critical characteristics of the item and specify the verification attributes for acceptance to the appropriate grade level.

DOE and its contractors should be cautious about accepting items based solely on supplier-generated documentation or part-number verification, unless the supplier's quality system for generating the documentation and maintaining part number configuration control has been previously verified through performance-based evaluations.

In addition, when the supply chain involves multiple suppliers, each step in the supply chain process should be validated by audit, source inspection, or other methods as appropriate.

The extent of engineering involvement should be commensurate with the risk and intended application of the item (i.e., graded approach). Engineering involvement is generally warranted to support procurement and product acceptance activities when items are known to have been previously misrepresented.

Engineering involvement may include

- developing technical specifications.
- determining critical characteristics of purchased items that should be specified in the purchase order and selecting those characteristics to be verified during receipt inspection or prior to use.
- determining specific verification testing requirements and methods applicable to the acceptance of products. The extent of verification testing should be based on the history of misrepresentation of the item, supplier past performance, the sample size and dollar value of the shipment, and the item's function in safety systems and mission critical facilities. In the absence of a performance-based audit, verification testing or inspection is appropriate, particularly when purchasing from suppliers who are neither the original manufacturers nor authorized distributors and for whom there is no past performance information. Verification testing may be performed during receiving inspection or post-installation inspection.
- evaluating acceptance test results.
- reviewing technical changes to and deviations from procurement documents.
- developing methods for use by maintenance or inspection personnel to indicate the acceptability of suspect items determined by engineering evaluation to be acceptable for use in their current application.
- participating in audits, surveillances, and source inspections to verify the technical performance capability of suppliers of items for safety systems.
- maintaining, modifying, or justifying the replacement of equipment involving design changes.

An engineering evaluation should be conducted to determine whether a system can be operated in its present configuration without modification or replacement of S/CIs, or whether the system must be locked out, tagged out, and removed from service immediately. Engineering evaluation results should specify any conditional use of the system and any compensatory actions that will ensure the least possible threat to public and worker safety. Results should be communicated to the local DOE/NNSA office in accordance with site procedures.

b) Discuss the importance of clearly specifying the contents (especially technical and quality requirements) of procurement documents.

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

c) Discuss the purpose and methods of supplier qualification during a typical procurement process, including the process approach used to evaluate the supplier.

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

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

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

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

d) Discuss the purpose and methods of supplier performance monitoring.

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

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- surveillance of manufacturing processes and methods;
- processing and use of change information;

- review of internal assessments;
- review and disposition of non-conformances;
- selection, qualification, and performance monitoring of sub-tier suppliers.

e) Discuss the methods for assuring that suppliers continue to provide acceptable items and services.

Refer to element "c" of this competency for a discussion of methods for assuring that suppliers continue to provide acceptable items and services.

f) Discuss the purpose and importance of acceptance inspection(s) during a typical procurement process.

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

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

- 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;
- verification or testing of items before or following shipment.

g) Discuss the purpose and importance of supplier documentation and controls.

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.

h) Discuss the purpose and methods of the commercial-grade item dedication process for items important to safety.

Items procured for safety applications in nuclear activities or SSCs should be either (1) purchased from a supplier whose quality assurance program has been evaluated and found acceptable, or (2) purchased as commercial-grade items for dedication to the safety service.

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

- testing the item
- inspecting the item
- 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

7. QA personnel shall have a working-level knowledge of suspect/counterfeit items.

a) Discuss the S/CI controls and reporting requirements contained in DOE O 440.1, Worker Protection Management for DOE Federal and Contractor Employees.

Management should implement S/CI controls as part of DOE's Quality Assurance Program to the extent commensurate with the risks posed by the facility and ensure that the controls contribute to a hazard-free workplace.

Management systems shall include

- assurance that items meet the requirements for their intended use;
- mechanisms to continually update information on S/CIs and associated suppliers;
- control of the introduction and use of S/CIs through design, procurement, and inspection/maintenance (no S/CIs shall be used or introduced intentionally unless found acceptable through the disposition process);
- identification and disposition of S/CIs in safety systems and applications that create potential hazards;
- maintaining current, accurate information on S/CIs and associated suppliers using all available sources and disseminating relevant information on S/CIs to field organizations and contractors;
- training and informing managers, supervisors, and workers of S/CI controls, including prevention, detection, and disposition of S/CIs;
- assurance that the standards and methods used in determining the acceptability of items is based on consensus standards and/or commonly accepted industry practices, unless inconsistent with applicable law or otherwise impractical;
- aggressive pursuit of legal remedies, both civil and criminal, to protect DOE's resources, employees, and mission.

S/CI controls shall include

- engineering involvement in the procurement process, particularly in development of specifications during inspection and testing, and when replacing, maintaining, or modifying equipment.
- implementation of procurement procedures that preclude the introduction of S/CIs by
  - identifying technical and quality assurance requirements in procurement specifications;
  - only accepting items that comply with the procurement specifications;
  - inspecting inventory and storage areas to identify, control, and disposition S/CIs.
- development and implementation of procedures for inspection, identification, evaluation, and disposition of S/CIs installed in safety systems. Engineering evaluations of S/CIs installed in safety systems or in applications that create potential hazards should consider potential risks to the public and workers, as well as cost/benefit considerations, and should include a schedule for replacement if replacement is required.
- routine maintenance cycles and/or inspection activities for non-safety systems that include provisions for the identification of S/CIs. S/CIs identified during these activities should be reported, evaluated, and dispositioned.

- consultation with the IG prior to destroying or disposing of S/CIs to determine whether there is need to retain them in the event of litigation.
- testing of procured or in-place S/CIs as necessary. Testing methods should be approved by engineering personnel.

b) Discuss the suspect/counterfeit item notification and reporting requirements in DOE O 440.1, and guidance in G 440.1-6, Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; DOE O 414.1A, Quality Assurance; and DOE O 232.1, Occurrence Reporting and Processing of Operations Information.

Note: DOE G 440.1-6 has been canceled and replaced by DOE G 414.1-3, Suspect/ Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance.

The purpose of the S/CI notification process is to provide a coordinated mechanism for the timely dissemination and field review of information concerning potential S/CIs. Based on the potential significance of the S/CIs and applicability to DOE/NNSA, the information may be provided to the complex using one of several methods:

- An EH safety alert may be issued and posted on the DOE EH S/CI Web site.
- S/CI points of contact in the field or at Headquarters may be notified.
- The DCS may be posted on the DOE EH S/CI Web site.
- An article may be published in the OE Summary.

Regardless of how the information is disseminated, field and Headquarters organizations should review the information for potential applicability to their own facilities and operations. When an organization identifies an S/CI, it should submit an Occurrence Reporting and Processing System (ORPS) report and notify the local IG. The ORPS report will then be reviewed by the original equipment (OE) group as part of its daily review of ORPS reports.

If EH determines that the S/CI issue is crosscutting and/or of significant concern, it is elevated to the Assistant Secretary for Environment, Safety and Health. A support group is convened as necessary with applicable representatives from the line and the General Counsel (GC) and IG. The GC and the IG representatives will assist in dealing with sensitive (closely held) information related to ongoing investigations. No information is to be withheld from DOE and the contractor community except whether a criminal investigation is planned or ongoing or who may have made the allegation. All other pertinent S/CI information will be provided. This support group assists EH in developing lines of inquiry to investigate and disposition the S/CI. Members of the support group will be designated by their management and will have the means and authority to act on behalf of the organization. Support groups will be formed on an ad-hoc basis, and may consist of representatives from organizations such as EH (lead), IG, GC, Environmental Management (EM), NNSA, and the Offices of Science, Fossil Energy, and Nuclear Energy.

EH will then send a memorandum to the applicable program secretarial officers (PSOs) describing the issue and requesting an investigation be conducted in accordance with the lines of inquiry. This memorandum will also include a request to respond to EH with a plan, a schedule for completing the investigation, the results of the investigation, and the PSO

evaluation of the results. The PSOs then direct their field organizations to conduct an investigation of the S/CI issue as they deem necessary. PSOs then evaluate and document the results of their investigation whether an S/CI is identified or not. If an S/CI is identified, an ORPS report is submitted per the requirements in DOE O 231.1A, and the IG notified, per the requirements dictated in DOE O 221.1. The PSOs also initiate the appropriate corrective measures to remedy the S/CI issue and collect the costs associated with this effort. The documented results of the investigation at each site, including any corrective actions, are forwarded to respective PSO who can evaluate the adequacy of the responses and then forward them to EH.

EH then consolidates the results of the PSO reports and reviews them for completeness. EH may make recommendations to the PSOs regarding the report results. EH then forwards consolidated information such as cost data and other information to the IG or other organizations as appropriate to close out the investigation.

DOE/NNSA field elements or contractors should report any S/CI discovered during receipt, maintenance, testing, inspection, or use, and when there is reason to believe that a fraudulent act occurred during the manufacture, shipping, testing, or certification of the S/CI. The following are some, but not all, indicators that should cause suspicion of fraud:

- Though item X was ordered and billed for, evidence exists that the supplier intentionally provided item Y.
- The S/CI, sold as new, shows evidence of prior use.
- Evidence shows that the manufacturer or supplier either intentionally provided altered or incomplete testing data, or did not disclose that some testing data were missing.
- Performance is inconsistent with certification or testing data furnished by the manufacturer or supplier.
- The product failure rate exceeds expectations.
- The manufacturer's name, logo, serial number, or manufacture date appear to have been altered.
- The product is certified as meeting specified criteria, but fails independent QA testing.

8. QA personnel shall have a working-level knowledge of testing and inspection techniques and methods.

a) Describe the use of dimensional measurement devices (e.g., proper instruments used for degree of accuracy required, temperature, cleanliness, and calibration effects on instruments as well as work pieces).

Dimensional measurement and metrology services use mechanical gaging, coordinate machine measurement (CMM), non-contact imaging, or other specialized methods to inspect and measure part dimensions and geometry. Metrology, the science of measurement, involves both theoretical and practical considerations. Dimensional measurement and metrology services perform two basic types of measurements: post-process and on-process. Post-process measurement is performed after a machined part is produced. On-process measurement is performed during the part-machining process. Typically, post-process measurements are used with high volume production runs of small parts. On-process measurement is suitable for larger parts and products with higher material costs and longer cycle times.

Dimensional measurement and metrology services use a variety of instruments and equipment to measure parts. A dimensional measurement system is a complete set of measuring instruments and equipment. Dimensional laboratory metrology may involve coordinate metrology and surface finishing processes under laboratory conditions. CMM measurement involves checking the dimensional and geometric accuracy of equipment from small engine blocks, sheet metal parts, and circuit boards. A CMM measurement device consists of a probe supported on three mutually perpendicular (X, Y, and Z) axes. Each axis has a built-in reference standard. Mechanical gaging can be specified as caliper type, friction-roller type, and probe type. Embedded measurement metrology includes the use of software with CMMs to carry out dimensional measurement.

Dimensional measurement and metrology services perform two types of metrology imaging: contact and non-contact. Both types of metrology imaging involve measuring the contour of a specimen by taking images of it. Various factors such as instrument limitations, environment, human factor, and procedure are taken into account to control measurement metrology process uncertainty. Other variables include temperature, flow, force, humidity, mass, hardness, and DC electricity.

b) Discuss the basic operating principles of the following:

- **Nondestructive examination (NDE) methods such as visual, radiography, magnetic particle, liquid penetrant, ultrasonic, spectral analysis, hardness tests, and eddy current.**
- **Destructive examination methods such as tensile tests, compression tests, fatigue tests, bend tests, and metallurgical sectioning.**
- **Control of non-conforming material and processes as the result of tests and inspections and in production settings.**

Nondestructive Examination Methods

Visual. Visual inspection, either with the naked eye or with the assistance of a 10X glass, is used to check for cracking, slag inclusion, undercutting, arc strikes, reinforcement, and profile. This process can locate discontinuities open to the surface only. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Radiography. Radiographic inspection is used to check for cracks, inclusions, lack of fusion, reinforcement, and thickness. The process consists of exposing one side of the joint to an x-ray or radioisotope source and placing a film on the other side of the joint to record an image as seen through the joint material. This process can locate discontinuities throughout the thickness of the material. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Magnetic Particle. Magnetic particle inspection processes are non-destructive methods for the detection of defects in ferrous materials. They make use of an externally applied magnetic field or direct current (DC) through the material, and the principle that the magnetic susceptibility of a defect is markedly poorer (the magnetic resistance is greater) than that of the surrounding material.

The presence of a surface or near surface flaw (void) in the material causes distortion in the magnetic flux through it, which in turn causes leakage of the magnetic fields at the flaw. This deformation of the magnetic field is not limited to the immediate locality of the defect,

but extends for a considerable distance, even through the surface and into the air if the magnetism is intense enough. Thus the size of the distortion is much larger than that of the defect and is made visible at the surface of the part by means of the tiny particles that are attracted to the leakage fields.

The most common method of magnetic particle inspection uses finely divided iron or magnetic iron oxide particles held in suspension in a suitable liquid (often kerosene). This fluid is referred to as carrier. The particles are often colored and usually coated with fluorescent dyes that are made visible with a hand-held ultraviolet (UV) light. The suspension is sprayed or painted over the magnetized specimen during magnetization with a direct current or with an electromagnet to localize areas where the magnetic field has protruded from the surface. The magnetic particles are attracted by the surface field in the area of the defect and hold on to the edges of the defect to reveal it as a build up of particles.

This inspection can be applied to raw material in a steel mill (billets or slabs) in the early stages of manufacturing (forgings, castings), or most commonly, to machined parts before they are put into service. It is also very commonly used for inspecting structural parts (e.g. landing gear) that have been in-service for some time to find fatigue cracks.

Liquid Penetrant. Liquid penetrant testing consists of applying a colored dye with a very low surface tension coefficient to a weld joint and allowing it to penetrate into any discontinuity open to the surface. Excess dye on the surface is removed and a white developer with an affinity for the dye is applied. The developer draws the dye out of any discontinuity where the dye had penetrated. This process can locate discontinuities open to the surface only. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Ultrasonic. Ultrasonic testing consists of using an ultrasonic signal that is pulsed through the material where any discontinuity would result in an echo indication. This process can locate discontinuities throughout the thickness of the material. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Spectral Analysis. The goal of spectral analysis is to describe the distribution (over frequency) of the power contained in a signal based on a finite set of data. Estimation of power spectra is useful in a variety of applications, including the detection of signals buried in wide-band noise.

Hardness Test. Hardness measurement can be defined as macro-, micro-, or nano-scale according to the forces applied and displacements obtained. Measurement of the macro-hardness of materials is a quick and simple method of obtaining mechanical property data for the bulk material from a small sample. It is also widely used for the quality control of surface treatment processes.

Eddy Current. This process uses a coil of wire wrapped around a piece of iron to generate a magnetic field that causes the eddy currents to form in a piece of metal. In the field of non-destructive testing (NDT), the coil is called the inspection probe. The magnetic field that is generated by the eddy currents can be detected using this same probe. The magnetic field being produced can be monitored by these eddy currents with an instrument called an

eddyscope. If there is a change in the magnetic field from the eddy currents, there is some sort of defect in the material that is being tested. When the instrument sees a change in the magnetic field generated by the eddy currents, it displays a change in the signal on the screen.

Destructive Examination Methods

Tensile Tests. Though a tensile test is relatively simple and has been around for a very long time, certain factors must be considered to ensure that the test will have valid results. Factors to consider include specimen shape, grip and face selection, and specimen alignment, among other things.

- Specimen Shape
  The specimen's shape is usually defined by the standard or specification being utilized, e.g., ASTM E8 or D638. Its shape is important because you want to avoid having a break or fracture within the area being gripped. Standards have been developed to specify the shape of the specimen to ensure the break will occur in the gage length (2 inches are frequently used) by reducing the cross-sectional area or diameter of the specimen throughout the gage length. This has the effect of increasing the stress in the gage length since stress is inversely proportional to the cross-sectional area under load.
- Grip and Face Selection
  Grip and face selection is a very important factor. By not choosing the correct set up, your specimen may slip or even break inside the gripped area (jaw break). This would lead to invalid results. The faces should cover the entire tab or area to be gripped. You do not want to use serrated faces when testing materials that are very ductile. Sometimes covering the serrated faces with masking tape will soften the bite, preventing damage to the specimen.
- Specimen Alignment
  Vertical alignment of the specimen is an important factor to avoid side loading or bending moments created in the specimen. Mounting the specimen in the upper grip assembly first and then allowing it to hang freely will help to maintain alignment for the test.

Compression Test. A compression test determines the behavior of materials under crushing loads. The specimen is compressed and deformation at various loads is recorded. Compressive stress and strain are calculated and plotted as a stress-strain diagram which is used to determine elastic limit, proportional limit, yield point, yield strength, and for some materials, compressive strength.

Fatigue Test. Such tests are useful in developing data from mechanical design, materials research and development, process and quality control, product performance, and failure analysis. Much valuable information can be obtained regarding the stability of materials under cyclic loading, or whether changes occur due to cyclic plastic straining, and when cracks begin to form.

Bend Test. The bend test is a simple and inexpensive qualitative test that can be used to evaluate both the ductility and soundness of a material. It is often used as a quality control test for butt-welded joints, having the advantage of simplicity of both test piece and equipment. No expensive test equipment is needed, test specimens are easily prepared, and if

required, the test can be carried out on the shop floor as a quality control test to ensure consistency in production.

The bend test uses a coupon that is bent in three-point bending to a specified angle.

The outside of the bend is extensively plastically deformed so that any defects in, or embrittlement of, the material will be revealed by the premature failure of the coupon.

The bend test may be free formed or guided. The guided bend test is where the coupon is wrapped around a former of a specified diameter and is the type of test specified in the welding procedure and welder qualification specifications.

Metallurgical Sectioning. Metallurgical sectioning with the use of a scanning electron microscope and energy dispersive x-ray attachment is an invaluable aid for examining the interface and determining the characteristics of glass and metal components.

Control of Non-Conforming Material
Technical staff and QC personnel should approve any deviation from design specifications of material or equipment received before the item is accepted into the stores system. They should also approve any upgrade of material or equipment from a non-safety to a safety category. An acceptance tag or label placed on the received material may be used to signify that the receiving inspection was performed and that the applicable requirements have been met.

A separate receiving and inspection area, as well as a separate holding area, should be provided. The latter area is used to hold material and equipment that has not been officially received into the stores system because of nonconformance.

Nonconforming material must also be clearly tagged or labeled to prevent it from being issued inadvertently. A tracking or follow-up method should be established to ensure that problems with nonconforming items are promptly resolved.

c) Discuss the advantages, disadvantages, and inherent limitations of destructive and nondestructive examination methods.

Nondestructive testing of all types of components and structures is used to detect different defects such as cracking and corrosion, and there are different methods of testing available, such as x-ray (where cracks show up on the film) and ultrasound (where cracks show up as an echo blip on the screen).

While destructive testing usually provides a more reliable assessment of the state of the test object, destruction of the test object usually makes this type of test more costly to the test object's owner than nondestructive testing. Destructive testing is also inappropriate in many circumstances, such as forensic investigation.

d) Describe testing and inspection methods commonly used in the following areas:
- **Electrical**
- **Mechanical**
- **Chemical**
- **Soil and concrete**

- **Welding/fabrication**
- **Computer software**

Electrical
The following are some of the basic test instruments used in electrical testing and inspection.

Voltmeter. Voltmeters are used extensively in industry where the surveillance of input and/or output voltages is vital for plant operation. A simple DC voltmeter can be constructed by placing a resistor, called a multiplier, in series with the ammeter meter movement, and marking the meter face to read voltage. Voltmeters are connected in parallel with the load being measured.

When a voltmeter is connected in a circuit, the voltmeter will draw current from that circuit. This current causes a voltage drop across the resistance of the meter, which is subtracted from the voltage being measured by the meter. This reduction in voltage is known as the loading effect and can have a serious effect on measurement accuracy, especially for low current circuits.

The accuracy of a voltmeter is defined as the ratio of measured voltage when the meter is in the circuit to the voltage measured with the meter out of the circuit.

Ammeter. The measurement of current being supplied to or from a component is measured by an ammeter. The ammeter measures electric current. It may be calibrated in amperes, milliamperes, or microamperes. To measure current, the ammeter must be placed in series with the circuit to be tested. When an ammeter is placed in series with a circuit, it will increase the resistance of that circuit by an amount equal to the internal resistance of the meter.

The accuracy of the ammeter is the ratio of the current when the meter is in the circuit to the current with the meter out of the circuit.

Ohmmeter. The ohmmeter is an instrument used to determine resistance. A simple ohmmeter consists of a battery, a meter movement calibrated in ohms, and a variable resistor.

Ohmmeters are connected to a component that is removed from the circuit. The reason for removing the component is that measurement of current through the component determines the resistance. If the component remains in the circuit, and a parallel path exists in the circuit, the current will flow in the path of least resistance and give an erroneous reading.

Wattmeter. The wattmeter is an instrument that measures DC power or true alternating current (AC) power. The wattmeter uses fixed coils to indicate current, while the movable coil indicates voltage. The fixed coils in series with one another serve as an ammeter. The two terminals are connected in series with the load. The movable coil, and its multiplier resistor, is used as a voltmeter, with the terminals connected in parallel with the load.

Wattmeters are rated in terms of their maximum current, voltage, and power. All of these ratings must be observed to prevent damage to the meter.

Ampere-Hour Meter. The ampere-hour meter registers ampere-hours and is an integrating meter similar to the watt-hour meter used to measure electricity usage in a home. Typical ampere-hour meters are digital indicators similar to the odometer used in automobiles. The ampere-hour meter is a DC meter that will register in either direction depending on the direction of current flow. For example, starting from a given reading, it will register the amount of discharge of a battery; when the battery is placed on charge, it will operate in the opposite direction, returning once again to its starting point. When this point is reached, the battery has received a charge equal to the discharge, and the charge is stopped. It is normally desired to give a battery a 10 percent overcharge. This is accomplished by designing the ampere-hour meter to run 10 percent slow in the charge direction. These meters are subject to inaccuracies and cannot record the internal losses of a battery. They attempt to follow the charge and discharge, but inherently do not indicate the correct state of charge. Similar to an ammeter, the ampere-hour meter is connected in series. Although the ampere-hour meters were used quite extensively in the past, they have been largely superseded by the voltage-time method of control.

Power Factor Meter. A power factor meter is a type of electrodynamometer movement when it is made with two movable coils set at right angles to each other. Two stationary coils are connected in series. Coils are mounted on a common shaft, which is free to move without restraint or control springs. These coils are connected with their series resistors. At a power factor of unity, one potential coil current leads and one lags the current by 30°; thus, the coils are balanced. A change in power factor will cause the current of one potential coil to become more in phase and the other potential coil to be more out of phase with the current, so that the moving element and pointer take a new position of balance to show the new power factor.

Ground Detector. The ground detector is an instrument that is used to detect conductor insulation resistance to ground. An ohmmeter, or a series of lights, can be used to detect the insulation strength of an ungrounded distribution system. Most power distribution systems in use today are of the grounded variety. However, some ungrounded systems still exist.

Synchroscope. A synchroscope indicates when two AC generators are in the correct phase relation for connecting in parallel, and shows whether the incoming generator is running faster or slower than the on-line generator. The synchroscope consists of a two-phase stator. The two-stator windings are at right angles to one another, and by means of a phase-splitting network, the current in one phase leads the current of the other phase by 90°, thereby generating a rotating magnetic field.

The stator windings are connected to the incoming generator, and a polarizing coil is connected to the running generator. The rotating element is unrestrained and is free to rotate through 360°. It consists of two iron vanes mounted in opposite directions on a shaft, one at the top and one at the bottom, and magnetized by the polarizing coil.

If the frequencies of the incoming and running generators are different, the synchroscope will rotate at a speed corresponding to the difference. It is designed so that if incoming frequency is higher than running frequency, it will rotate in the clockwise direction; if incoming frequency is less than running frequency, it will rotate in the counterclockwise direction. When the synchroscope indicates 0° phase difference, the pointer is at the “12 o’clock” position and the two AC generators are in phase.

Meggar. The megger is a portable instrument used to measure insulation resistance. The megger consists of a hand-driven DC generator and a direct reading ohmmeter. The moving element of the ohmmeter consists of two coils that are rigidly mounted to a pivoted central shaft and are free to rotate over a C-shaped core. These coils are connected by means of flexible leads. The moving element may point in any meter position when the generator is not in operation.

As current provided by the hand-driven generator flows through the coil, the coil will tend to set itself at right angles to the field of the permanent magnet. With the test terminals open, giving an infinite resistance, no current flows in coil A. Therefore, coil B will govern the motion of the rotating element, causing it to move to the extreme counter-clockwise position, which is marked as infinite resistance.

Power Quality Monitors. Power quality monitors are intended to give all necessary information about significant power quality disturbances over a long period varying from weeks to months. These instruments identify and record the characteristics of many types of disturbances changing on a timescale of microseconds to hours. Fast transients require high sample rate analog-to-digital converters giving a large data throughput. Operating over a long timescale, this gives an enormous amount of data to be handled. These instruments must either record very little of the data handled, have large storage facilities, or communicate the data to a storage facility by means of a modem. To prevent overloading of memory with discrete event type disturbances, monitors have adjustable thresholds that determine the level at which a disturbance is recorded.

Mechanical

The following are some of the basic test instruments used in mechanical testing and inspection.

Brinell Hardness Test. The Brinell hardness test method consists of indenting the test material with a 10 mm diameter hardened steel or carbide ball subjected to a load of 3000 kg. For softer materials, the load can be reduced to 1500 kg or 500 kg to avoid excessive indentation. The full load is normally applied for 10 to 15 seconds in the case of iron and steel, and for at least 30 seconds in the case of other metals. The diameter of the indentation left in the test material is measured with a low-powered microscope. The Brinell harness number is calculated by dividing the load applied by the surface area of the indentation.

Rockwell Hardness Test. The Rockwell hardness test method consists of indenting the test material with a diamond cone or hardened steel ball indenter. The indenter is forced into the test material under a preliminary minor load, usually 10 kgf. When equilibrium has been reached, an indicating device, which follows the movements of the indenter and so responds to changes in depth of penetration of the indenter, is set to a datum position. While the preliminary minor load is still applied, an additional major load is applied with a resulting increase in penetration. When equilibrium has again been reached, the additional major load is removed, but the preliminary minor load is still maintained. Removal of the additional major load allows a partial recovery, reducing the depth of penetration. The permanent increase in depth of penetration resulting from the application and removal of the additional major load is used to calculate the Rockwell hardness number.

V-Notch Test. The V-notch test is designed to assess impact toughness, which is the ability of a material to resist against fracture under the effect of shock loading.

Drop-Weight Test. The drop weight test is a test weight that is raised to a selected height and released. In turn, it strikes another weight which is in contact with the test sample.

Tension Test. A tension test is a test performed on a given sample using a machine such as an Instron. The test slowly pulls the sample apart and details the strain of the material up to the failure point.

Fatigue Test. The fatigue test is performed similarly to the tension test, with the main difference being that the sample is cycled between tension and compression until the sample fails. The strain on the sample is measured until the test piece fails.

Creep Test. To determine creep properties, a material is subjected to prolonged constant tension or compression loading at constant elevated temperature. Deformation is recorded at specified time intervals, and a creep vs. time diagram is plotted. Slope of curve at any point is the creep rate. If failure occurs, it terminates the test, and the time for rupture is recorded. If the specimen does not fracture within the test period, creep recovery may be measured.

Corrosion Test. In order to quantify the corrosion resistance of a material, it is common practice to submit the material to harsher environments than normally encountered in service with the goal of accelerating the damage. Alternatively, a corroded surface and the corrosion products formed during normal exposure can be studied with very sensitive surface analysis techniques to try to amplify the visibility and characteristics of the damage. Since most corrosion processes occur at the metal/environment interface, much progress in the study of corrosion mechanisms can be related to the gigantic advances made in surface analysis techniques. In fact, scientists involved in the study of fundamental processes of corrosion have often been the first to explore the application of new surface analysis techniques to materials engineering problems.

Chemical

A chemical test is a qualitative or semi-quantitative procedure designed to prove the existence of a chemical compound or chemical group with the aid of a specific reagent. Following are some typical chemical tests and their uses:

- Barium chloride, which tests for sulfates
- The Beilstein test, which tests for halides qualitatively
- The Borax bead test, which tests for certain metals
- The Carius halogen method, which measures halides quantitatively
- The chemical test for cyanide, which tests for the presence of cyanide
- Copper sulfate, which tests for the presence of water
- Flame tests, which test for metals
- The Gilman test, which tests for the presence of a Grignard reagent
- The Kjeldahl method, which quantitatively determines the presence of nitrogen
- Nessler's reagent, which tests for the presence of ammonia
- Ninhydrin, which tests for ammonia or primary amines
- The sodium fusion test, which tests for the presence of nitrogen, sulfur, and halides in a sample
- The Zerewitinoff determination, which tests for any acidic hydrogen

Soil and Concrete
For evaluation and design of DOE facilities with SSCs in PC-3 or PC-4, laboratory tests for both static and dynamic properties (e.g., shear modulus, damping, liquefaction resistance) are generally required. The dynamic property tests may include cyclic triaxial tests, cyclic simple shear tests, cyclic torsional shear tests, and resonant column tests.

Both static and dynamic tests should be conducted as recommended in ASTM standards or test procedures acceptable to the DOE. The ASTM specification numbers for static and dynamic laboratory tests can be found in the annual books of ASTM Standards, in volume 04.08.

For coarse geological materials such as coarse gravels and sand-gravel mixtures, special testing equipment and a testing facility should be used (e.g., the University of California Rockfill Testing Facility, Richmond, California). A larger sample size is required for laboratory testing of this type of material (e.g., samples with a 12-inch diameter were used in the Rockfill Testing Facility). It is generally difficult to obtain in-situ undisturbed samples of unconsolidated gravely soils for laboratory tests. If it is not feasible to collect test samples and, thus, no laboratory test results are available, the dynamic properties should be estimated from the published data of similar gravely soils.

Site Response Analysis. As part of the quantification of earthquake ground motions at a facility site, an analysis of soil response effects on ground motions may be needed. Note that a specific analysis is not required if the site is a hard rock site or if the subsurface soil conditions have already been adequately accounted for in the selection and use of strong motion data and attenuation relationships for subsurface conditions similar to those that exist at the site. For facilities with SSCs in PC-1 or PC-2, it is sufficient to comply with the criteria for ground motions specified in the model building codes, although sufficient site-specific information is needed to select the proper site category.

Site response analyses (often referred to as site amplification analyses) are relatively more important when the site surficial soil layer is a soft clay and/or when there is a high stiffness contrast (wave velocity contrast) between a shallow soil layer and underlying bedrock because a few ground motion recordings have been obtained for such conditions and have shown strong local soil effects on ground motion. Site response analyses are always important for those sites having predominant frequencies within the range of interest for the SSCs being evaluated. Thus, the stiffness of the soil and bedrock as well as the depth of soil deposit should be carefully evaluated.

In a site response analysis, the ground motions (usually acceleration time histories) that are defined at bedrock or outcrop are propagated through an analytical model of the site soils to determine the influence of the soils on the ground motions. The required soil parameters for the site response analysis include the depth, soil type, density, shear modulus and damping, and their variations with strain levels for each of the soil layers. Internal friction angle, cohesive strength, and over-consolidation ratio for clay are also needed for non-linear analyses. The results of the site response analysis shall show the input motion (rock response spectra), output motion (surface response spectra), and spectra amplification function.

Strength and dynamic property tests for soils fall into two basic types: tests for determining the compaction characteristics of the soil, and tests that determine the shear strength of soil.

Compaction Testing. In general, compaction tests consist of compacting a number of soil layers with a rammer or vibrating hammer. The number of soil layers, the weight of the rammer or vibrating hammer, and the number of compacting blows or the duration of the hammer test vary from test to test. These tests are performed several times at each set of conditions, and then the conditions are varied. The independent variable is typically water content of the soil, and the dependent variable is resulting dry density (the density of the soil if all water were removed). The results of dry density versus water content are plotted to obtain the optimum water content value. At low water content, most soils tend to be stiff and difficult to compact. As water content increases, soil becomes more workable, facilitating compaction and resulting in higher dry densities up to the point of the optimum water content. As more water is added, the dry density lowers because the water is now a larger portion of the soil volume.

Shear Testing. Shear tests measure the shear strength of soils. One general test is the triaxial test. This test involves placing the specimen under axial load in a rubber sleeve. This results in equal all around pressure on the sides of the specimen, and a deviator stress is applied to the top and bottom of the specimen. The loading is increased until specimen failure occurs. The test can also be run with drainage from the specimen. The goal is to best simulate the field conditions of the soil in the applications for which it will be used. Other shear tests have been designed for specific materials such as clay or sand. These tests also determine at what point the material will fail under a given set of conditions.

Concrete Testing. Assuming that the structural design has been confirmed and the formwork has been satisfactorily installed, the remaining inspection primarily involves the materials to be placed. First, the inspector would inspect the completed forms for cleanliness and absence of extraneous materials. The inspector should check the trip sheet from the batch plant for proper mix formula and batching time. The inspector should note the time of commencement of placement of concrete to assure that mixing time and/or rotation cycle limit has not been exceeded. Based on a sampling plan, a sample of concrete should be drawn, and a slump test and entrained air test should be performed. The temperature of the concrete should be measured. All test results should meet the parameters as specified by the job.

Welding/Fabrication

The following are some typical types of tests and inspections for welds.

Visual. Visual inspection of a weld, either with the naked eye or with the assistance of a 10X glass, is used to check for cracking, slag inclusion, undercutting, arc strikes, reinforcement, and profile. This process can locate discontinuities open to the surface only. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Radiographing. Radiographic inspection of a weld is used to check for cracks, inclusions, lack of fusion, reinforcement, and thickness. The geometry of the weld joint must lend itself to radiography (e.g., a butt weld of similar thickness materials). The process consists of exposing one side of the joint to an x-ray or radioisotope source and placing a film on the other side of the joint to record an image as seen through the joint material. This process can locate discontinuities throughout the thickness of the material. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Dye Penetrant. Dye penetrant testing of a weld consists of applying a colored dye with a very low surface tension coefficient to the weld joint and allowing it to penetrate into any discontinuity open to the surface. Excess dye on the surface is removed and a white developer with an affinity for the dye is applied. The developer draws the dye out of any discontinuity where the dye had penetrated. This process can locate discontinuities open to the surface only. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Ultrasonic. Ultrasonic testing of a weld consists of using an ultrasonic signal that is pulsed through the weld material where any discontinuity would result in an echo indication. This process can locate discontinuities throughout the thickness of the material. Acceptance criteria are typically found in code documents such as the ASME code or contract documents.

Computer Software
Walkthroughs and more formal inspections, such as Fagan inspections, can be used to identify defects in source code, as well as design descriptions and other software development process output.

The software developer should perform unit testing prior to system level verification and validation techniques, including acceptance testing. Developer testing can be very structured and formal, using automated tools or less formal methods. In addition to unit testing, functional, structural, timing (performance testing), stress, security, and human-factors testing are useful testing methods.

These methods can be applied using a graded or tailored approach to ensure the known risks are mitigated appropriately. Other techniques such as error seeding; equivalence class testing; branch and path testing; statistical-based, boundary value testing; and code coverage analysis may all be beneficial testing techniques to ensure robust and reliable software.

9. QA personnel shall have a working-level knowledge of inspection and test planning methodology.

a) Discuss the criteria/logic used to determine critical characteristics that need to be verified through inspection (i.e., operational and design requirements) and testing.

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

- Identification of characteristics to be examined
- Required qualifications of individuals who perform the examinations
- Descriptions of examination methods, including equipment and calibration requirements
- Acceptance and rejection criteria
- Suitable environmental conditions
- Shelf life and maintenance
- Required safety measures
- Mandatory hold points, when applicable

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

b) Describe the merits of inspection at source, receipt, in process, and final stages.

Merits of inspection at the source include the following:

- Partnership arrangements with fewer suppliers mean less variation in vital process inputs.
- If your suppliers have proven to be effective at controlling their output, you don't need to monitor the supplier and their product as closely.

Without a good system of receiving inspection and testing, suppliers may furnish items which do not meet the bid specifications. Further more, no matter how large, how efficient, or how reliable a supplier may be, errors do occur. To insure that the requirements are actually met, to protect the using agency from receiving material below the level of acceptable quality, and to prevent unfairness to unsuccessful bidders, receiving inspections are necessary.

Merits of in-process inspection include the following:

- Reduced tooling and fixturing costs
- Reduced manufacturing set-up time
- Reduced time and costs spent on machining bad parts
- Error elimination by continuously comparing work with original CAD model
- Optimization of subsequent numerical control (NC) paths
- Increased productivity through defining and managing part features

Final inspections verify workmanship quality and conformance to customer requirements.

c) Compare the advantages and disadvantages of inspection by item attributes versus inspection of process variables.

There are two categories of data: variable or attribute. Variable data comes from measurements on a continuous scale, such as temperature, time, distance, and weight. Attribute data is based on discrete distinctions such as good/bad, percentage defective, or number defective per hundred. Variable data imparts a higher quality of information because it does not rely on sometimes arbitrary distinctions between good and bad.

10. QA personnel shall have a working-level knowledge of metrology and calibration systems.

a) Discuss the use of primary, secondary, and working standards.

A primary standard is a standard reference unit or physical constant maintained by the National Bureau of Standards upon which all measurement units in the United States are based.

A secondary standard is a standard of unit measurement derived from a primary standard.

A working standard is a standard of unit measurement calibrated from either a primary or secondary standard that is used to calibrate other devices or make comparison measurements.

b) Discuss the purpose and application of calibration systems with respect to:
- **Process/product quality**
- **Accuracy**
- **Precision**

Calibration refers to the process of setting the magnitude of the output (or response) of a measuring instrument to the magnitude of the input property or attribute within specified accuracy and precision. For example, a thermometer could be calibrated so that it showed the temperature in Celsius at the correct point.

For physical constants, weights, and measures, there are known and agreed values in the International System of Units (SI). Such constants include the length of the meter, the mass of the kilogram, and the volume of a liter.

In the United States, the National Institute of Standards and Technology (NIST), a part of the Federal Government, maintains standards and is considered the arbiter and ultimate (in the U.S.) authority for values of SI units and industrial standards. NIST also defines traceability (by which an instrument's accuracy is established in an unbroken chain relating an instrument's measurements through one or more derivative standards to a standard maintained by NIST), as well as uncertainty.

Accuracy is the degree of veracity, while precision is the degree of reproducibility. The analogy used here to explain the difference between accuracy and precision is the target comparison.

In this analogy, repeated measurements are compared to arrows that are fired at a target. Accuracy describes the closeness of arrows to the bull's eye at the target center. Arrows that strike closer to the bull's eye are considered more accurate. The closer a system's measurements to the accepted value, the more accurate the system is considered to be.

To continue the analogy, if a large number of arrows are fired, precision would be the size of the arrow cluster. (When only one arrow is fired, precision is the size of the cluster one would expect if this was repeated many times under the same conditions.) When all arrows are grouped tightly together, the cluster is considered precise since they all struck close to the same spot, if not necessarily near the bull's eye. The measurements are precise, though not necessarily accurate.

However, it is not possible to reliably achieve accuracy in individual measurements without precision. If the arrows are not grouped close to one another, they cannot all be close to the bull's eye. (Their average position might be an accurate estimation of the bull's eye, but the individual arrows are inaccurate.)

Ideally a measurement device is both accurate and precise, with measurements all close to and tightly clustered around the known value.

The accuracy and precision of a measurement process is usually established by repeatedly measuring some traceable reference standard. Such standards are defined in the International System of Units and maintained by national standards organizations such as NIST.

Precision is usually characterized in terms of the standard deviation of the measurements, sometimes called the measurement process's standard error. The interval defined by the standard deviation is the 68.3% (one sigma) confidence interval of the measurements. If enough measurements have been made to accurately estimate the standard deviation of the process, and if the measurement process produces normally distributed errors, then it is likely that 68.3% of the time, the true value of the measured property will lie within one standard deviation, 95.4% of the time it will lie within two standard deviations, and 99.7% of the time it will lie within three standard deviations of the measured value.

This also applies when measurements are repeated and averaged. In that case, the term standard error is properly applied: the precision of the average is equal to the known standard deviation of the process divided by the square root of the number of measurements averaged. Further, the central limit theorem shows that the probability distribution of the averaged measurements will be closer to a normal distribution than that of individual measurements.

With regard to accuracy, one can distinguish

- the difference between the mean of the measurements and the reference value, the bias. Establishing and correcting for bias is necessary for calibration.
- the combined effect of that and precision.

A common convention in science and engineering is to express accuracy and/or precision implicitly by means of significant figures. Here, when not explicitly stated, the margin of error is understood to be one-half the value of the last significant place. For instance, a recording of 8430 m would imply a margin of error of 5 m (the last significant place is the tens place), while 8000 m would imply a margin of 500 m. To indicate a more accurate measurement that just happens to lie near a round number, one would use scientific notation: 8.000×10^3 m indicates a margin of 0.5 m. However, reliance on this convention can lead to false precision errors when accepting data from sources that do not obey it.

Looking at this in another way, a value of 8 would mean that the measurement has been made with a precision of "1" (the measuring instrument was able to measure only up to the 1's place) whereas a value of 8.0 (though mathematically equal to 8) would mean that the value at the first decimal place was measured and was found to be zero. (The measuring instrument was able to measure the first decimal place.) The second value is more precise. Neither of the measured values may be accurate (the actual value could be 9.5 but measured inaccurately as 8 in both instances). Thus, accuracy can be said to be the correctness of a measurement, while precision could be identified as the ability to resolve smaller differences.

Precision is sometimes stratified into (1) repeatability, which is the variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period, and (2) reproducibility, which is the variation arising when using the same measurement process among different instruments and operators, and over longer time periods.

A measurement can be both accurate and precise. For instance, if all the arrows hit the bull's eye of the target, they are both near the true value (accurate) and near one another (precise).

c) Discuss the requirements for calibration programs contained in the following:

- **10 CFR 830, Subpart A, Quality Assurance**
- **DOE O 414.1A, Quality Assurance, requirements applicable to work processes and inspection and testing regarding control of measurement and test equipment**
- **ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Basic Requirement 12 (with appropriate guidance), regarding control of measurement and test equipment**

10 CFR 830
Criterion 5, Performance Work Processes, in 10 CFR 830.122 states, "Calibrate and maintain equipment used for process monitoring or data collection."

DOE O 414.1C
The following is an excerpt from DOE G 414.1-2:

> Measuring and test equipment (M&TE) used for inspections, tests, monitoring, and data collection should be calibrated, maintained, and controlled using a documented process. M&TE should be checked before use to ensure that it is of the proper type, range, accuracy, and precision and that it is uniquely identified and traceable to its calibration data. Procedures should be established for testing, retesting, adjusting, and recalibrating M&TE. M&TE should be calibrated to standards traceable to NIST or other nationally recognized standards when appropriate. If no nationally recognized standard exists, the basis for calibration should be documented. When calibrating and/or checking M&TE for use, consideration should be given to computer programs that are part of the M&TE. The use of each item of M&TE should be traceable and associated with the item of M&TE. This is because measurements and tests performed with the M&TE may need to be reevaluated if the item of M&TE is subsequently found to be out of its acceptable calibration range. Systems that rely on recording the identity of the M&TE in work packages are ineffective because it is usually almost impossible to review all work packages to identify each use of a particular item of M&TE.

ASME NQA-1-2000
Refer to this document for information regarding calibration.

d) Discuss the components of an effective calibration recall system.

Calibrated equipment should have a calibration sticker affixed indicating

- date last calibrated
- next calibration due date
- calibration source

Note: Equipment too small for label identification may have a label positioned adjacent to it, so long as the label indicates the tool number or is identified with a control number that is traceable to a calibration record.

Prior to the due date, the inspection department should send out a calibration notice indicating the equipment control number and due date. The calibration notice should be completed and returned with the equipment calibrated.

A calendar or log should be used as to show the next calibration cycle. The calendar or log should be from the present to one year forward at a minimum. When a tool is calibrated, the next due date should be recorded on the appropriate date.

Based on this calendar or log, the calibration due notices should be issued two weeks prior to the due date. Recall notices should be required from outside calibration sources at the beginning of each month.

e) Discuss the importance of calibration traceability.

A traceability chain is an unbroken chain of comparisons that ensures a measurement result or the value of a standard is related to references at a higher level, ending at the final level with a primary standard.

In the USA, industry ensures traceability to the highest international level direct from NIST.

f) Discuss methods for determining a proper calibration interval.

From reviews of calibration service history, it was decided that calibration intervals needed to be adjusted to meet an end of period (EOP) percent in-tolerance criterion, and interval adjustments needed to be based on historical service data. The term "reliability target" was coined to represent the percent in-tolerance criterion, and the available service history data indicated an item's as-found condition as in-tolerance, out-of-tolerance, damaged, etc. Data of this sort came to be referred to as "attributes data."

During the late 1960s and 1970s, methods began to appear that determined calibration intervals from such data. These methods employed maximum likelihood estimation (MLE) and reliability modeling tools. They were later refined and expanded, have been documented in the public domain, and have been implemented in commercially available software.

Much of the M&TE in today's inventories are multi-parameter items or consist of individual single-parameter items, such as gage blocks, treated in the aggregate as a set. Ordinarily, an item is pronounced out-of-tolerance if any single instrument parameter or item in a set is found out-of-tolerance. This practice is costly and seriously compromises risk management.

That the practice is costly stems from the fact that the calibration intervals of multi-parameter M&TE are often driven by a small subset of calibrated parameters. Since the identity of the offending parameters is obscured, intervals are shortened by the performance of the subsets, and the bulk of parameters are calibrated needlessly. This is a particularly undesirable outcome if the out-of-tolerance parameters are scarcely or never used.

The risk management compromise is due to the fact that risks are present at the parameter level, while data needed to do risk analysis are supplied at the item level. Since the whole purpose of periodic calibration is to control false accept and false reject risks, this is a major

disconnect that should not be taken lightly. Following are some characteristics of two common methods for determining calibration intervals.

Interval analysis of parametric attributes data includes the following characteristics and benefits:

- Well-established methods
- MLE methods
- Reliability modeling tools
- Algorithms for adjusting item recall cycles using parameter calibration intervals
- Adjustment using parameter reliability targets
- Adjustment using item-level reliability targets
- Adjustment for stratified calibration
- Application of reliability targets to individual parameters or parameter subsets
- Expedited identification of problem parameters
- Data that allow risk analysis and management at the parameter level
- History data utility that is less sensitive to calibration procedure changes, except in cases where tolerance limits are altered

Interval analysis of parametric variables data yields all the benefits of the analysis of parametric attributes data listed above. Additional benefits are listed below:

- Parameter values and bias uncertainties can be projected as functions of time elapsed since calibration.
- Either EOP reliability targets or EOP uncertainty targets can be met.
- The utility of history data is rarely affected by calibration procedure changes.
- Meaningful feedback control can be established for parameters found out-of-tolerance at calibration.
- The shelf-life problem, in which delays exist between calibration and receipt for service or return to service, can be more readily dealt with than with attributes data.
- Less data are needed to produce viable intervals than with attributes data analysis.
- Parameter bias drift trends can be displayed using statistical process control-style charts.
- As-found data as well as drift information can be provided to MTE users, if desired.

The only potential drawbacks of variables data analysis as compared to attributes data analysis are (1) while articles have been written providing analysis methodologies, a widely accepted analytical methodology has not yet been established within the metrology community, and (2) variables data entry seems at first to be more time consuming than attributes data entry.

11. QA personnel shall have a familiarity-level knowledge of statistical process control and sampling procedures for work processes, inspection/testing, and quality improvement.

a) Discuss the following statistical terms and their inter-relationships:

- **Mean**
- **Median**
- **Mode**
- **Variance**
- **Mean variance**
- **Standard deviation**

Mean
The mean, in general terms, is the average value of the data set.

An average is a value that is typical or representative of a set of data. The mean of a set of quantitative data is defined as the sum of the measurements divided by the number of measurements contained in the data set.

The arithmetic mean, or briefly the mean, of a set of N numbers X1, X2, X3, …, XN is denoted by X (read "X bar"), or the symbol m for a population, and is defined as:

$$\overline{X} = \frac{X_1 + X_2 + X_3 + \cdots + X_N}{N} = \frac{\sum_{j=1}^{N} X_j}{N} = \frac{\sum X}{N}$$

Example:
For the data set 5 3 7 9 8 5 4 5 8, the mean is:

$$\frac{7+3+5+8+8+5+4+5+9}{9} = \frac{54}{9} = 6$$

Median
The median of a set of numbers — arranged in order of magnitude — is either the middle value for a data set with an odd number of members, or the average of the two middle values if the data set contains an even number of members.

Example:

	Odd-member set	Even-member set
Data set	7 3 5 9 7 5 4 5 9	2 3 6 4 2 7 2 7 9 8
Order data set	3 4 5 5 **5** 7 7 9 9	2 2 2 3 **4 6** 7 7 8 9
Median	5	$\frac{4+6}{2} = 5$

Mode
The mode of a set of numbers is that value which occurs with the greatest frequency. The mode may not exist, and even if it does exist, it may not be unique.

Examples:

	Example 1	Example 2	Example 3
Data set	3 4 **5 5 5** 7 8 8 9	3 5 8 10 12 15 16	2 3 **4 4 4** 5 5 **7 7 7** 9
Mode	5	No mode	4 and 7, bimodal

Variance
One of the most commonly used measures of data variation is the variance, which is termed s2 for a population and S2 for a sample. The formulas are as follows:

Population or $\sigma^2 = \frac{\sum(x-\mu)^2}{N}$ or Sample or $S^2 = \frac{\sum(x-\bar{x})^2}{N-1}$

Example:
This example shows how to calculate a sample variance.
Step 1. Compute the sample mean.
Step 2. Compute the deviation of each measurement from the mean: (X- $\overline{X}$).
Step 3. Square each deviation: X- $\overline{X}^2$.
Step 4. Sum the square deviations: $\sum\left(X-\overline{X}\right)^2$.
Step 5. Divide the sum by (number of measurements – 1).

Mean Variance
This analysis is primarily used to measure financial risk associated with portfolios. The idea behind it is that variance is a measure of risk. Mean variance analysis entails minimizing risk (variance) for a particular expected return (mean), or maximizing expected return for a particular level of risk.

Standard Deviation
The standard deviation is the square root of variance. The formulas for standard deviation are as follows:

Population or $\sigma^2 = \sqrt{\frac{\sum(x-\mu)^2}{N}}$ or Sample $S^2 = \sqrt{\frac{\sum\left(x-\bar{x}\right)^2}{N-1}}$

Example:
The standard deviation for a group of children aged 5, 6, 8, and 9 is:

$$S = \sqrt{S^2} = \sqrt{\frac{\sum\left(x-\bar{x}\right)^2}{N-1}} = \sqrt{2.5} = 1.58$$

b) Discuss in general, the following sampling procedures:
- **Simple random sampling**
- **Stratified sampling**
- **Cluster sampling**
- **Systematic sampling**
- **Acceptance sampling**

Simple Random Sampling
Simple random sampling is a sampling procedure that ensures that each element in the population has an equal chance of being selected. Assume there is a school with a 1000

students divided equally into boys and girls, and you wanted to select 100 of them for further study. You might put all their names in a drum and then pull out 100 names. Not only does each person have an equal chance of being selected, but we can also easily calculate the probability of a given person being chosen. Since we know the sample size (n) and the population (N), it becomes a simple matter of division:

$$n/N \times 100 \text{ or } 100/1000 \times 100 = 10\%$$

This means that every student in the school has a 10% or 1 in 10 chance of being selected using this method.

Stratified Sampling

In this random sampling technique, the whole population is first divided into mutually exclusive subgroups or strata, and then units are selected randomly from each stratum. The segments are based on some predetermined criteria such as geographic location, size, or demographic characteristic. It is important that the segments be as heterogeneous as possible. Assume one wanted to determine the spending patterns of a hotel's guests. Knowing that the business clientele behaves quite differently from the leisure guests, you might want to separate them into different groups or strata. However, the hotel is dealing with a downtown property where 80% of the clientele are there on business, and only 20% of the guests are there for leisure purposes. In simple random sampling, there is no assurance that a sufficient number of leisure travelers would actually be included in the sample.

Using the rule of thumb about sample size determination, we need at least 100 respondents for our leisure segment. This means that we would need four times as many business travelers, since they represent four times as many guests at the hotel, for a total of 500 respondents. This is referred to as proportionate stratified sampling. Disproportionate sampling is only undertaken if a particular strata is very important to the research project but occurs in too small a percentage to allow for meaningful analysis unless its representation is artificially boosted.

In this technique, you over-sample and then weight your data to re-establish the proportions. Assume the hotel only has enough budget to survey 300 guests, but still wants at least 100 leisure travelers to have a sufficient number for further analysis. This means that the hotel must over-sample for leisure travelers at a ratio of 2:1. Therefore, the hotel would need to weight each of the business travelers by 2 (i.e. 2 x 2 = 4) to end up with the proper proportions.

Cluster Sampling

Contrary to simple random sampling and stratified sampling where single subjects are selected from the population, in cluster sampling the subjects are selected in groups or clusters. This approach avoids the constraints of costs and time associated with a very dispersed population. Let us assume you wanted to conduct interviews with hotel managers in a major city about their training needs. You could decide that each hotel in the city represents one cluster, and then randomly select a small number, e.g., 10. You would then contact the managers in these 10 properties for interviews. When all units of the selected cluster are interviewed, it is referred to as one-stage cluster sampling. If the subjects to be interviewed are selected randomly within the selected clusters, it is called two-stage cluster

sampling. This technique might be more appropriate if the number of subjects within a unit is very large (e.g., instead of interviewing managers, you want to interview employees).

You could also combine cluster sampling with stratified sampling. For instance, in the above example of wanting to interview employees in randomly selected clusters, you might want to stratify the employees based on some characteristic deemed most relevant to your study (e.g., seniority, job function) and then randomly select employees from each of these strata. This type of sampling is referred to as "multistage sampling."

Systematic Sampling
Systematic sampling is the selection of every nth element from a sampling frame, where n, the sampling interval, is calculated as:

$$n = \text{Number in population}/\text{Number in sample}$$

Using this procedure, each element in the population has a known and equal probability of selection. This makes systematic sampling functionally similar to simple random sampling. It is however, much more efficient and much less expensive to do.

The researcher must ensure that the chosen sampling interval does not hide a pattern. Any pattern would threaten randomness. A random starting point must also be selected.

Acceptance Sampling
Acceptance sampling is a procedure used for sentencing incoming batches. The most widely used plans are given by the Military Standard tables developed during World War II. The original version of the standard (MIL STD 105A) was issued in 1950. The last revision (MIL STD 105E) was issued in 1989, but canceled in 1991.

Acceptance sampling involves an inspection plan. An inspection plan includes the sample size/s (n), the acceptance number/s (c), and the rejection number/s (r). The single sampling procedure with these parameters is as follows: Draw a random sample of n items from the batch. Count the number of nonconforming items within the sample (or the number of nonconformities, if more than one nonconformity is possible on a single item). If the number of nonconforming items is c or less, accept the entire batch. If it is r or more, then reject it. In most cases r =c+1 (for double and multiple plans, there are several values for the sample sizes and acceptance and rejection numbers).

The standard includes three types of inspection (normal, tightened, and reduced inspection). The type of inspection that should be applied depends on the quality of the last batches inspected. At the beginning of inspection, normal inspection is used. The types of inspection differ as follows:

- Tightened inspection (for a history of low quality) requires a larger sample size than that required for normal inspection.
- Reduced sampling (for a history of high quality) has a higher acceptance number relative to normal inspection (so it is easier to accept the batch).

There are special switching rules between the three types of inspection, as well as a rule for discontinuation of inspection. These rules are empirically based.

c) Discuss the terms "confidence interval" and "confidence limit."

Confidence Interval
A confidence interval gives an estimated range of values which is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data.

If independent samples are taken repeatedly from the same population, and a confidence interval is calculated for each sample, then a certain percentage (confidence level) of the intervals will include the unknown population parameter. Confidence intervals are usually calculated so that this percentage is 95%, but we can produce 90%, 99%, and 99.9% confidence intervals for the unknown parameter.

The width of the confidence interval gives us some idea about how uncertain we are about the unknown parameter (see precision). A very wide interval may indicate that more data should be collected before anything very definite can be said about the parameter.

Confidence intervals are more informative than the simple results of hypothesis tests (where we do or don't reject H_0) since they provide a range of plausible values for the unknown parameter.

Confidence Limit
Confidence limits are the lower and upper boundaries or values of a confidence interval, that is, the values which define the range of a confidence interval.

The upper and lower bounds of a 95% confidence interval are the 95% confidence limits. These limits may be taken for other confidence levels, for example, 90%, 99%, and 99.9%.

d) Discuss control charts and their relationship to statistical process controls.

Every process varies. If you write your name ten times, your signatures will all be similar, but no two signatures will be exactly alike. There is an inherent variation, but it varies between predictable limits. If, as you are signing your name, someone bumps your elbow, you get an unusual variation due to what is called a special cause. If you are cutting diamonds, and someone bumps your elbow, the special cause can be expensive. For many, many processes, it is important to notice special causes of variation as soon as they occur.

There is also common cause variation. Consider a baseball pitcher. If he has good control, most of his pitches are going to be where he wants them. There will be some variation, but not too much. If he is wild, his pitches are not going where he wants them; there's more variation. There may not be any special causes — no wind, no change in the ball — just more common cause variation. The result is that more walks are issued, and there are unintended fat pitches out over the plate where batters can hit them. In baseball, control wins ball games. Likewise, in most processes, reducing common cause variation saves money.

Happily, there are easy-to-use charts which make it easy see both special and common cause variation in a process. They are called control charts, or sometimes Shewhart charts, after their inventor, Walter Shewhart, of Bell Labs. There are many different subspecies of

control charts that can be applied to the different types of process data which are typically available.

All control charts have three basic components:

- A centerline, usually the mathematical average of all the samples plotted
- Upper and lower statistical control limits that define the constraints of common cause variations
- Performance data plotted over time

Things to Look For. The point of making control charts is to look at variation, seeking special causes and tracking common causes. Special causes can be spotted using several tests:

- 1 data point falls outside the control limits
- 6 or more points in a row steadily increase or decrease
- 8 or more points in a row are on one side of the centerline
- 14 or more points alternate up and down

In those charts that pair two charts together, you will want to look for these anomalies in both charts.

The simplest interpretation of the control chart is to use only the first test listed. The others may indeed be useful (and there are more not listed here), but be mindful that, as you apply more tests, your chances of making Type I errors, i.e., getting false positives, go up significantly.

Types of Errors. Control limits on a control chart are commonly drawn at 3 standard deviations from the center line because 3-sigma limits make a good balance point between two types of errors.

Type I or alpha errors occur when a point falls outside the control limits even though no special cause is operating. The result is a witch-hunt for special causes and adjustment of things here and there. The tampering usually distorts a stable process and wastes time and energy.

Type II or beta errors occur when you miss a special cause because the chart isn't sensitive enough to detect it. In this case, you will go along unaware that the problem exists and thus won't be able to root it out.

All process control is vulnerable to these two types of errors. The reason that 3-sigma control limits balance the risk of error is that, for normally distributed data, data points will fall inside 3-sigma limits 99.7% of the time when a process is in control. This makes the witch-hunts infrequent, but still makes it likely that unusual causes of variation will be detected.

C. Assessment, Oversight, and Improvement

1. QA personnel shall demonstrate a working-level knowledge of assessment principles and techniques. Reference DOE G 414.1-1,Management Assessment and Independent Assessment.

a) Describe the assessment requirements applicable to DOE and contractor organizations.

Assessment requirements applicable to DOE and contractor organizations ensure that managers

- assess their management processes and identify and correct problems that hinder the organization from achieving its objectives;
- plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement;
- establish sufficient authority and freedom from line management for independent assessment teams;
- ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

b) Explain the essential elements of assessments, the relationship and differences between management and independent assessments, and the role of quality assurance personnel relative to the two assessment types.

Managers must perform management assessments to comply with the 10 CFR 830 and DOE O 414.1C. Management assessments look at the total picture: how well the management system meets the customer's requirements; the expectations for safely performing work; and the organizational mission, goals, and objectives. The emphasis of management assessment is on management issues that affect performance and related processes such as strategic planning, personnel qualification and training, staffing and skills mix, communication, and cost control; organizational interfaces; and mission objectives. The purpose of this type of assessment is to identify the management aspects of performance and make improvements. Management assessment is an introspective self-analysis to determine whether the management infrastructure is properly focused on achieving desired results. Typically, management assessments are performed at a greater frequency than independent assessments and cover a broader spectrum.

Independent assessments evaluate the performance of work processes with regard to requirements, compliance, and expectations for safely performing the work and achieving the goals of the organization. The focus of independent assessments should be the items and services produced and their associated processes. The purpose is to improve product/service performance and process effectiveness. Independence is defined as not having direct responsibility for the work being assessed. Independent assessments typically are performed by personnel from organizations or work units outside the one being assessed. Thus, management receives an objective view of the assessed activity. Independent assessments are typically performed less frequently than management assessments, but go into greater depth.

Management is responsible for developing and implementing a coherent plan that balances management and independent assessments and other forms of feedback and improvement to satisfy the requirements of 10 CFR 830 and DOE O 414.1C.

c) Describe how the results of management assessments are used by management to improve their management processes.

Management assessments should be reported in accordance with the organization's management assessment reporting protocols. Because of the nature of management assessments, corrective actions may be required by any level of management or by other organizations.

d) Describe how the results of independent assessments are used by the management assessment process.

For independent assessments, the proposed corrective actions should be reviewed for concurrence by the assessment team leader, with input from the assessment team. The senior line management to whom the assessed organization is accountable should approve the corrective actions. This will help ensure that the planned actions will be effective in resolving the problem areas and deficiencies reported by the assessment team.

e) Describe the fundamental differences between performance and compliance based assessments.

A compliance-based assessment focuses on verifying compliance with requirements through the implementation of procedures. Compliance assessment begins with a determination of the contractual and regulatory requirements binding the assessed organization. Assessors then verify that requirements flow down to implementing documents such as procedures, whose implementation is in turn verified. Assessing for compliance alone may not adequately identify higher level systemic or programmatic problems or determine the effectiveness of the program. In many situations an organization has written procedures that appear to implement the requirements; however, in practice the intent of the requirements is not fully achieved because of variables such as the way those procedures are executed.

A performance-based assessment takes a different approach by focusing first on the adequacy of the process that produced a product or service and then on the product itself. If problems are found in the product or work processes, then the assessor evaluates the methods and procedures used to implement the applicable requirements. This is done to find the failure that led to the problems. In performance-based assessment, great emphasis is placed on getting the full story on a problem before coming to a conclusion. If an assessor sees a problem with the execution of a welding process, he or she should determine the extent of the problem. Is it limited to one welder? Is it limited to one process? Can the problem be traced to the qualification program for the welder or to the qualification program for the welding process? Or is there a problem with the weld material itself, indicating an engineering or procurement problem?

While the assessor must be familiar with requirements and procedures, in performance-based assessment, the assessor's experience and knowledge play an integral part in determining whether requirements are satisfied. Therefore, participants in performance-based

assessments must be technically competent in the areas they are assessing. For example, if an assessor is evaluating a welding process, the assessor relies heavily on his or her knowledge of welding codes, welding processes, and metallurgy, rather than relying on just verifying simple procedure compliance.

Performance-based assessment usually provides the most useful information to management; however, it requires a much higher level of competence on the part of the assessment team. In practice, assessments are likely to include elements of both methods.

Organizations should establish procedures for planning and performing management and independent assessments. These should address training and qualification of personnel, planning the assessment processes, performance protocols and tools, reporting, distributing reports, and developing and implementing corrective actions and other follow-up activities.

f) Describe the contents of a typical assessment report.

Assessment reports are required to communicate the issues identified during an assessment. Assessment team leaders have the overall responsibility for preparing the report and obtaining approval for its release from their senior management. The assessment report may be formal or informal, depending on the level of assessment performed, but should provide a clear picture of the results in terms of the programs, systems, and processes assessed. The report should be clear and easy to understand and should include only facts that directly relate to assessment observations and results. It should include sufficient information to enable the assessed organization to check the report for accuracy (if such a check was not done during the assessment) and to develop and implement appropriate improvement plans. Every effort should be made to ensure assessment reports are concise, accurate, and understandable. For example, summary information may be clearer or more easily understood if presented graphically. In preparing the report, authors should also remember that many people who will read the report have had no active role in the assessment and the report may be their only source of information regarding its conduct and results. A recognized good practice is to provide a draft copy of the report to the assessed organization to allow the staff to comment on the factual accuracy (if a draft for this purpose was not presented at the post-assessment meeting); however, the review is only to confirm factual accuracy, and not to contest or argue the assessment team's conclusions. Specific report formats may vary considerably from one organization to the next. In developing a report format, the assessment organization should solicit input from report recipients to ensure the report meets their needs. An independent assessment report usually includes the following sections:

- Executive summary
- Observations
- Results
- Attachments

g) Explain the essential elements and processes associated with the following assessment activities:

- **Plan and schedule**
- **Management of the assessment team**
- **Communicating team findings**
- **Analyzing data and determination of overall performance**

- **Conduct of exit interviews**
- **Closure process, tracking to closure, and follow up**
- **Corrective action implementation**

Plan and Schedule
Management assessments should be planned in a systematic manner by the individual managers to address all areas under their responsibility, and to focus on those areas presenting the greatest risk for failure or potential for improvement or that have not been covered by an independent assessment. Senior management should retain overall responsibility for the planning and performance of management assessments. Results of the planning process should be documented in an assessment plan. Those responsible for planning individual assessments should consider the following:

- A descriptive title or name for the assessment area
- A brief description of the area or activity to be evaluated
- Identification of the assessment team leader and team members
- A schedule for the start and completion of the assessment, including issuance of the assessment report
- Other information related to the actual assessment evaluation (e.g., performance objectives, management systems, resource availability, efficiency measures, effectiveness measures)

Management assessment planning should include the mechanics of performing the assessment such as the expectations for time involved, assessment tools that may be used, reporting requirements, and how areas for improvement will be identified, tracked, and closed.

Management assessments should focus on the identification and resolution of both systemic and cultural management issues and problems that may contribute to customer expectations not being met. Assessments should include evaluating conditions such as the state of employee knowledge, motivation, and morale; communication between employees and management; and the adequacy of human and material resources.

The purpose of independent assessment planning is to ensure assessments efficiently address the objectives of the assessment program with the least amount of disruption to the facility/organization being assessed. The level of planning will vary significantly depending on scope, breadth, and the complexity of the system or process being assessed. The planning process should provide for input from the assessed organizations and consideration of their customers and stakeholders.

Specific budget requirements and required resources and support should be identified as early in the planning process as possible. Administrative issues such as the need for any review documents before the actual assessment visit and considerations for travel and clearances should be addressed.

It is important to remember that each assessment needs to characterize a program, system, or process during a limited time. Effective planning will ensure this occurs. There are many scheduling and planning approaches to satisfying these requirements. Appendix C of DOE G 414.1-1A describes tools to aid in assessment planning, and appendix D provides an example of planning and scheduling independent assessments using an integrated, risk-based approach.

Management of the Assessment Team
Effective assessments may be accomplished through use of an assessment team with combined skills and experiences. Training for assessors should address the policies and procedures of the assessing organization. To enhance assessment performance and capability, new assessment personnel should participate in on-the-job training with qualified, experienced assessors before being considered fully trained or receiving a required qualification.

Communicating Team Findings
Refer to element "f" of this competency for a discussion about communicating team findings.

Analyzing Data and Determination of Overall Performance
Effective assessments use a combination of tools and techniques to maximize the productivity of the assessment team and resources. Such assessment techniques include document reviews, interviews, observation, inspection, and performance testing. Use of the planning tools also allows for more complex analysis and systematic coverage of the areas being assessed. In using these techniques, the assessor should not forget that the objective is to verify accomplishment of an organization's mission. To save time, the assessor should gather only data and information relevant to overall program performance and the achievement of program objectives.

It is generally not acceptable to identify suspicions about the adequacy or inadequacy of a program, system, or process. Investigations should be sufficiently thorough and information gathered with sufficient diligence that accurate, detailed conclusions and issues can be provided to assist the organizations that will receive the final report.

In using any of these techniques, assessors should maintain good records of the assessment results. These may include personal notes or other information to support the assessment and may be included in the checklist information. These records are useful in writing the report and any associated findings and recommendations and will become invaluable if questions arise during the report review process. All classified notes should be disposed of properly in accordance with established and agreed-upon procedures. A discussion of each of the techniques follows.

Document Review. Document review is used extensively during an assessment to substantiate the information obtained during interviews and observation. During the course of an assessment, questions may arise concerning what is heard and seen. The review of documents, including logs, procedures, work orders, and other data provides a method for answering these questions and validating the assessment results. The drawback of document review is that the accuracy of the records cannot be ascertained by review alone. This technique should be combined with interviews, observation, inspection, and/or performance testing to complete the picture of performance. Records and documents should be selected carefully to ensure they adequately characterize the program, system, or process being assessed.

Interviews. Interviews provide a means to verify the results of observation, document review, inspection, and performance testing. In addition, interviews allow the responsible person to explain and clarify those results. The interview helps to eliminate misunderstandings about program implementation and provides a venue where apparent conflicts or recent changes can be discussed and the organization and program expectations can be described.

Tools developed during assessment planning are used to prepare for the interview. Assessors should also prepare questions in advance to keep the interview focused.

Observation. Observation, the viewing of actual work activities, is often considered the most effective technique for determining whether performance is adequate. Assessors should understand the effect their presence has on the person being observed and convey an attitude that is helpful, constructive, positive, and unbiased. The primary goal during observation is to obtain the most complete picture possible of the performance, which should then be put into perspective relative to the overall program, system, or process.

Before drawing final conclusions, the assessor should verify the results through at least one other technique.

Inspection. Inspections are performed to verify the adequacy and condition of physical facilities, systems, equipment, and components. Usually inspections are used to obtain additional information concerning other items evaluated during the assessment, such as equipment labeling, configuration control, the status of system lineups, the adequacy of construction, or material storage.

Inspections may also be performed to gain information and data for interviews and/or work observation. While on these inspections, the assessor must heed all security and safety requirements. It is always a good practice to be accompanied by someone familiar with the facility.

Performance Testing. Performance testing is used to observe the response of personnel or equipment by creating a specific situation and noting performance. This technique is especially useful when activities of interest would not normally occur during an assessment visit. It is also used when timeliness and appropriateness of the response are critical to an organization (e.g., emergency responses).

Conduct of Exit Interviews

Assessment programs can gain value from a post-assessment exit meeting. This meeting is used primarily to present the assessment summary and provide the assessed organization an opportunity to verify the factual accuracy of assessment results. To facilitate this, assessors should be prepared to provide detailed supporting information for those results (ideally, a draft assessment report should be available at this time). This meeting also offers an opportunity for the assessed organization to present its management position and any plans for addressing the results.

Reasonable time should be allowed to discuss any concerns, but this meeting should not be used to argue the assessment agenda or methodology.

Closure Process, Tracking to Closure, and Follow up

An integral part of a successful corrective action program is the capability to maintain a systematic approach for tracking and reporting the status of the corrective actions to successful closure and implementation. This may be accomplished manually or electronically.

Maintaining and updating this information provides consistent data for tracking and analyzing program status and trends. The process used to track and report corrective action progress should

be readily accessible and provide sufficient data to appraise, analyze, and report the status of corrective actions affecting the safety, mission performance, and security of the site/organization.

Characteristics of an effective corrective action tracking and reporting system include the following:

- The number of data elements to enter, track, trend, and report information should be standardized and relevant for the reader to fully comprehend what, how, when, and by whom the identified problem will be effectively resolved so it will not recur. An excessive number of data elements to track and report may become too cumbersome and complicated, and may over-burden the ability of the system to provide qualitative and consistent information.
- The process for populating data elements should be clearly promulgated and enforced.
- The system should employ information technology that implements user-friendly, controlled access to the system and flexible reporting.
- A dedicated, highly reliable, automated database system may be the most cost-effective approach for tracking the corrective action plan (CAP) implementation, and it may significantly enhance data collection, storage management, and processing of data and information in a timely manner. For the DOE Corrective Action Management Program (CAMP), the Corrective Action Tracking System (CATS) is used.
- A basic and simple process requiring minimal training and easy access to enter and retrieve data by both the computer technical expert and novice entry level member up through senior management will allow for increased participation and involvement by all personnel involved in identifying the findings and implementing corrective actions.
- The system should contain an automated workflow or a relationship capability for linking findings to corrective actions.
- The system should contain a pre-designed reporting capability for generating summary statistics and reporting timely, consistent, and accurate corrective action information.
- The information to be entered into the system should be consistent with simple, well-defined data elements and attributes for the data to be entered. Unorganized and inconsistent data collection significantly reduces the usefulness of the data. Guidance for the type of information to enter into the system should be thorough, clearly defined, and easily understood with a minimum of training and instruction.
- Access security to the data should be an integral component of the system. Access should be limited to only those with a need to know. That may include members involved in the identification of finding and implementing the associated corrective actions. The corrective action information may delineate vulnerabilities of a site or organization and should not be available to the general population. Editor access to the system for updating data should be restricted to those registered personnel authorized by their management to access and enter only data involving the specified sites or organizations for which they have received authority. For the CATS, registration is required for readers and editors.
- The system should possess the capability to pinpoint problem areas and track trends. It should maintain historical data that supports ongoing problem resolution, trend analysis, and recurrence control activities.
- The system should allow flexible reporting, CAP changes and status, and real-time visibility of open and closed findings and corrective actions.
- The system should be able to integrate and link with other applicable databases.

After a reasonable period of time has elapsed, follow-up activities should be performed to verify the effectiveness of the corrective actions and how they were implemented. The verification should, at a minimum, sample the corrective actions to determine whether the problem/issue to be addressed has been resolved. The organization's reporting systems (e.g., noncompliance tracking system, occurrence reporting and processing system, external oversight reports and regulatory violations, performance indicators) should be reviewed for evidence of the problem (or a similar problem) recurring. The same techniques used to conduct assessments may be used for verifying corrective actions; however, there are several common ways to verify the implementation of corrective actions, including

- reassessment of the deficient areas;
- review of new or revised quality-affecting documents such as manuals, procedures, and training records;
- verification during the next scheduled assessment;
- verification by conducting a surveillance covering the areas of concern.

Corrective Action Implementation
Managers responsible for the activities assessed are also responsible for the development of effective corrective actions for the problem areas or deficiencies discovered during the assessment.

At a minimum, the corrective actions should include the following:

- Measures to correct each deficiency
- Identification of all root causes for significant deficiencies
- Determination of the existence of similar deficiencies
- Corrective actions to preclude recurrence of like or similar deficiencies
- Assignment of corrective action responsibility
- Completion dates for each corrective action

For independent assessments, the proposed corrective actions should be reviewed for concurrence by the assessment team leader, with input from the assessment team. The senior line management to whom the assessed organization is accountable should approve the corrective actions. This will help ensure that the planned actions will be effective in resolving the problem areas and deficiencies reported by the assessment team.

Management assessments should be reported in accordance with the organization's management assessment reporting protocols. Because of the nature of management assessments, corrective actions may be required by any level of management or by other organizations.

h) Discuss the conduct of formal meetings between DOE management and senior contractor management to discuss results of quality assurance assessments.

Refer to element "g" of this competency for a discussion of exit interviews.

i) Discuss the ethical responsibilities of quality assurance personnel when conducting assessments.

To uphold and advance the honor, dignity, and status of the quality assessment profession, the assessor is expected to

- not perform or engage in any acts or practices prohibited by any federal, state, or local law;
- be honest and impartial;
- compete fairly, extend friendship, and project confidence to all associates and business contacts;
- act professionally as a faithful agent or trustee of his or her employer;
- be able to document the professional qualifications needed to provide clear, objective evidence of the degree of his or her technical and systems training;
- undertake only those assessments compatible with the degree of training, experience, and proficiency he or she holds about the technical or systems operations being assessed;
- report any business connections, financial interests, employment history, or affiliations which might influence, or appear to influence, judgment, or impair the equitable character needed for the assessment;
- acknowledge the development of programs by the assessor on a consultation basis which may jeopardize the independence of his or her ability to assess the suitability of those programs to meet the requirements of the standard(s);
- not disclose information concerning the business affairs or technical processes of the assessed organization without consent to do so;
- issue reports that are constructive in nature that clearly identify the requirement against which conformance is being measured, and which clearly define the degree of conformance or nonconformance of the operation being assessed, and where appropriate, point out improvements to areas where short comings are noted;
- ensure the operation (program) being assessed is viewed objectively;
- qualify any findings documented against noncompliant requirement(s).

2. QA personnel shall have a working-level knowledge of quality improvement principles and processes. Reference DOE G 414.1-2, Quality Assurance Management System Guide.

a) Identification of quality problems (includes clearly defined variations from requirements).

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

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

Problems that are not significant and that cannot be readily corrected on the spot should be identified and documented (e.g., by logging) and handled in an expedient manner that may

not follow the more formal processes for quality problem documentation (e.g., nonconformance report) and disposition.

Software quality problem reporting may be managed in a software-specific process. However, a software-specific process should include the same elements as the overall quality management process, and should address the same quality problems listed in DOE G 414.1-2A, section 4.3.2, including

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

b) Resolution of quality problems.

A quality problem resolution process should consist of

- identifying a condition adverse to quality;
- evaluating its significance and extent;
- analyzing the problem and determining its causes;
- reporting the planned actions to the organization identifying the problem;
- assigning responsibility for correcting the problem;
- taking prompt corrective (remedial) action and documenting that action;
- training or retraining on processes, procedures, or management systems;
- taking steps to prevent recurrence;
- replicating the actions where appropriate;
- verifying implementation;
- documenting closure;
- determining the effectiveness of the corrective and preventive actions for significant problems.

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

Quality problem resolution typically involves

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

c) Analysis and prioritization of quality problems to identify immediate, short-term, and long term corrective as well as preventive measures.

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
- affecting the ability to meet customer requirements

d) Quality improvement, including feedback, monitoring, method of measuring effectiveness, and programmatic adjustments.

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.

3. QA personnel shall have a working-level knowledge of quality improvement methods, including: problem analysis techniques used to identify problems/potential improvements; analysis tools to determine potential causes of problems; and systems to identify, track, and complete corrective action(s) or improvement opportunities. Reference G 414.1-1, G 450.4-1, and G 414.1-2.

a) Describe the application of effective problem analysis principles and techniques, including the following:

- **Root cause analysis**
- **Causal factor analysis**
- **Change analysis**
- **Barrier analysis**
- **Management Oversight Risk Tree (MORT) analysis**

Root Cause Analysis

Any root cause analysis method that includes the following basic steps may be used:

- Identify the problem. Remember that actuation of a protective system constitutes the occurrence but is not the real problem; the unwanted, unplanned condition or action that resulted in actuation is the problem to be solved. For example, dust in the air actuates a false fire alarm. In this case, the occurrence is the actuation of an engineered safety feature. The smoke detector and alarm functioned as intended; the problem to be solved is the dust in the air, and not the false fire alarm. Another example is when an operator follows a defective procedure and causes an occurrence. The real problem is the defective procedure; the operator has not committed an error. However, if the operator had been correctly trained to perform the task and, therefore, could reasonably have been expected to detect the defect in the procedure, then a personnel problem may also exist.
- Determine the significance of the problem. Were the consequences severe? Could they be next time? How likely is recurrence? Is the occurrence symptomatic of poor attitude, a safety culture problem, or other widespread program deficiency? Base the level of effort of subsequent steps of your assessment upon the estimation of the level of significance.

- Identify the causes immediately preceding and surrounding the problem.
- Identify the reasons why the causes in the preceding identification step existed, working your way back to the root cause (the fundamental reason that, if corrected, will prevent recurrence of this and similar occurrences throughout the facility and other facilities under your control). This root cause is the stopping point in the assessment of causal factors. It is the place where, with appropriate corrective action, the problem will be eliminated and will not recur.

Causal Factor Analysis
Causal factor analysis is used for multi-faceted problems or long, complex causal factor chains. Cause and effects diagrams describe the time sequence of a series of tasks and/or actions and the surrounding conditions leading to an event. The event line is a time sequence of actions or happenings, while the conditions are anything that shapes the outcome and can range from physical conditions (such as an open valve or noise) to attitude or safety culture. The events and conditions as given on a chart describe a causal factor chain.

Change Analysis
Change analysis looks at a problem by analyzing the deviation between what is expected and what actually happened. The evaluator essentially asks what differences occurred to make the outcome of this task or activity different from all the other times this task or activity was successfully completed. This technique consists of asking the questions: What? When? Where? Who? How? Answering these questions should provide direction toward answering the root cause determination question: Why? Primary and secondary questions included within each category will provide the prompting necessary to thoroughly answer the overall question. Some of the questions will not be applicable to any given condition. Some amount of redundancy exists in the questions to ensure that all items are addressed. Several key elements include the following:

- Consider the event containing the undesirable consequences.
- Consider a comparable activity that did not have the undesirable consequences.
- Compare the condition containing the undesirable consequences with the reference activity.
- Set down all known differences whether they appear to be relevant or not.
- Analyze the differences for their effects in producing the undesirable consequences. This must be done with careful attention to detail, ensuring that obscure and indirect relationships are identified (e.g., a change in color or finish may change the heat transfer parameters and consequently affect system temperature).
- Integrate information into the investigative process that are relevant to the causes of, or that are the contributors to, the undesirable consequences.

Change analysis is a good technique to use whenever the causes of the condition are obscure, you do not know where to start, or you suspect a change may have contributed to the condition. Not recognizing the compounding of change (e.g., a change made five years previously combined with a change made recently) is a potential shortcoming of change analysis. Not recognizing the introduction of gradual change as compared with immediate change also is possible. This technique may be adequate to determine the root cause of a relatively simple condition. In general, though, it is not thorough enough to determine all the causes of more complex conditions.

Barrier Analysis

There are many things that should be addressed during the performance of a barrier analysis. The questions listed below are designed to aid in determining what barrier failed, thus resulting in the occurrence:

- What barriers existed between the second, third, etc., condition/situation and the second, third, etc., problem?
- If there were barriers, did they perform their functions? How?
- Did the presence of any barriers mitigate or increase the occurrence severity? Why?
- Were any barriers not functioning as designed? Why?
- Was the barrier design adequate? Why?
- Were there any barriers in the condition/situation source(s)? Did they fail? Why?
- Were there any barriers on the affected component(s)? Did they fail? Why?
- Were the barriers adequately maintained?
- Were the barriers inspected prior to expected use?
- Were any unwanted energies present? Why?
- Is the affected system/component designed to withstand the condition/situation without the barriers? Why?
- What design changes could have prevented the unwanted flow of energy? How?
- What operating changes could have prevented the unwanted flow of energy? How?
- What maintenance changes could have prevented the unwanted flow of energy? How?
- Could the unwanted energy have been deflected or evaded? How?
- What other controls are the barriers subject to? Why?
- Was this event foreseen by the designers, operators, maintainers, anyone?
- Is it possible to have foreseen the occurrence? How?
- Is it practical to have taken further steps to have reduced the risk of the occurrence?
- Can this reasoning be extended to other similar systems/components?
- Were adequate human factors considered in the design of the equipment?
- What additional human factors could be added? Should be added?
- Is the system/component user friendly?
- Is the system/component adequately labeled for ease of operation?
- Is there sufficient technical information for operating the component properly? How do you know?
- Is there sufficient technical information for maintaining the component properly? How do you know?
- Did the environment mitigate or increase the severity of the occurrence? How?
- What changes were made to the system/component immediately after the occurrence?
- What changes are planned to be made? What changes might be made?
- Have these changes been properly/adequately analyzed for effect?
- What related changes to operations and maintenance have to be made now?
- Are expected changes cost effective? Why? How do you know?
- What would you have done differently to have prevented the occurrence, disregarding all economic considerations (as regards operation, maintenance, and design)?
- What would you have done differently to have prevented the occurrence, considering all economic concerns (as regards operation, maintenance and design)?

Barrier analysis is a systematic process that can be used to identify physical, administrative, and procedural barriers or controls that should have prevented the occurrence. This

technique should be used to determine why these barriers or controls failed and what is needed to prevent recurrence.

Management Oversight Risk Tree Analysis
Management oversight risk tree (MORT) analysis is used to prevent oversight in the identification of causal factors. The left side of the tree lists specific factors relating to the occurrence, and the right side of the tree lists the management deficiencies that permit specific factors to exist. The management factors all support each of the specific barrier/ control factors. Included is a set of questions to be asked for each of the factors on the tree. As such, it is useful in preventing oversight and ensuring that all potential causal factors are considered. It is especially useful when there is a shortage of experts to ask the right questions. However, because each of the management factors may apply to the specific barrier/control factors, the direct linkage or relationship is not shown but is left up to the analyst. For this reason, casual factor analysis and MORT analysis should be used together for serious occurrences: one to show the relationship and the other to prevent oversight.

b) Describe the application of root cause analysis processes in the establishment of corrective actions and improvement opportunities.
- **Event and causal factor charting**
- **Root cause coding**
- **Generation of recommendation(s)**

Event and Causal Factor Charting
Event and causal factor charting utilizes a block diagram to depict cause and effect. This technique is most effective for solving complicated problems because it provides a means to organize the data, provides a concise summary of what is known and unknown about the event, and results in a detailed sequence of facts and activities.

The first block on the chart is the primary effect. For each effect, there is a cause that becomes the effect in the next block to the right. For each cause (effect), list in a block just below the cause (effect) two reasons you know it to be true. If only one reason is known or not firm, then all possible causes should be evaluated as potential causes. When this process gets to the point where a cause(s) can be corrected to prevent reoccurrence, then the root cause or causes have been found.

Root Cause Coding
Root cause coding is used to assign codes to the root causes of an event. Codes are assigned based on categories. Three major categories of root causes are
- technical (equipment, software, and forms)
- organizational (policies, procedures, and protocols)
- human (knowledge-based, rule-based, and skill-based causes)

This is an application that is used in most types of software for root cause analysis.

Generation of Recommendations
Recommendation generation is the process of developing recommendations for correcting the cause as identified in the root cause investigation. As issues arise in the root cause analysis, potential recommendations for correcting the root cause may be identified.

c) Describe various data gathering techniques and the use of trending and history when analyzing problems.

Typical data gathering techniques for typical problems discovered in oversight or from contractor incidents are addressed below:

- A review of similar problems, the lessons learned database, and operating experience weekly summaries can lead to workable ways of solving an issue.
- Document searches and reviews can provide useful information. The type of problem being investigated may be evident from site or nationwide documentation. Previous solutions and their utility may be identified. Document reviews may have trails to root or contributing causes.
- Interviews can provide insight into issues concerning staff morale, general safety attitudes, and sight culture that may have led to problems, and can identify precursor conditions or areas that need watching.
- Numerical, electronic, and database record reviews are helpful if looking for trends.
- Statistical screening techniques, rank correlations, control charts, and other statistical techniques can be useful in detecting trends or determining if a trend actually exists.
- Other safety analysis techniques, such as event trees, fault trees, timelines, and "what if" techniques, can be applied in retrospect to look for causes and contributing factors.

d) Using event report information, apply any problem analysis techniques to identify the problems and how they could have been avoided.

This is a performance-based competency. The qualifying official will evaluate the completion of this competency.

4. QA personnel shall have a working-level knowledge to trend performance.

a) Discuss the key process methodology used in the trending analysis of operations information.

The general methodology for trending and analyzing DOE and contractor performance data combines simple and descriptive statistical methods to organize the data with engineering management knowledge and insights concerning process operations. This approach entails the use of control charts, count charts, X-charts, U-charts, distribution charts, and standard data evaluation and analysis techniques.

b) Using an actual list of performance measures, determine what type of assessments should be performed and in what areas.

c) Given a set of assessment report data for a specified period, analyze the information for quality trends or compliance problems.

Elements "b" and "c" are performance-based competencies. The qualifying official will evaluate the completion of these competencies.

5. **QA personnel shall have a working-level knowledge of how to conduct independent assessments of the contractor's approved QAP implementation in accordance with all applicable QA requirements and standards. Reference G 414.1-1 and G 414.1-2.**

   a) **Discuss the means for determining the adequacy and effectiveness of a work activity being assessed.**

To shape a comprehensive assessment program that optimizes the application of each assessment type, it may be helpful to visualize the organization as having three interlinked levels of activity. For this discussion, these levels will be referred to as "process," "system," and "program." A process is a collection of steps or actions that yield some intermediate outcome. A system is made up of two or more processes that may operate independently or interdependently and may yield a complete product or service. A program is the most complex level, and consists of multiple, interdependent systems that often require many interfaces to provide the desired product or service.

Process Level Assessments. Process level assessments involve examination of work controls and verification that they are being implemented effectively. This level of assessment is critical for ensuring that the worker, the public, and the environment are protected from harm. Process level assessments should also assess the effectiveness of the processes from a quality and customer satisfaction perspective.

System Level Assessments. System level assessments focus on whether appropriate leadership and support systems are provided to enable the implementation of work processes. These assessments are performed to ensure human and material resources are being properly used to achieve an organization's mission and objectives. This level of assessment may range from informal daily oversight of performance to formal periodic evaluations using established protocols.

Program Level Assessments. Program level assessments are used to determine whether overall organizational programs are properly established and implemented. They are appropriate for evaluating complex organizations from several perspectives; consequently, program assessments usually examine the integration of the many systems designed to achieve organizational goals and customer expectations (with an emphasis on ES&H factors).

The following paragraphs demonstrate how the different types and levels of assessment could be applied to an organization's work control methods. Some of the elements within the work control system are planning, identifying hazards, identifying controls, and scheduling, performing, verifying/testing, and documenting the work performed.

At the process level, assessments would be performed by independent assessors to verify compliance with procedures and to ensure the work control documents (e.g., procedures, instructions, radiation surveys, permits, and safety checklists) accurately reflect the task and associated hazards.

At the system level, assessments would be performed to determine whether all the necessary elements and interfaces are addressed to ensure the system is capable of consistently meeting requirements and customer expectations. A management assessment of the work control system might determine the cost and resource allocation issues that impact the system.

At the program level, a maintenance management program, which relies on the work control system, would use results from the process and system level assessments to determine the effectiveness of the entire maintenance program. This program assessment could be performed as either a management assessment or an independent assessment. A management assessment might focus on comparing the strategic goals for maintenance with actual performance to determine whether the rewards and recognition plan targeted to improve maintenance has had the desired effect. The independent assessment might compare the program results with contractual and regulatory commitments or customer requirements.

Independent assessment emphasis is placed on system performance in support of programs and to determine its ability to deliver products and services that meet customer expectations. Independent assessments may also be used to confirm management assessment results where organizational vulnerability is high (e.g., there is the potential for a regulatory penalty, or a significant ES&H hazard exists).

From the first-line management perspective, the primary focus of assessments should be the capability of systems and the processes that support them. To ensure that these systems contribute to program goals, managers must evaluate system performance based on these goals. Ultimately, management, with support from assessments, is responsible for planning the balance and application of independent and management assessments to ensure they improve and add value to the organization.

b) Discuss some criteria that may be used by line management to determine the significance of issues or observations.

Most of the formal methods for identifying, predicting, and evaluating significance have been designed for application in specific contexts or for specific project proposals. The determination of significance from predictions of the nature of impacts is a source of debate in the field of assessment. Of particular concern is the use of formal quantitative methods for comparing project alternatives to produce a total impact score for each alternative. It has been argued that these techniques remove the responsibility for the decision from the responsible authorities. It is necessary to distinguish between impact magnitude and impact significance. Impact magnitude is determined by prediction based on empirical measurements, while impact significance is an expression of the cost of a predicted impact to society. Significance can be determined in terms of a three stage process involving scaling, weighting, and aggregation:

- Scaling is the standardization of empirical data onto a common scale to allow comparisons between different types of impacts.
- Weighting is the imposition of values (by professionals and/or the public) onto a range of impacts.
- Aggregation is the combination of different types of impact values to produce composite scores. This facilitates comparison of project alternatives and allows a final preference ranking to be achieved.

c) Discuss conventional assessment team member qualification requirements.

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

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

d) Describe the benefits of monitoring or surveillance of contractor activities.

The benefits of monitoring and surveillance are

- the identification of high-risk conditions;
- the identification of the most serious and/or the most prevalent conditions;
- the monitoring of the trends of these conditions, and the implementation and impact of intervention.

e) Discuss how QA criteria are evaluated in a readiness review.

QA criteria are evaluated by considering the following:

- What is the organization structure of this activity?
- Are functional responsibilities for QA defined and implemented for this activity?
- What is the organization structure of the QA oversight of this activity?
- Is the QA organization independent of the line management organizations?
- What is the commitment of upper, middle, and lower management to the QA program and its implementation?
- How is quality policy promulgated and quality improvement implemented throughout the organization associated with this activity?
- Are QA audits, surveillances, and nonconformance reports part of the QA program?
- What are the QA interface points with organizations that support this activity, and how is QA communicated to and implemented through them?
- What is the process for determining the QA requirements for _____ and/or its contractors for this activity, and what is the review/approval/ implementation status of this process?
- How are quality problems identified, documented, corrected, and prevented in the future for this activity?
- How are Readiness Assessment and Operational Readiness Review results integrated with quality improvement and operational efficiency?
- How are quality and efficiency improvements implemented, and how are lessons learned applied to this activity?
- Review the graded approach and any criteria for determining which QA management requirements are implemented for various types of work.
- What are the levels of risk associated with an activity?
- What is the process for grading the application of QA requirements for activities? Does it identify consequences, requirements, and the depth/extent/rigor necessary in application of those requirements?
- What is the level of commitment of this activity's senior management to QA?
- What are the greatest concerns regarding QA and ISMS implementation?
- Are controls and verifications applied to this activity consistent with their importance to the safety, cost, schedule, and success of this mission?

- Are controls documented and communicated to personnel involved in this activity to ensure appropriate application and implementation?
- What is the QA Plan?
- Is the QA Plan approved? If not, when will it be approved?
- What is the review process for the approval of the QAP for this activity?
- What is the process for determining the QA requirements for _____ and its contractor(s) for this activity, and what is the review/approval/implementation status of this process?
- What is/are the major contractor's QA Plan(s), and is it/are they implemented?

f) Discuss the "performance-based" assessment method of a quality assurance program.

Performance-based assessment takes a different approach by focusing first on the adequacy of the process that produced a product or service, and then on the product itself. If problems are found in the product or work processes, then the assessor evaluates the methods and procedures used to implement the applicable requirements. This is done to find the failure that led to the problems.

In performance-based assessment, great emphasis is placed on getting the full story about a problem before coming to a conclusion. If an assessor sees a problem with the execution of a welding process, he or she should determine the extent of the problem. Is it limited to one welder? Is it limited to one process? Can the problem be traced to the qualification program for the welder or to the qualification program for the welding process? Or is there a problem with the weld material itself, indicating an engineering or procurement problem?

While the assessor must be familiar with requirements and procedures, in performance-based assessment, the assessor's experience and knowledge play an integral part in determining whether requirements are satisfied. Therefore, participants in performance-based assessments must be technically competent in the areas they are assessing. For example, if an assessor is evaluating a welding process, the assessor relies heavily on his or her knowledge of welding codes, welding processes, and metallurgy, rather than relying on just verifying simple procedure compliance.

Performance-based assessment usually provides the most useful information to management; however, it requires a much higher level of competence on the part of the assessment team.

Organizations should establish procedures for planning and performing management and independent assessments. These should address training and qualification of personnel, planning the assessment processes, performance protocols and tools, reporting, distributing reports, and developing and implementing corrective actions and other follow-up activities.

6. QA personnel shall have a working-level knowledge of how to oversee the effective implementation of appropriate QA criteria. Reference G414.1, and P 450.5, Line ES&H Oversight.

a) Describe the goals, objectives, and methods used to conduct effective oversight of QA activities contained in 10 CFR 830, Subpart A, Quality Assurance, and DOE G 414.1-2, Quality Assurance Management System Guide.

The objectives and goals of the oversight of QA activities are

- to ensure that DOE/NNSA products and services meet or exceed customers' expectations.
- to achieve quality assurance for all work based upon the principles that
  - quality is assured and maintained through a single, integrated, effective QA program (i.e., management system);
  - management support for planning, organization, resources, direction, and control is essential to QA;
  - performance and quality improvement require thorough, rigorous assessment and corrective action;
  - workers are responsible for achieving and maintaining quality;
  - environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.
- to establish quality process requirements to be implemented under a QAP for the control of suspect/counterfeit items (S/CIs), safety issue corrective actions, and safety software.

b) Evaluate the organizational effectiveness in conforming to selected elements of the QAP such as:

- **Management assessment**
- **Quality improvement**
- **Actual performance to schedule**
- **Performance of corrective action**

This is a performance-based competency. The qualifying official will evaluate the completion of this competency.

c) Discuss the reporting techniques for communicating evaluation results to DOE and contractor management.

Refer to competency "6a" for a discussion of assessment reporting.

Acronyms	
AC	alternating current
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASQ	American Society for Quality
ASQC	American Society for Quality Control
ASTM	American Society for Testing and Materials
CAD	computer aided design
CAMP	Corrective Action Management Program
CAP	corrective action plan
CATS	Corrective Action Tracking System
CMM	coordinate machine measurement
DC	direct current
DEAR	Department of Energy Acquisition Regulations
DOE	Department of Energy
DOE-OA	DOE Office of Independent Oversight and Performance Assessment
DP	defense programs
ECP	Employee Concerns Program
EH	Environment, Health, and Safety
EM	environmental management
EOP	end of period
EPA	Environmental Protection Agency
EPI	emergency public information
ES&H	Environment, Safety and Health
FAR	Federal Acquisition Regulation
FEM	field element manager
FEOSH	federal employee occupational safety and health
GC	General Counsel
IEEE	Institute of Electrical and Electronics Engineers
IG	Inspector General
ISM	integrated safety management
ISMS	Integrated Safety Management System
ISO	International Organization for Standardization
M&O	management and operating
M&TE	measuring and test equipment
MLE	maximum likelihood estimation
MORT	management oversight risk tree
MTE	measuring test equipment
NARA	National Archives and Records Administration
NC	numerical control
NDE	nondestructive examination
NDT	nondestructive testing

NEPA	National Environmental Policy Act
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Administration
NRC	Nuclear Regulatory Commission
OE	original equipment
ORPS	Occurrence Reporting and Processing System
P&ID	piping and instrumentation drawing
PAAA	Price-Anderson Amendments Act
PM	preventive maintenance
PSO	program secretarial officer
QA	quality assurance
QA Rule	Quality Assurance Rule
QAP	QA program
QARD	quality assurance requirements and description
QC-1	Quality Management Policy
RA	radiological area
S&M	surveillance and maintenance
S&S	safeguards and security
S/CI	suspect/counterfeit item
SDO	standards development organization
SI	System of Units
SO	Secretarial Officer
SQA	software quality assurance
SSCs	structures, systems, and components
UV	ultraviolet

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