National Nuclear Security Administration

Quality Assurance
Qualification Standard

DOE-STD-1150-2002

July 2012 | Reference Guide

The Functional Area Qualification Standard References Guides are developed to assist operators, maintenance personnel, and the technical staff in the acquisition of technical competence and qualification within the Technical Qualification Program.

Please direct your questions or comments related to this document to the Office of Leadership and Career Management, Technical Qualification Program (TQP) Manager, Albuquerque Complex.

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ACRONYMS

AC	alternating current
ALARA	as low as reasonably achievable
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
CAP	corrective action plan
CD	critical decision
CFR	Code of Federal Regulation
CGD	commercial grade dedication
CM	configuration management
CMM	coordinate machine measurement
CPIC	capital planning and investment control
CRD	contractor requirements document
DC	direct current
DCS	data collection sheet
DEAR	Department of Energy Acquisition Regulations
DI	defective items
DOE	Department of Energy
DSA	documented safety analysis
EO	Executive Order
EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
ES&H	environment, safety, and health
ESH&Q	environment, safety, and health and quality
FAQS	functional area qualification standard
FAR	Federal Acquisition Regulations
FEOSH	Federal Employee Occupational Safety and Health
FY	fiscal year
HQ	headquarters
HSS	Office of Health, Safety, and Security
IAEA	International Atomic Energy Agency
IG	inspector general
ISM	integrated safety management
ISMS	integrated safety management system
ISO	International Organization for Standardization
IT	information technology
kg	kilogram
KSA	knowledge, skill, and ability
M&TE	measuring and test equipment
MIL STD	military standard
MORT	management oversight risk tree

MPI	magnetic particle inspection
NARA	National Archives and Records Administration
NDE	non-destructive examination
NDI	non-destructive inspection
NDT	non-destructive testing
NDTT	nil-ductility transition temperature
NEPA	National Environmental Policy Act
NIST	National Institute of Standards and Technology
NMMP	nuclear maintenance management program
NMMP-DD	nuclear maintenance management program description documentation
NNSA	National Nuclear Security Administration
NQA	nuclear quality assurance
NRC	Nuclear Regulatory Commission
OCIO	DOE Office of the Chief Information Officer
OIG	Office of Inspector General
OMB	Office of Management and Budget
ORPS	occurrence reporting and processing system
PAAA	Price-Anderson Amendments Act
PC	performance category
PdM	predictive maintenance
PL	Public Law
PM	preventive maintenance
PMT	post maintenance testing
QA	quality assurance
QAP	quality assurance program
QARD	quality assurance requirements and description
QC-1	DOE/NNSA Weapons Quality Policy
QMS	quality management system
R&R	repeatability and reproducibility
RCM	reliability-centered maintenance
RMA	records management application
RTR	real-time radiography
SASW	spectral analysis of surface waves
S/CI	suspect/counterfeit item
SQA	software quality assurance
S&S	safeguards and security
SSC	structures, systems, and component
STD	standard
STI	scientific and technical information
TECDOC	technical document
TQP	Technical Qualification Program
U.S.	United States
U.S.C.	United States Code
UT	ultrasonic testing

V&V	verification and validation
WR/WO	work request/work order

PURPOSE

The purpose of this reference guide is to provide a document that contains the information required for a Department of Energy (DOE)/National Nuclear Security Administration (NNSA) technical employee to successfully complete the Quality Assurance (QA) Functional Area Qualification Standard (FAQS). Information essential to meeting the qualification requirements is provided; however, 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-Standard (STD)-1150-2002, *Quality Assurance Functional Area Qualification Standard*. The qualification standard for the quality assurance functional area contains 24 competency statements.

PREFACE

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.

A comprehensive list of acronyms is provided at the beginning of this document. It is recommended that the candidate review the list prior to proceeding with the competencies, as the acronyms, abbreviations, and symbols may not be further defined within the text unless special emphasis is required.

The competencies and supporting knowledge, skill, and ability (KSA) statements are taken directly from the FAQS. Most corrections to spelling, punctuation, and grammar have been made without remark. Only significant corrections to errors in the technical content of the discussion text source material are identified. Editorial changes that do not affect the technical content (e.g., grammatical or spelling corrections, and changes to style) appear without remark. When they are needed for clarification, explanations are enclosed in brackets.

Every effort has been made to provide the most current information and references available as of July 2012. However, the candidate is advised to verify the applicability of the information provided. It is recognized that some personnel may oversee facilities that utilize predecessor documents to those identified. In those cases, such documents should be included in local qualification standards via the TQP.

In the cases where information about an FAQS topic in a competency or KSA statement is not available in the newest edition of a standard (consensus or industry), an older version is referenced. These references are noted in the text and in the bibliography.

This reference guide includes streaming videos to help bring the learning experience alive. To activate the video, click on any hyperlink under the video title. Note: Hyperlinks to video are shown in entirety, due to current limitations of eReaders.

TECHNICAL COMPETENCIES

A. QA Program Management

1. QA personnel shall demonstrate a working level of knowledge of DOE QA policy, programs, processes, and regulatory requirements contained in:

- **DOE O 414.1A, 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**

[Note: DOE O 414.1A has been superseded by DOE O 414.1D.]

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

The following is taken from the World Nuclear Association, *Price-Anderson Act of 1957, United States*.

The Price-Anderson Amendments Act (PAAA), originally enacted by Congress in 1957, limits the liability of the nuclear industry in the event of a nuclear accident in the United States (U.S.). At the dawn of the nuclear industry in the U.S., private insurance companies did not willingly underwrite a nuclear power plant fully. The lack of financial security would have hindered the development of the nuclear industry. The Federal government intervened with this amendment to the 1946 Atomic Energy Act.

The main purpose of the PAAA is to ensure the availability of a large pool of funds (currently about $10 billion) to provide prompt and orderly compensation to members of the public who incur damages from a nuclear or radiological incident no matter who might be liable. The act provides "omnibus" coverage, that is, the same protection available for a covered licensee or contractor extends through indemnification to any persons who may be legally liable, regardless of their identity or relationship to the licensed activity. Because the act channels the obligation to pay compensation for damages, a claimant need not sue several parties but can bring its claim to the licensee or contractor.

The PAAA requires Nuclear Regulatory Commission (NRC) licensees and DOE contractors to enter into agreements of indemnification to cover personal injury and property damage to those harmed by a nuclear or radiological incident, including the costs of incident response or precautionary evacuation and the costs of investigating and defending claims and settling suits for such damages. The scope of the act includes nuclear incidents in the course of the operation of power reactors; test and research reactors; DOE nuclear and radiological facilities; and transportation of nuclear fuel to and from a covered facility.

Video 1. Price-Anderson Amendments Act
http://www.youtube.com/watch?v=zcP6Q1A-c1Q

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 414.1A, Quality Assurance, and 10 CFR 830, Subpart A, Quality Assurance.

[Note: DOE P 450.4 has been superseded by DOE Policy 450.4A and DOE P 450.5 has been canceled. DOE O 414.1A has been superseded by DOE O 414.1D.]

DOE Policy 450.4A, *Integrated Safety Management Policy*

The purpose of DOE P 450.4A is to establish DOE's expectation for safety, including integrated safety management (ISM) that will enable the Department's mission goals to be accomplished efficiently while ensuring safe operations at all departmental facilities and activities.

DOE O 414.1D, *Quality Assurance*

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

- All work, as defined in DOE O 414.1D, is conducted through an integrated and effective management system.
- Management support for planning, organization, resources, direction, and control is essential to QA.
- Performance and quality improvement require thorough, rigorous assessment and effective corrective actions.
- All personnel are responsible for achieving and maintaining quality.
- Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products.

Except for the equivalences and exemption in DOE O 414.1D, paragraph 3.c, DOE O 414.1D applies to all DOE departmental elements and contractors whose contract includes requirements documents (CRDs) included in DOE O 414.1D.

10 Code of Federal Regulation (CFR) 830, Subpart A, "Quality Assurance Requirements"

This subpart establishes QA 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.

The following is taken from DOE O 414.1D.

Each departmental element and associated field element(s) must identify and assign a senior manager to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QA program (QAP). Using a graded approach, the organization must develop a QAP and implement the approved QAP. The QAP must do the following:

- Describe the graded approach used in the QAP.

- Implement QA criteria as defined in DOE O 414.1D, attachment 2, *Quality Assurance Criteria*, as well as the requirements in DOE O 414.1D, attachment 3, *Suspect/Counterfeit Items Prevention*, for all facilities, and for nuclear facilities, the requirements in DOE O 414.1D, attachment 4, *Software Quality Assurance Requirements for Nuclear Facilities*. Note: This requires that all software meet applicable QA requirements in DOE O 414.1D, attachment 2, using a graded approach.
  - Describe how the criteria/requirements are met, using the documented graded approach.
  - Flow down the applicable QA requirements and responsibilities throughout all levels of the organization.
  - Use appropriate national or international consensus standards in whole or in part, consistent with regulatory requirements and secretarial officer direction. When standards do not fully address these requirements, the gaps must be addressed in the QAP. Currently acceptable standards include
    - American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2008 with the NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*
    - American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/American Society for Quality (ASQ) Q9001-2008
    - ANSI/ASQ Z 1.13-1999, *Quality Guidelines for Research*
- Clearly identify the standards, or parts of the standards, that are used.

For QAP approvals and changes, each departmental element and associated field element(s) must do the following:

- Submit a QAP to the designated DOE approval authority.
- Review the QAP annually, or on a periodic basis defined in the QAP, and update the QAP, as needed. Submit a summary of the review of the QAP and, if necessary, submit the modified QAP to the DOE approval authority. Editorial changes to the QAP, that do not reduce or change commitments, do not require approval.
- Regard the QAP as approved 90 calendar days after receipt by the approval authority, unless approved or rejected at an earlier date.

The contractor must identify and assign an individual to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QAP. The contractor, using a graded approach, must develop a QAP and conduct work according to the approved QAP that meets the requirements of the CRD. The QAP must do the following:

- Describe the graded approach used in the QAP.
- Implement QA criteria as defined in DOE O 414.1D, attachment 2, as well as the requirements in attachment 3 for all facilities, and the requirements in attachment 4 for nuclear facilities, and describe how the criteria/requirements are met, using the documented graded approach. Note: This requires that all software meet applicable QA requirements in attachment 2, using a graded approach.
- Use appropriate national or international consensus standards consistent with contractual and regulatory requirements, and secretarial officer direction. Clearly identify the standards, or parts of the standards, that are used. When standards do not

fully address the CRD requirements, the gaps must be addressed in the QAP. Select and document the appropriate choices below:

- For hazard category 1, 2, and 3 nuclear facilities:
  - Existing facilities, or new facilities and major modifications to existing facilities achieving critical decision 1 (CD-1) prior to the issuance of DOE O 414.1D containing this CRD, continue to use the consensus standard cited in the DOE-approved QAP consistent with secretarial officer direction.
  - New facilities and major modifications to existing facilities achieving CD-1 after DOE O 414.1D containing this CRD has been issued use ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), part I and applicable requirements of part II. Note: Where NQA-1, part II language uses the terms "nuclear power plant" or "nuclear reactor," these terms are considered equivalent to the term "nuclear facility" used in this CRD.
  - Consensus standard(s) that provide an equivalent level of quality requirements as required in DOE O 414.1D, paragraphs 1.c.(1)(b) may be used in lieu of those specified to implement the requirements of this CRD. The QAP must document how this consensus standard is (or a set of consensus standards are) used, as well as how they are equivalent to the consensus standard listed in DOE O 414.1D, paragraph 1.c.(1)(b).
- For other activities and facilities use in whole or in part appropriate standards. Examples of appropriate standards include:
  - ASME NQA 1-2008
  - ANSI/ISO/ASQ Q9001-2008
  - ANSI/ASQ Z 1.13-1999

For QAP approvals and changes, the contractor must do the following:

- Submit a QAP to DOE for approval within 90 days of being awarded a DOE contract.
- Implement the QAP as approved by DOE.
- Review the QAP annually, and update as needed. Submit a summary of the annual review of the QAP and, if necessary, submit the modified QAP to the DOE approval authority. Editorial changes, that do not reduce or change commitments, do not require approval.
- Regard a QAP as approved by DOE, 90 calendar days after receipt by DOE, unless approved or rejected by DOE at an earlier date. Receipt includes acknowledgement by the receiving organization, and every official submittal to DOE restarts the 90 day clock.
- For subcontractor, vendor, and supplier activities that are not governed by the contractor's DOE-approved QAP, evaluate their program to ensure they meet applicable QA requirements.

Video 2. Development and implementation of the QAP
http://www.youtube.com/watch?v=oAc5B4SmCr8

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

[Note: DOE O 414.1A has been superseded by DOE O 414.1D from which the following is taken.]

Any exemption to DOE O 414.1D affecting nuclear facilities requires concurrence from the appropriate central technical authority per DOE O 410.1, *Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements*.

The following is taken from DOE G 460.1-1.

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.

The requesting organization submits the request for an exemption with supporting justification to the operations office manager. The following may be used as guidance for the contents of the application:

- Description of activity or condition
- Reference to the requirement(s) for which the exemption is sought
- The specific activities that would be necessary to implement the requirement(s) for which an exemption is sought
- For environment, safety, and health (ES&H) requirements, steps taken to provide protection and statement of whether adequate safety is provided and, if not, assessment of residual risk
- The alternative or mitigating actions that have or will be taken to ensure adequate safety and protection of the public, the workers, and the environment for the period during which the exemption will be effective
- Identification and justification of the acceptance of any additional risks that will be incurred if the exemption is granted
- What benefit is realized by not meeting the requirement from which the exemption is sought
- Whether the exemption being requested is temporary or permanent, and for temporary exemptions, indicate when compliance will be achieved

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

[Note: DOE O 414.1A has been superseded by DOE O 414.1D.]

The following is taken from 10 CFR 830.122.

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

- Criterion 1—Management/Program
  - Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

- Establish management processes, including planning, scheduling, and providing resources for the work.

- Criterion 2—Management/Personnel Training and Qualification
  - Train and qualify personnel to be capable of performing their assigned work.
  - Provide continuing training to personnel to maintain their job proficiency.
- Criterion 3—Management/Quality Improvement
  - Establish and implement processes to detect and prevent quality problems.
  - Identify, control, and correct items, services, and processes that do not meet established requirements.
  - Identify the causes of problems and work to prevent recurrences as a part of correcting the problem.
  - Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
- Criterion 4—Management/Documents and Records
  - Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
  - Specify, prepare, review, approve, and maintain records.
- Criterion 5—Performance/Work Processes
  - Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.
  - Identify and control items to ensure their proper use.
  - Maintain items to prevent their damage, loss, or deterioration.
  - Calibrate and maintain equipment used for process monitoring or data collection.
- Criterion 6—Performance/Design
  - Design items and processes using sound engineering/scientific principles and appropriate standards.
  - Incorporate applicable requirements and design bases in design work and design changes.
  - Identify and control design interfaces.
  - Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.
  - Verify or validate work before approval and implementation of the design.
- Criterion 7—Performance/Procurement
  - Procure items and services that meet established requirements and perform as specified.
  - Evaluate and select prospective suppliers on the basis of specified criteria.
  - Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
- Criterion 8—Performance/Inspection and Acceptance Testing
  - Inspect and test specified items, services, and processes using established acceptance and performance criteria.
  - Calibrate and maintain equipment used for inspections and tests.

- Criterion 9—Assessment/Management Assessment
  - Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.
- Criterion 10—Assessment/Independent Assessment
  - Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
  - Establish sufficient authority, and freedom from line management, for the group performing independent assessments.
  - Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

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

[Note: DOE G 414.1-2 has been superseded by DOE G 414.1-2B Admin Chg 1, *Quality Assurance Program Guide*.]

The following is taken from DOE G 414.1-2B.

DOE G 414.1-2B provides information on principles, requirements, and practices used to establish and implement an effective QAP or quality management system (QMS) consistent with the requirements of 10 CFR 830 Subpart A and DOE O 414.1D. The guide may 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 (QMS) 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 10 CFR 830, subpart A and DOE O 414.1D. Use of the guide in conjunction with appropriate standards will facilitate development and approval of a QAP compliant with the 10 CFR 830, subpart A and DOE O 414.1D. An organization may select alternative methods to document and implement its QMS as long as the requirements of the 10 CFR 830, subpart A and DOE O 414.1D are satisfied. The content of the QMS 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 DOE O 414.1D and 10 CFR 830, subpart A require that an organization develop, document, and maintain an effective QAP, also referred to as a QMS. The goal of the QMS is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. To do so, the QMS should describe methods for planning, performing, assessing, and improving the adequacy of work, including work assigned to parties outside the organization. The QMS is intended to complement the DOE integrated safety management system (ISMS).

The criteria of 10 CFR 830, "Nuclear Safety Management," prescribe a comprehensive management system for DOE work. The focus of the QMS 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 QMS'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 QMS. 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 414.1-2, 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 following is taken from DOE P 450.4A.

The Department will implement ISMSs to systematically integrate safety into management and work practices at all levels in the planning and execution of work. All organizations will develop, maintain, and implement ISMSs for their operations and work practices, based upon the ISM guiding principles and core functions. To improve effectiveness and efficiency, organizations are expected to tailor their safety management system to the hazards and risks associated with the work activities supporting the mission, including using established mechanisms to tailor requirements. Decisions impacting safety are made by technically qualified managers with knowledge of the operations and after consideration of hazards, risks, and performance history. To complement these systems and mechanisms, the Department expects all organizations to embrace a strong safety culture where safe performance of work and involvement of workers in all aspects of work performance are core values that are deeply, strongly, and consistently held by managers and workers. The Department encourages a questioning attitude by all employees and a work environment that fosters such attitude.

The ultimate responsibility and accountability for ensuring adequate protection of the workers, the public, and the environment from the operation of DOE facilities rests with DOE line management. The Department will meet this responsibility by

- establishing functions and clear lines of responsibilities, authorities, and appropriate accountabilities;

- measuring safety management performance, with special emphasis on work-related to high-consequence activities by evaluating incident reports; using ES&H performance measures; and assessing performance; and
- holding itself and its contractors accountable at all organizational levels for safety performance through codified safety regulations, contract clauses, DOE directives, and the use of contractual and regulatory enforcement tools.

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

The following is taken from DOE G 414.1-2B.

A graded approach to implementing the QAP complies with requirements, rules, and regulations, and cannot compromise public, employee, or facility safety or adversely impact the environment. 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 QAP's application of requirements should be determined by the use of a grading process, before performing the activity. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost schedule, and success of the program. Care should be taken to not double grade. Once the requirements are specified in the technical procurement documents, the grading should have been done and this becomes the set of requirements that should be met.

Consider the use of grading 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 DOE O 414.1D or 10 CFR 830, subpart A.

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

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- impact/consequences on the programmatic mission of a facility;
- the particular characteristics of a facility or activity;
- the relative importance of radiological and nonradiological hazards; and
- any other relevant factors.

The first step in the grading process is to identify the hazards, consequences, and probability of failures for the work being performed. The second step is to specify the 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 appropriate requirements and controls. The necessary degree of rigor should be applied 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 QAP, periodically reviewed in light of changes that may have occurred, and, if appropriate, revised to reflect those changes.

The graded approach cannot be used to grade QA criterion to zero that has the effect of eliminating all verifications of the requirement. Even in the least stringent application, compliance with applicable portions of stated requirements is mandatory unless an exemption is approved through an appropriate process.

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

Risk is a fundamental consideration in determining the extent to which 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 documents, 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 based on the hazards, complexity, and/or relative risk.

Based on an evaluation using these risk factors as applicable, the QAP requirements may be selected for DOE and NNSA funded facilities, activities, or organizations. Depending on the evaluation, the applicable QAP requirements could be extensive and very prescriptive, or few with only limited prescription requirements, or few with combination of limited and very prescriptive requirements. As examples, if a contractor is tasked with designing a safety-related or mission important item or facility, the most important QAP requirement would be the design control processes, consequently the specified QAP requirements would likely include ASME NQA-1, requirement 3, *Design Control*, requirements as well as less prescriptive requirements for organization, training, document control, records, and assessments. If this task were managed by a headquarter organization, their specified QAP would emphasize the review and acceptance of deliverables, performance of contractor assessments, and less prescriptive requirements for organization, training, and records.

In contrast with the example of a contractor responsible for a single design would be a contractor assigned the task of constructing or modifying a safety-related or mission important facility. Due to the risks associated with these facilities, all applicable requirements of a national consensus standard, such as ASME NQA-1, would be specified with the possible exception of ASME NQA-1, requirement 3 regarding design controls. Assuming this work is managed by a site office, their QAP would emphasis training, and the review, inspection, and the assessment of the contractor activities. The site office QAP could designate NQA-1, graded as appropriate, or an ISO as the standard to implement the QA requirements.

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.

[Note: DOE O 414.1D no longer contains attachment 2, *Safety Issue Corrective Action Process*. The following material is given to answer the KSA.]

The following is taken from DOE G 414.1-5 (archived).

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 DOE G 414.1-5 (archived), paragraph 4.

Evaluate Each Problem Finding and 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 DOE G 414.1-5 (archived), paragraph 5.

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 DOE G 414.1-5 (archived), paragraph 6.

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 follow-up 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 follow-up 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 have 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 DOE G 414.1-5 (archived), paragraph 7.

2. QA personnel shall 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.

The following is taken from DOE G 414.1-2B.

The goal of the QAP is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. The QAP is defined as the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work. Defining the proper structure for the organization and the management processes necessary to conduct work within the organization is critical to ensure that work can be controlled and conducted safely. This allows the organization to efficiently conduct work safely, as well as meeting or exceeding applicable requirements and expectations.

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

The following is taken from DOE G 414.1-2B.

The QAP should describe the organizational structure and interfaces, functional responsibilities, and levels of authority. The role of DOE and contractor senior management is to establish and cultivate principles that integrate quality requirements into daily work. Management is responsible for leadership and commitment to quality achievement and improvement in a way that ensures the safety of the public, workers, and the environment. Management retains the primary responsibility and accountability for the scope and implementation of the QAP. 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. In addition, senior management is responsible for establishing the processes, including planning, scheduling, and providing resources for the work. DOE and contractor senior management should ensure flowdown of the QA requirements and responsibilities throughout all levels of the organization. DOE should ensure proper oversight of the flowdown of requirements by their contractors to subcontractors, vendors, and suppliers. Management should promote effective achievement of performance objectives through integrated implementation of the QAP and ISMS.

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

Refer to competency A1, element "h" 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**

Origin of stop work authority

The following is taken from 10 CFR 851.20.

The driver for the stop work authority is 10 CFR 851, "Worker Safety and Health Program," which contains the following requirement.

Establish procedures to permit workers to stop work or decline to perform an assigned task because of a reasonable belief that the task poses an imminent risk of death, serious physical harm, or other serious hazard to workers, in circumstances where the workers believe there is insufficient time to utilize normal hazard reporting and abatement procedures.

Intended Purpose

The following is taken from DOE G 435.1-1, chapter 1.

DOE O 440.1B, *Work Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*, requires that DOE elements and contractors implement procedures to allow workers, through their supervisors, to stop work when they discover employee exposures to imminent danger or other serious hazards. A worker has the right to decline to perform an assigned task because of a reasonable belief that, under the circumstances, the task poses an imminent risk of death or serious bodily harm to that individual, coupled with a reasonable belief that there is insufficient time to seek effective redress through the normal hazard reporting and abatement procedures.

When a situation with an imminent danger is discovered, immediate action must be taken either to correct the dangerous condition or practice, or to remove all employees from exposure to the dangerous condition until the condition or practice has been removed. Imminent danger means a situation that could reasonably be expected to cause death or serious physical harm unless immediate actions are taken.

Legal Implications

The following is taken from DOE G 435.1-1, chapter 1.

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. This 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.

Compliance with this requirement is demonstrated by having the necessary procedures, mechanisms, and training in place to effect shutdown or curtailment of activities that pose an imminent danger or other serious hazard to workers or the public, or are not protective of the environment.

Video 3. Stop work authority

http://www.bing.com/videos/search?q=What+is+the+stop+work+authority%3f&view=detail&mid=004CEF1E6ACFAF7581F2004CEF1E6ACFAF7581F2&first=0

3. QA personnel shall 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.

The following is taken from Nuclear Regulatory Commission Regulatory Guide 1.33—*Quality Assurance Program Requirements (Operation).*

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

The following is taken from the Environmental Protection Agency, *Quality System for Environmental Data and Technology.*

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.

The following is taken from the Environmental Protection Agency, *Quality System, Doing Business with EPA: Quality Specifications for non-EPA Organizations.*

Title 48 CFR 46, "Quality Assurance," allows Federal agencies to select a national consensus standard as a basis for their quality specifications. EPA has selected ANSI/American Society for Quality Control (ASQC) E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, 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 QA 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 following is taken from the revised document.

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; and
- 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 QA 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, *Quality Management Systems—Fundamentals and Vocabulary*; ISO 9001:2000, *Quality Management Systems—*Requirements; and ISO 9004:2000, *Quality Management Systems—Guidelines for Performance Improvements*. 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 diverse organizations in many areas. Some of these areas include manufacturing, processing, servicing, and so on.

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 QA 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 QAP. The QARD contains regulatory requirements and program commitments necessary for the development of an effective QAP. 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 from the development stage 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.

Video 4. ISO 14001

http://www.bing.com/videos/search?q=ISO+14001&view=detail&mid=2BC2E5E26BB8FA655F052BC2E5E26BB8FA655F05&first=0

DOE/NNSA Nuclear Weapons QA Requirements QC-1

The purpose of this document, *Weapon Quality Policy* (QC-1), is to establish the QMS 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, DOE O 414.1D, and DOE 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.

The following is taken from Office of Management and Budget (OMB) Circular No. A-119 Revised, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.*

Voluntary consensus standards are standards developed or adopted by voluntary consensus standards bodies, domestic and international. These standards include provisions requiring

that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. For purposes of this circular, "technical standards that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.

All Federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, Federal agencies must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards to the OMB through the National Institute of Standards and Technology (NIST).

Video 5. NRC consensus standards program
http://www.bing.com/videos/search?q=consensus+standards&view=detail&mid=DFA0789C68114F0792AADFA0789C68114F0792AA&first=0

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 O 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**

[Note: Updates on these DOE regulations, Orders, and standards are listed under 4.a.]

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 proper citation is 48 CFR 970, "DOE Management and Operating Contracts," from which the following is taken.]

10 CFR 970 provides departmental policies, procedures, provisions, and clauses that supplement the FAR (Federal Acquisition Regulations) and other parts of the DEAR for the award and administration of the Department's management and operating contracts as defined in 48 CFR 17.6, "Management and Operating Contracts." See 48 CFR 970.5200, "Scope of Subpart," for guidance regarding which provisions and clauses to include in management and operating contracts.

DOE O 430.1, Life-Cycle Asset Management

[Note: DOE O 430.1 has been cancelled by DOE O 430.1B chg 2, *Real Property Asset Management,* from which the following is taken.]

DOE O 430.1B chg 2 establishes a corporate, holistic, and performance-based approach to real property life-cycle asset management that links real property asset planning, programming, budgeting, and evaluating to program mission projections and performance outcomes. To accomplish this objective, DOE O 430.1B chg 2 identifies requirements and establishes reporting mechanisms and responsibilities for real property asset management.

DOE O 413.3A, Program and Project Management for the Acquisition of Capital Assets

[Note: DOE O 413.3A has been superseded by DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets,* from which the following is taken.]

DOE O 413.3B provides the DOE elements, including the NNSA, with program and project management direction for the acquisition of capital assets with the goal of delivering projects within the original performance baseline, cost and schedule, and fully capable of meeting mission performance, safeguards, and security; and environmental, safety, and health requirements unless impacted by a directed change.

To implement OMB circulars to include: A-11, part 7, *Capital Programming Guide*, that prescribes new requirements and leading practices for project and acquisition management; A-123, *Management's Responsibility for Internal Control*; that defines management's responsibility for internal control in Federal agencies; and A-131, *Value Engineering*, that requires that all Federal agencies use value engineering as a management tool.

DOE O 200.1, Information Management Program

[Note: DOE O 200.1 has been superseded by DOE O 200.1A, *Information Technology Management*. The following information is taken from DOE O 200.1A.]

The DOE's overarching mission, to advance the national, economic, and energy security of the U.S. and to promote scientific and technological innovation, is enabled, advanced, and reliant on information and information systems that must be effectively managed to ensure mission success.

DOE O 200.1A is consistent with DOE P 413.1 (archived), *Program and Project Management Policy for the Planning, Programming, Budgeting, and Acquisition of Capital Assets*, and supports the statutory and regulatory requirements provided in the Clinger-Cohen Act, the E-Government Act, the Government Performance Results Act, the Government Paperwork Elimination Act, and departmental directives that address effective information technology (IT) management of Federal information and information systems, and delineates departmental requirements and responsibilities to address the following IT management areas:

- Acquisition, use, and management of IT
  - IT strategic planning
  - Capital planning and investment control (CPIC)
  - Enterprise architecture
  - Hardware and software acquisition
- IT operations and use
  - Access for people with disabilities
  - Web policy
  - Personal use
  - Public access
  - Software piracy
- Cyber security management
- Spectrum management
- Records management

DOE N 203.1, Software Quality Assurance

[DOE N 203.1 has expired.]

DOE O 250.1, Directives System Order

[Note: DOE O 250.1 has been superseded by DOE O 251.1C, *Departmental Directives Program,* from which the following is taken.]

The purpose of DOE O 251.1C is to

- define requirements and responsibilities for implementing the DOE directives program in support of the Secretary's memorandum of September 10, 2007, "Principles Governing Departmental Directives." Note: Upon issuance of DOE O 251.1C, the Secretary's memorandum of September 10, 2007 will be incorporated as a policy directive in accordance with this Order; and
- establish directives as the primary means to set, communicate, and institutionalize policies, requirements, responsibilities, and procedures for departmental elements and contractors.
  - Directives facilitate achievement of DOE's strategic and operational goals. They also help ensure safe, secure, efficient, cost-effective operations and compliance with applicable legal requirements.

- Directives promote operational consistency throughout the DOE complex and foster sound management.

DOE O 360.1B, *Federal Employee Training*

[Note: DOE O 360.1B has been superseded by DOE O 360.1C, *Federal Employee Training*, from which the following is taken.]

The purpose of DOE O 360.1C is to establish requirements and responsibilities for DOE Federal employee training according to 5 United States Code (U.S.C.), chapter 41, *Training*.

DOE O 425.1C, *Startup and Restart of Nuclear Facilities*

[Note: DOE O 425.1C has been superseded by DOE O 425.1D, *Verification of Readiness to Start Up or Restart Nuclear Facilities*, from which the following is taken.]

The purpose of DOE O 425.1D is to establish the requirements for the DOE, including NNSA, for verifying readiness for startup of new hazard category 1, 2, and 3 nuclear facilities, activities, and operations, and for the restart of existing hazard category 1, 2, and 3 nuclear facilities, activities, and operations that have been shut down. The readiness reviews (operational readiness reviews or readiness assessments) are not intended to be line management tools to achieve readiness. Rather, the readiness reviews provide an independent verification of readiness to start or restart operations.

DOE Order 5480.19, *Conduct of Operations for DOE Facilities*

[Note: DOE Order 5480.19 has been replaced by DOE O 422.1, *Conduct of Operations*, from which the following is taken.]

The objective of DOE O 422.1 is to define the requirements for establishing and implementing conduct of operations programs at DOE, including NNSA, facilities and projects. A conduct of operations program consists of formal documentation, practices, and actions implementing disciplined and structured operations that support mission success and promote worker, public, and environmental protection. The goal is to minimize the likelihood and consequences of human fallibility or technical and organizational system failures. Conduct of operations is one of the safety management programs recognized in the Nuclear Safety Rule (10 CFR 830), but it also supports safety and mission success for a wide range of hazardous, complex, or mission-critical operations, and some conduct of operations attributes can enhance even routine operations. It supports the ISMS by providing concrete techniques and practices to implement the ISM core functions of develop and implement hazard controls and perform work within controls. It may be implemented through facility policies, directives, plans, and safety management systems and need not be a stand-alone program.

The term “operations” encompasses the work activities of any facility or organization from building infrastructure, to print shops and computer centers, to scientific research and to nuclear facilities. While many hazards can be dealt with through engineered solutions, people still have to perform operations, and they can and do make mistakes. The purpose of DOE O 422.1 is to ensure that management systems are designed to anticipate and mitigate the consequences of human fallibility or potential latent conditions and to provide a vital barrier to prevent injury, environmental insult or asset damage, and to promote mission success.

DOE O 433.1, *Maintenance Management Program for DOE Nuclear Facilities*

[Note: DOE O 433.1 has been superseded by DOE O 433.1B, *Maintenance Management Program for DOE Nuclear Facilities*, from which the following is taken.]

The purpose of DOE O 433.1B is to define the safety management program required by 10 CFR 830.204, "Documented Safety Analysis," paragraph (b)(5) for maintenance and the reliable performance of SSCs that are part of the safety basis required by 10 CFR 830.202, "Safety Basis," at hazard category 1, 2, and 3 DOE nuclear facilities.

DOE-STD-1073-2003, *Configuration Management Program*

[Note: The title of this document has been changed to *Configuration Management*.]

The purpose of this standard is to define the objectives of a configuration management (CM) 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.

The size, complexity, and missions of DOE nuclear facilities vary widely and CM processes may need to be structured to individual facilities, activities, and operations. It would generally be inappropriate to apply the same CM standards to widely different activities, for example, a reactor facility and a small, simple laboratory. The detailed examples and methodologies in DOE-STD-1073-2003 are provided to aid those developing their CM processes; however, they are provided for guidance only and may not be appropriate for application to all DOE nuclear activities. The individuals defining the CM process for a particular nuclear activity will need to apply judgment to determine if the examples and methods presented in DOE-STD-1073-2003 are appropriate for the activity.

Nevertheless, the basic objectives and general principles of CM are the same for all activities. The objectives of CM are to

- establish consistency among design requirements, physical configuration, and documentation for the activity; and
- maintain this consistency throughout the life of the facility or activity, particularly as changes are being made.

DOE O 435.1, *Radioactive Waste Management*

[Note: DOE O 435.1 has added a change 1.]

The objective of DOE O 435.1, chg 1 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*

[Note: DOE O 451.1B has added an admin change 3.]

The purpose of DOE O 451.1B, chg 3 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, "National Environmental Policy Act Implementing Procedures"). The goal of establishing the requirements and responsibilities presented here is to ensure efficient and effective implementation of DOE's NEPA responsibilities through teamwork. A key responsibility for all participants is to control the cost and time for the NEPA process while maintaining its quality.

DOE O 460.2A, *Departmental Materials Transportation and Packaging Management*

The objectives of DOE O 460.2A 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*

[Note: DOE O 470.1 has been replaced by DOE O 470.4B, *Safeguards and Security Program*, from which the following has been taken.]

The purpose of DOE O 470.4B is to establish responsibilities for the DOE safeguards and security (S&S) program, and to establish program planning and management requirements for the S&S program. The requirements identified in DOE O 470.4B and its attachments and appendices are based on national policy promulgated in laws, regulations, Executive Orders (EOs), and national standards to prevent unacceptable adverse impacts on national security, the health and safety of DOE and contractor employees, the public, or the environment.

DOE O 151.1C, *Comprehensive Emergency Management System*

The objectives of DOE O 151.1C are:

- Establish policy and 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.
- Establish requirements for comprehensive planning, preparedness, response, and recovery activities of emergency management programs or for organizations requiring DOE/NNSA assistance.
- Describe an approach to effectively integrate planning, preparedness, response, and recovery activities for a comprehensive, all-emergency management concept.
- Describe an approach to effectively integrate planning, preparedness, response, and recovery activities for a comprehensive, all-emergency management concept.
- Integrate public information and emergency planning to provide accurate, candid, and timely information to site workers and the public during all emergencies.
- Promote more efficient use of resources through greater flexibility (i.e., the graded approach) in addressing emergency management needs consistent with the changing missions of the Department and its facilities.
- Ensure that the DOE emergency management system is ready to respond promptly, efficiently, and effectively to any emergency involving DOE/NNSA facilities, activities, or operations, or requiring DOE/NNSA assistance.
- Integrate applicable policies and requirements, including those promulgated by other Federal agencies and interagency emergency plans into the Department's emergency management system. In compliance with the statutory requirements in 42 U.S.C.

7274k, *Baseline Environmental Management Report*, DOE hereby finds that DOE O 151.1C is necessary for the fulfillment of current legal requirements and conduct of critical administrative functions.

- Eliminate duplication of emergency management effort within the Department.

DOE O 442.1A, *Department of Energy Employee Concerns Program*

As a service to all departmental elements, the purpose of DOE O 442.1A is to establish a DOE employee concerns program that ensures employee concerns related to such issues as ES&H, 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*

[Note: DOE O 225.1A has been superseded by DOE O 225.1B from which the following is taken.]

DOE O 225.1B prescribes organizational responsibilities, authorities, and requirements for conducting investigations of certain accidents occurring at DOE sites, facilities, areas, operations, and activities.

The purpose of the accident investigation is to understand and identify the causes (individual and organizational) that contributed to the accident so those deficiencies can be addressed and corrected. This is intended to prevent recurrence and promote improved environmental protection and safety and health of DOE employees, contractors, and the public.

Accident investigations are used to promote the values and concepts of a learning organization. The Department's ISM feedback and improvement function envisions organizations that are continually monitoring performance; identifying deviations or questionable conditions; self-assessing; and using quality analysis to improve. An essential component of organizational learning is learning from accidents and near misses. This requires, through the application of DOE O 225.1B, going beyond the surface levels and understanding how the underlying sources of operational vulnerability combined to result in failure. The explanation of how the failure was able to emerge in a normally safe and reliable system will lead to an understanding of where the system and processes can be improved and promote accident prevention.

DOE O 232.1, *Occurrence Reporting and Processing of Operations Information*

[Note: DOE O 232.1 was cancelled by DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*, from which this information was taken.]

The objectives of DOE O 232.2 are:

- Ensure that the DOE/NNSA are informed about events that could adversely affect the health and safety of the public or the workers, the environment, DOE missions, or the credibility of the Department.
- Promote organizational learning consistent with DOE's ISMS goal of enhancing mission safety, and sharing effective practices to support continuous improvement and adaption to change.

DOE O 210.1, Performance Indicators and Analysis of Operations Information

[Note: This Order has been canceled.]

DOE G 430.1-2, *Implementation Guide for Surveillance and Maintenance During Facility Transition and Disposition*

DOE G 430.1-2 was prepared to provide guidance on surveillance and maintenance 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. The other three guides are:

- DOE G 430.1-3, *Deactivation Implementation Guide*
- DOE G 430.1-4, *Decommissioning Implementation Guide*
- DOE G 430.1-5, *Transition Implementation Guide*

Requirements for surveillance and maintenance are stated in DOE O 430.1B, which identifies the minimum requirements for transition and disposition of an excess DOE facility. DOE G 430.1-2 is part of the DOE directives system, and is consistent with the principles and core functions of DOE P 450.4A. Other documents to be consulted to support the planning and conduct of transition and disposition activities include the following:

- DOE-STD-1120-2005, *Integration of Environment, Safety and Health Into Facility Disposition Activities*
- The good practice guides associated with life-cycle asset management

DOE G 430.1-3, *Deactivation Implementation Guide*

DOE G 430.1-3 was prepared to aid in the development, planning, and implementation of deactivation requirements and activities at DOE facilities that have been declared excess to any future mission requirements. It is one of the four guides developed to provide guidance for facility transition and disposition activities (see DOE G 430.1-2).

DOE G 430.1-4, *Decommissioning Implementation Guide*

DOE G 430.1-4 was prepared to aid in the planning and implementation of decommissioning activities at DOE 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 (see DOE G 430.1-2 description).

DOE N 221.6, *Reporting Fraud, Waste, and Abuse*

[Note: DOE N 221.6 has been canceled. There is no successor notice.]

DOE-STD-1082-94, Preparation, Review, and Approval of Nuclear Safety Requirements

[Note: DOE-STD-1082-94 has been canceled. There is no successor standard.]

DOE-STD-1083-95, *Requesting and Granting Exemptions to Nuclear Safety Rules*

[Note: DOE-STD-1083-95 has been superseded by DOE-STD-1083-2009, *Processing Exemptions to Nuclear Safety Rules and Approval of Alternative Methods for Documented Safety Analyses*, from which the following information is taken.]

DOE may grant temporary or permanent exemptions to its nuclear safety requirements in 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 shall utilize any procedures deemed necessary and appropriate to comply with the exemption responsibilities. DOE-STD-1083-2009 establishes an acceptable procedure to be used to request and grant exemptions to DOE nuclear safety rules in accordance with 10 CFR 820.

DOE-STD-1083-2009 provides a procedure to be used to request and approve a methodology to develop a DSA other than the methodologies explicitly included in 10 CFR 830, appendix A, table 2.

DOE-STD-1083-2009 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 835, "Occupational Radiation Protection"
- Any other rule in 10 CFR that DOE has adopted and determined to be related to nuclear safety

DOE-STD-7501-99, *The DOE Corporate Lessons Learned Programs*

DOE-STD-7501-99 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. DOE-STD-7501-99 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. The objective of DOE-STD-7501-99 is to enhance lines of communication among these activities with minimal impact to the processes and methods that currently exist. It encourages the use of a common language and institutional framework to facilitate DOE-wide sharing of work and organizational complexities. DOE-STD-7501-99 is designed to promote improved sharing of lessons learned across programs, not to create additional, overlapping programs or impose new requirements.

DOE-STD-7501-99 broadens the concept of lessons learned to include all areas of DOE business as practiced by DOE and contractor personnel at all levels of management and work performance. It is intended to support identification and sharing of good practices as well as lessons learned from unintended outcomes.

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

The following is taken from DOE O 414.1C (archived).

A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:

- Implements QA criteria as defined in paragraph 3 of this CRD, suspect/counterfeit item (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 (for nuclear-related activities)
  - ANSI/ISO/ASQ Q9001-2000 (for nonnuclear activities)
  - ANSI/ASQ Z 1.13, 1999 (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, QMS 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 450.4A
  - DOE/NNSA QC-1
  - DOE/RW-0333P
  - DOE/Carlsbad Field Office CBFO-94-1012, Revision 11, *Quality Assurance Program Description,* (for the Waste Isolation Pilot Plant and related activities)

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

5. QA personnel shall 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.

The following is taken from DOE G 414.1-2B.

The Office of Health, Safety and Security (HSS) has corporate responsibility for DOE's S/CI process. This responsibility includes the collection and review of information from internal and external sources, and the identification and dissemination of potential S/CI and DI (defective items) information to the DOE complex. S/CI information sources include occurrence reporting and processing system (ORPS), government industry data exchange program, the Institute of Nuclear Power Operation, Nevada Test Site database, accident investigation reports, and NRC generic communications.

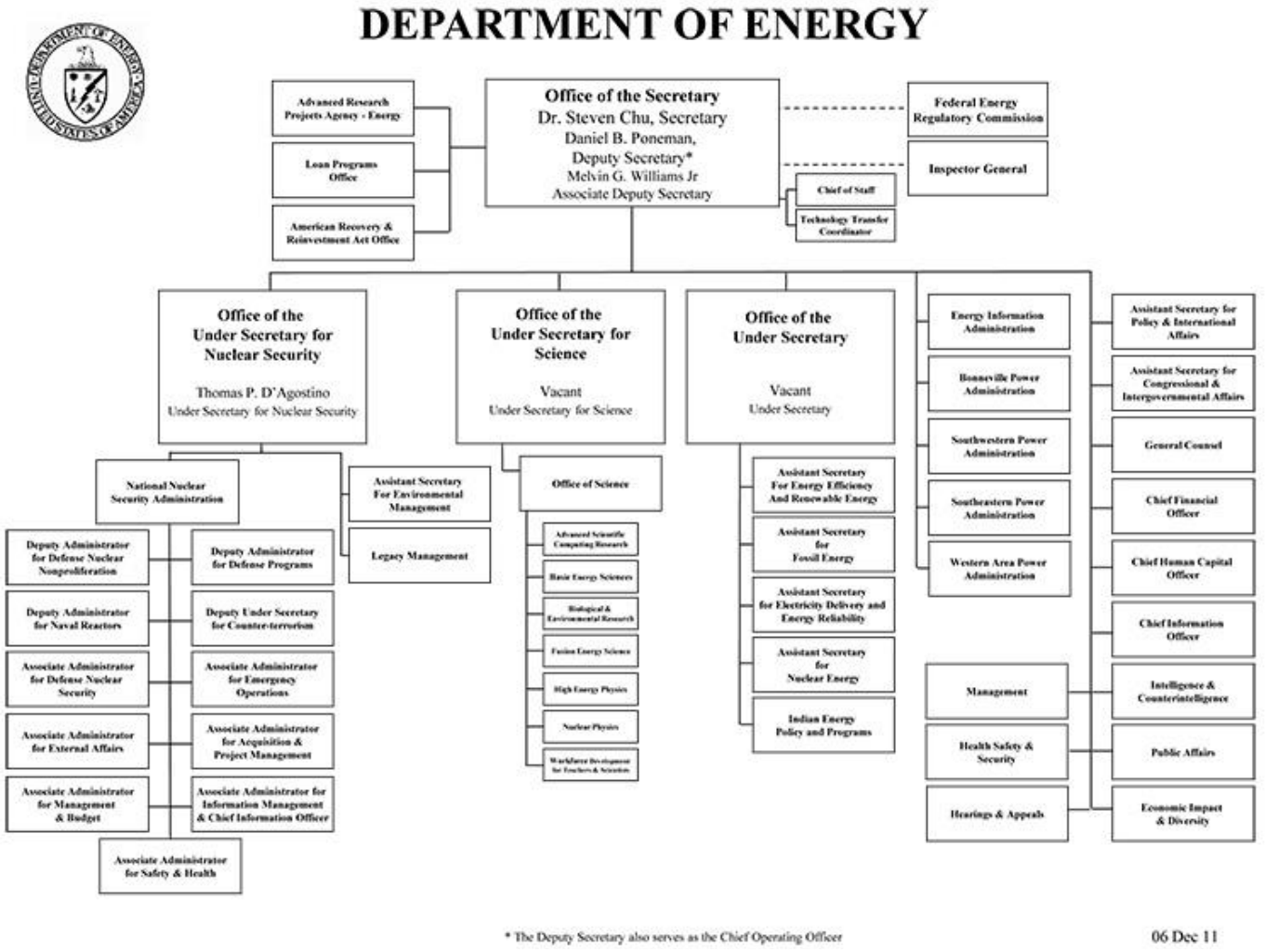
S/CI information is shared via other methods. The HSS operating experience committee conducts monthly conference calls and periodically discusses specific information regarding newly identified S/CIs or offers presentations from internal and external organizations concerning the status of existing and/or the development of S/CI programs. The operations experience Wiki page (http://operatingexperience.doe-hss.wikispaces.net/) hosts a dedicated web space for S/CI specific information, including informational publications, presentations, and videos from internal and external organizations.

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

The following is taken from the Office of Health, Safety and Security, draft copy of *Organizational Sustainability: A New Direction for DOE*.

DOE is a diverse and complex organization consisting of eight program offices, six operations offices, over twenty national laboratories and technical centers, and approximately fifty other field facilities spread out over the entire nation. Thousands of employees are performing a myriad of tasks in nearly all engineering and science disciplines utilizing multi-billion dollar budgets funded by the taxpayer.

The challenges to effectively manage an operation this complex are obvious. Information transfer from one organizational level to the next must be organized in such a way that enables effective governance and strategic decision-making while optimizing limited financial resources. Executive level decisions must be based on sound information such that more dollars can be funneled to good science and research and less money spent on needless bureaucracy. Figure 1, *DOE organization*, shows the elements of DOE and how they are interconnected.



Source: DOE Webpage

Figure 1. DOE organization

[Note: There are no formal written procedures within DOE for communicating between organizational elements. The following, taken from a recent white paper by Ms. Colette Broussard, Director, Office of Quality Assurance Policy and Assistance (HS-23), may be of use with respect to this competency statement and KSA.]

In an organization committed to quality, communication flows both directions (i.e., from top management down through to the worker and from the worker all the way through to top management). In the DOE HQ (top management) deals with the field offices (middle management) who have the responsibility for direct oversight and direction of the contractor management and contractor (worker) work. Within DOE, the overall QA program responsibility for QA policy and program maintenance as well as independent oversight of its effectiveness, lies within HSS. The overall responsibility for implementation at HQ, as well as in the field and contractor organizations, rests with the line management. Line management and HSS must interface with each other to ensure requirements are being interpreted correctly, implemented appropriately, and lessons learned are used for continuous improvement of training of personnel, execution of operations and the written directives/requirements.

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

The following is taken from DOE's Opennet, *Programs to Encourage Public Participation at Department of Energy Sites*.

The DOE is committed to improving communications with the public and to actively encourage public input into decisions. Initiatives have included educational tours and lectures, the formulation of citizens' advisory boards, public meetings, information fairs, local media tours and briefings, and the formation of outreach programs. All initiatives are tailored to needs expressed by the local and general public. Together with improved accessibility to information, the programs are designed to foster good relations with the Department's neighbors and to provide them with the opportunity to participate actively in the consideration of means to address current issues and concerns.

Each of the Department's sites has tailored its programs to the needs of its particular neighbors, its mission, and the resources available.

The benefits derived from these policies and procedures include the following:

- The sites have built trust and credibility with the public by encouraging an open environment for communication and participation.
- The Department's openness, including the many public participation activities and initiatives, have strengthened the dialogue among the DOE, the public and regulatory officials, and have helped all parties to better understand and respond to diverse ideas, attitudes, and concerns.
- Concerned citizens, environmentalists, and special interest groups can now tour many facilities, and receive information on site activities, issues, and concerns.
- Citizens have access to management personnel through public involvement initiatives.

DOE has improved relations with its key stakeholders.

- The public has increased opportunities to visit and learn about site activities and is encouraged to participate in the DOE decision-making process.
- Public interest organizations, local government organizations, educational institutions, environmental specialists, researchers, and scientists benefit from having greater access to and information about activities at DOE sites.

6. QA personnel shall 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)**

Assessment Reports

The following is taken from DOE G 414.1-1B.

Assessment reports are required for documentation of assessment results. Assessment team leaders have the overall responsibility for preparing the report and obtaining appropriate approval for its release as applicable. The report may be formal (e.g., distributed by memorandum) or informal (e.g., letter to file or email), 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 assessment report should be clear, concise, accurate, 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 develop and implement appropriate improvement plans.

Technical Reports

The following is taken from DOE O 241.1B.

Scientific and technical information (STI) that contains findings, analyses, or results related to research and development or other scientific and technological endeavors; is generated by work funded by DOE or performed at DOE facilities; and is deemed by the originator to be useful beyond the originating organization (i.e., intended to be published or disseminated). Transparency and accessibility of STI support the continued advancement of a sound science and technology base to help guide and inform the nation's critical public policy decisions; advance the national economic, and energy security of the U.S.; facilitate the accomplishment of DOE mission objectives; and maximize the public value of such efforts. STI is produced in various media (e.g., textual, audiovisual, multimedia, and digital) and is disseminated as technical reports; conference papers and presentations; journal articles; theses and dissertations; patents; scientific and technical software; etc. The majority of DOE-funded STI is publicly releasable, with a small percentage requiring restricted access.

Technical Papers

The following is taken from Columbia University *Writing Technical Articles.*

A good research paper has a clear statement of the problem the paper is addressing, the proposed solution(s), and results achieved. It describes clearly what has been done before on the problem, and what is new. The goal of a paper is to describe novel technical results.

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 two to three years.
- Outline the rest of the paper.
- 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 following:

- The architecture of the proposed system(s) to achieve the model, which should be more generic than a personal 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 the approach and results sections, which go together, are written first. 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 the paper a title.

QAP

The following information is taken from DOE G 414.1-2B.

DOE O 414.1D and 10 CFR 830, subpart A require that an organization develop, document, implement, and maintain an effective QAP. The goal of the QAP is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. The QAP is defined as the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

The focus of the QAP should be to properly and safely accomplish the DOE mission. The QAP should be integrated with the ISMS as described in DOE P 450.4A and 48 CFR 970.5204-2, "Laws, Regulations, and DOE Directives."

The QAP should describe the organizational structure and interfaces, functional responsibilities, and levels of authority. The scope, depth, and rigor of the QAP's application of requirements should be determined by the use of a grading process. The logic, method of implementation, and basis for grading should be documented in the QAP, periodically reviewed in light of changes that may have occurred, and, if appropriate, revised to reflect those changes.

DOE O 414.1D requires the QAP to clearly identify the standards, or parts of the standards, used to address the requirements. In many cases, the particular standards to be used are specified by the customer. The standards selected should suit the products and services of the organization and its customers.

Work Process Documents

The following is taken from DOE G 414.1-2B.

Work process documents are the procedures, work instructions, or other appropriate means used to define work processes. 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 can serve as the point of integration for the ISM and QA into an integrated management approach.

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.

Video 6. How to write and speak effectively
http://www.dailymotion.com/video/xh81oq_how-to-write-speak-and-think-more-effectively_news

Video 7. Effective writing
http://www.youtube.com/watch?v=4XPUcJGABXI

Video 8. Technical writing
http://www.youtube.com/watch?v=WyVd3FL4sVE&feature=related

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

This is a performance-based KSA. The Qualifying Official will evaluate its completion.

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

Source: National Archives and Records Administration

Figure 2. National Archives and Records Administration, Washington DC

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

The following is taken from DOE G 414.1-2B.

Procedures, work instructions, or other appropriate means used to define work processes should be documented and controlled. Controls are documented and communicated to facility/activity personnel to ensure appropriate application.

The following is taken from DOE/NNSA QC-1.

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.

The following is taken from DOE G 414.1-2B.

A document control system should be in place to control the preparation, review, approval, issue, control, and revision of documents. Documents should be used by organizations, projects, or programs to control policy administrative and/or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data to be controlled for reference purposes. The document control system should be established to supply the appropriate 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 450.4A 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 performed. Records may be in a variety of forms (e.g., electronic; written or printed; microfilm; photographs; radiographs; or optical disks). Typical records include procedures; plans, and manuals; training and qualification results; acceptance test results; technical/regulatory correspondence; operational records; design basis descriptions, design review results, design revisions, CM data; and quality problem resolutions or any other required information.

Records should be compiled in a records management system as described in DOE O 243.1A, *Records Management Program*. The system should include provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records. Procedures for record retention, protection, preservation, correction, traceability, accountability, and retrievability should be specified. The records management system should have schedules for records retention and disposition consistent with the requirements of DOE O 200.1A.

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 (NARA), 36 CFR, “Parks, Forests, and Public Property,” chapter XII, “National Archives and Records Administration,” 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.

The following is taken from DOE O 243.1A.

Recordkeeping requirements:

- Establish recordkeeping requirements as prescribed by laws, regulations, directives, and processes, and reflect adequate and proper documentation of the Department’s organizations, missions, functions, policies, and decisions.
- Provide mandatory records management training, including the management of electronic and vital records, for all Federal personnel, as appropriate for their responsibilities. Such training will include records management training for all new employees and an annual refresher course.

- Ensure that departing Federal employees identify and transfer any records in their custody to an appropriate custodian, or the person assuming responsibility for the work.
- Identify and arrange for NARA appraisal and transfer of records proposed to be of permanent value based on historical, evidential, or informational content.
- Maintain electronic records according to 36 CFR, subchapter B, "Records Management," by building electronic records keeping or by capturing the electronic information systems' records in an electronic records management application (RMA).
- Identify and address records management requirements during the planning, development, or redesign of electronic information systems with an emphasis on
  - business processes that support the records management life cycle and the identification, description, and preservation of record content;
  - design and development practices that incorporate records management requirements, to ensure new systems and systems redesign address applicable legal requirements for managing electronic records.
- Protect electronic records against technological obsolescence according to 36 CFR, subchapter B.
- Develop and implement procedures and processes for electronic records that
  - prevent unauthorized addition, modification or deletion;
  - protect the records against power interruptions;
  - provide a secure audit trail to enable addition, modification, or deletion of records and retrieval activities;
  - prevent deletion of a record identifier once it is defined;
  - prevent deletion of indexes, categories, labeling, or other records identification;
  - retain records in an accessible and usable format until the authorized disposition date;
  - provide adequate recovery and rebuild procedures so that records may be restored following a system or storage media malfunction;
  - maintain the integrity of redacted records and ensure that redacted material is not accessible by unauthorized persons.
- Manage e-mail records along with their metadata and attachments by means of an electronic information system that has electronic records keeping functionality, or an electronic RMA. The records may not be deleted from the e-mail system until the RMA or electronic information system electronic records keeping functionality has been implemented as required by DOE O 243.1A, paragraph 4.i., and the record's authorized retention period has elapsed, or the records have been copied to paper or microform or some other suitable media. Transitory records (i.e., records that may be destroyed in 180 days or less) may be managed in their native e-mail system.
- Back up all electronic systems containing electronic records regularly according to business needs and manage backups according to DOE records disposition schedules.
- Capture and manage records created or received via social media platforms, including websites and portals, or from personal e-mail used for departmental business. Capture and preserve such records according to NARA-approved disposition scheduled and DOE-approved guidance.

- Manage web content and web management and operating records by ensuring the records are captured, retained for appropriate retention periods, and disposed of according to NARA-approved disposition schedules and recordkeeping guidance.
- Conduct internal evaluations of records management practices and programs, including assessing the economy of the operation, at least every three years. Prepare and submit evaluation reports to departmental records officer within 60 days of completing the evaluation. Guidance on conducting evaluations may be obtained from the DOE Office of the Chief Information Officer (OCIO) Records Management Division.

Identify and manage vital records according to DOE O 243.2, *Vital Records*.

Video 9. National Archives and Records Administration
http://www.youtube.com/watch?v=-GjlNGntjSU

d. Discuss methods of record storage and retrieval requirements.

The following is taken from DOE O 243.1A.

Maintain up-to-date inventories, file plans, or electronic information systems that provide for the identification, location, and retrieval of all categories of records created and received in the course of official business. Store inactive records in facilities that meet the requirements of applicable Federal regulations found in 36 CFR, subchapter B. See NARA Bulletin 2008-06, *Records Storage Facility Standards*, for additional guidance.

Maintain and dispose of records according to NARA-approved records disposition schedules, as posted on the OCIO records management web pages. Request approval for disposition from authorities at NARA for all unscheduled records. Apply disposition schedules according to applicable Federal regulations found in 36 CFR, subchapter B.

Preserve records beyond their approved retention periods when they have been placed under a destruction moratorium for purposes of audits, litigation, Freedom of Information Act appeals, and similar obligations. A destruction moratorium will be lifted only by the departmental records officer, in coordination with the DOE/NNSA Office of General Counsel, or an office of chief counsel.

Video 10. Electronic records management
http://www.archives.gov/era/

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

The following is taken from 36 CFR 1220.18.

Temporary records are any Federal records that have been determined by the Archivist of the United States to have insufficient value (on the basis of current standards) to warrant its preservation by NARA. This determination may take the form of

- records designated as disposable in an agency records disposition schedule approved by NARA (SF 115, *Request for Records Disposition Authority*); or

- records designated as disposable in a general records schedule.

Lifetime Records

The following is taken from U.S. Nuclear Regulatory Commission Regulation NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition.*

Lifetime records are those that meet one or more of the following criteria:

- Significant value in demonstrating capability for safe operation
- Significant value in maintaining, reworking, repairing, replacing, or modifying an item
- Significant value in determining the cause of an accident or malfunction of an item
- Provision of required baseline data for in-service inspections and in-service tests

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.

Permanent Records

The following is taken from 36 CFR 1220.18.

Permanent records are any Federal records that have been determined by NARA to have sufficient value to warrant its preservation in NARA, even while they remain in agency custody. Permanent records are those for which the disposition is permanent on SF 115 approved by NARA on or after May 14, 1973.

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

[Note: DOE O 200.1 has been superseded by DOE O 200.1A from which the following is taken.]

Information technology will be managed consistent with all statutory, regulatory, OMB, and Department requirements, including the E-Government Act and Federal Information Security Management Act, the Government Performance Results Act, the Government Paperwork Elimination Act, and the strategic and operational plans of the Department. Integrated IT management will be administered by the OCIO and supported by various working groups fulfilling the following requirements.

Acquisition, use, and management of IT

- Information technology strategic planning
  - Maintain the information resources management strategic plan that links IT planning and investment decisions to program mission and goals and establishes Department-wide IT performance goals, objectives, and measures.
  - Conduct IT performance management, including the development of performance measures that are quantitative and outcome-oriented.
- Capital planning and investment control
  - Implement CPIC processes that effectively manage the selection, control, and evaluation of departmental IT investments, ensuring prioritization and sound management, including fulfilling OMB reporting requirements for IT

investments, as detailed in OMB Circular A-11, *Preparation, Submission, and Execution of the Budget*, for exhibits 300 and 53.
    - Ensure that projects and programs are utilizing a systems development life-cycle methodology that effectively manages the development and maintenance of IT systems.
- Enterprise architecture that supports mission needs and provides business value through collaboration among departmental elements
    - Comply with OMB direction and DOE directives.
    - A governance process that promotes integrated business analysis in support of management decision-making.
    - Align with the CPIC process.
    - Maintain target enterprise architecture aligned with departmental and program secretarial office strategic plans.
- Hardware and software acquisition
    - Perform software asset management including the tracking, licensing, and utilization of DOE's software license inventory. Develop and maintain procedures to prevent illegal or inappropriate use of software licenses.
    - Ensure that DOE IT hardware acquisition and replacement practices are consistent with departmental strategic and operational plans, and all statutory, regulatory, administrative, and OMB requirements. They will consist of processes that support DOE in making better hardware decisions and enhancing hardware management.
    - Oversee software QAPs to ensure that all software owned or maintained by DOE is subjected to formal QA, pursuant to DOE O 414.1D.
- IT operations and use
    - Ensure software acquisition requirements adhere to the 1998 amendment to the Rehabilitation Act, section 508, to provide access for people with disabilities.
    - Ensure that OMB and established DOE web policy and website requirements are met and all public websites are available to persons with limited English proficiency, per EO 13166, *Improving Access to Services for People with Limited English Proficiency*, and corresponding Department of Justice, secretarial memorandum, Access to Programs and Activities by Persons with Limited English Proficiency, dated April 11, 2006.
    - Promote appropriate personal use of government equipment, consistent with departmental requirements.
    - Promote procedures to prevent illegal or inappropriate use of software licenses.
- Oversee cyber security policies, procedures, and practices to ensure that they are consistent with OMB and established departmental requirements.
- Manage spectrum management processes consistent with regulatory guidance, OMB requirements, and the strategic and operational plans of DOE.
- Manage records management processes consistent with regulatory guidance, OMB requirements, and the strategic and operational plans of DOE.

Video 11. Revolutionizing IT in government
http://www.youtube.com/watch?v=InI5n3NTvR4&feature=related

B. General Technical Performance

1. **QA personnel shall 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., Federal Employee Occupational Safety and Health (FEOSH)).**

The following is taken from DOE PD-440-04, revision 1, *Federal Employee Occupational Safety and Health Program (FEOSH).*

Line management is responsible for the overall integrity and implementation of the FEOSH program for DOE. In order to implement an effective program, line management will support and initiate awareness activities; workplace inspections; investigation of safety and health concerns; hazard communication, abatement, and control; employee training; and other safety- and health-related initiatives. Line managers and supervisors are responsible for the safety and health practices of their employees in their respective work areas and when performing work activities when away from their assigned office.

Managers, site managers, and employees must analyze the hazards to employees at their normal work station and while on official travel. The following methods can be used to identify work-related hazards faced by employees in Department-occupied space, at DOE sites, or while on official travel:

- Hazard analysis
- Accident/incident investigations
- Routine self-assessment
- Inspections

Hazard analysis

Hazard analysis of a work activity can be conducted either informally or formally. It is most effective when performed informally during the course of daily work activities by supervisory and non-supervisory employees and qualified safety and health professionals. The primary goal for identifying hazards in the workplace or activity is to determine why they exist so effective mitigating actions can be taken. Hazards identified include office hazards and vehicle operation hazards.

Accident investigation

Accident investigation is a systematic search to uncover facts and details of a loss-producing event and to determine what recommendations and corrective actions are needed in order to prevent a recurrence.

Self-assessment

Self-assessment is a systematic process of evaluating the effectiveness of safety and health policies and programs as well as the systems that support them. The most basic form of self-assessment is conducting daily walk-through of the work space and regular review of work activities.

Investigation

Inspections of work areas help to improve employee safety and health. Types of inspections vary but usually fall into three main categories: periodic/annual, compliance-oriented, and employee concerns. The objective of an inspection is to improve employee working conditions through systematic identification and subsequent abatement of hazards.

Hazard prevention and control can be accomplished via the following:

- Engineering controls
- Work practice controls
- Administrative controls
- Preventative maintenance
- Emergency preparedness
- Personal protective equipment
- Occupational medical programs
- Training program

Video 12. Identifying hazards in the workplace

http://www.ehow.com/video_5112526_identifying-health-safety-hazards-workplace.html

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

The following is taken from 10 CFR 63.142.

DOE shall establish a QAP that complies with the requirements of 10 CFR 63.142, "Quality Assurance Criteria," at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout the facility life according to those policies, procedures, or instructions.

DOE shall establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality. These measures must ensure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

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

The following is taken from DOE G 414.1-2B.

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

Managers are responsible for ensuring that personnel 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 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. Before workers begin work, management should provide adequate information on the following:

- Customer requirements
- 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
- Data requirements for the work and final product
- Acceptance criteria applicable to the work and final product
- Procedures for verification of the completed work using established criteria

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.

The following is taken from DOE G 414.1-2B.

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

- prevent the use of incorrect or DIs
- identify and control S/CI(s)
- provide for the control and maintenance of items

The identification and control process should apply from the manufacture and receipt of the item through delivery, installation, or use. The process should provide for the identification and configuration control of installed or replacement items consistent with specified requirements. Suitable information used for identification can include listing the unique part, lot, heat, model, version, or serial numbers on the item or in records traceable to the item, or both. Physical identification of items is preferred.

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

The following is taken from DOE G 414.1-2B.

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

The following is taken from DOE/NNSA QC-1.

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.

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

The following is taken from DOE/NNSA QC-1.

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.

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

[Note: DOE O 433.1 has been superseded by DOE O 433.1B.]

a. Define each of the following maintenance-related terms and explain their relationship to each other:

- **Corrective**
- **Planned**
- **Preventive**
- **Reliability-centered**
- **Predictive**

The following is taken from DOE G 433.1-1A.

Corrective

Corrective maintenance is performed in response to failed or malfunctioning equipment, systems, or facilities in order to restore their intended function and design capabilities. Analysis should be performed to determine the causes of unexpected failure and the corrective action that should be taken, including feedback into the preventive and predictive maintenance (PdM) programs, and training and qualification programs. The establishment of priorities for corrective maintenance should be based on plant objectives and the relative importance of the equipment.

Planned
Planned maintenance is maintenance scheduled as a result of periodic maintenance results indicating a future failure.

Preventive
Preventive maintenance (PM) consists of all those systematically planned and scheduled actions performed to prevent equipment failure. The PM program should define the required activities and the frequency with which they should be performed. Selection of required PM actions should be based on manufacturers' recommendations, plant experience, and good engineering practice. PM frequency should be based on adequately implementing the entire program, considering such elements as regulatory requirements, consensus standards, vendor recommendations, as low as reasonably achievable (ALARA) considerations, and performance monitoring. A documented basis for the planned actions should be provided.

Video 13. What is preventive maintenance?
http://www.ehow.com/video_4766699_definition-preventive-maintenance.html

Reliability-Centered
Reliability-centered maintenance (RCM) is a structured process commonly used to determine the equipment maintenance strategies required for any physical asset to ensure that it continues to fulfill its intended functions in its present operating context. RCM provides a systematic method for analyzing functions, failure modes, and periodic maintenance to monitor and maintain equipment to ensure it continues to meet its functional requirements.

Predictive
Predictive maintenance consists of measurements or tests performed to detect equipment or system conditions. These activities should be less invasive, time consuming, and costly than preventive or corrective maintenance. The results of PdM can be analyzed to determine what degree of maintenance is required and when it is needed. This provides benefits similar to PM without performing unneeded maintenance with its cost and potential for human error. Corrective maintenance efficiency may be improved by directing repair efforts at problems detected using PdM techniques. Industry studies have shown significant savings and improved reliability using PdM. PdM should be integrated into the overall maintenance program so that proactive repair planned maintenance may be performed before equipment failure.

The following is taken from DOE G 433.1-1A.

A maintenance work-control program should be integrated with the planning system and with ISMS. The work-control program should ensure work activities are consistent with the facility safety basis and effectively identified, initiated, planned, approved, scheduled, coordinated, performed, and reviewed for adequacy and completeness. The program should ensure the availability and operability of the SSCs that are part of the safety basis. The work-control program should apply the same policies and procedures for non-facility contractor and subcontractor personnel conducting maintenance on the site as facility personnel.

The work-control system should provide the data necessary to properly plan and schedule maintenance activities, as well as to support failure analysis and maintenance history. The maintenance organization should establish high standards for all maintenance personnel supervising and performing maintenance activities. Maintenance management should be

involved and oversee work to ensure these standards are met and work is conducted according to DOE, contractor, and facility policies and procedures.

Configuration control is maintained by ensuring that systems and equipment are restored to their original condition following maintenance.

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

The following is taken from DOE G 433.1-1A.

A maintenance work control program should be integrated with the planning system and with ISMS. The work control program should ensure work activities are consistent with the facility safety basis and effectively identified, initiated, planned, approved, scheduled, coordinated, performed, and reviewed for adequacy and completeness. The program should ensure the availability and operability of the SSCs that are a part of the safety basis. The work control program should apply the same policies and procedures for non-facility contractor and subcontractor personnel conducting maintenance on the site as facility personnel. The work-control system should provide the data necessary to properly plan and schedule maintenance activities, as well as to support failure analysis and maintenance history.

DOE requires facility operators to develop and implement a nuclear maintenance management program (NMMP) for hazard category 1, 2, and 3 nuclear facilities under DOE control. DOE O 433.1B, requires each organization to develop NMMP-DD (description documentation) that addresses the topics listed in DOE O 433.1B and that the NMMP-DD be submitted to DOE for review and resubmission for review and approval is required at least every three years.

The following is taken from DOE O 433.1B.

Federal and contractor organizations must submit NMMP-DD to DOE/NNSA for review and approval prior to the startup of new hazard category 1, 2, and 3 nuclear facilities and at least every three years for all nuclear facilities. NMMP-DD must be, at a minimum, an applicability matrix or a combination of multiple documents. The following elements must be covered:

- Correlation of the requirements in DOE O 433.1B, attachment 2, *Maintenance Management Program Requirements for DOE Nuclear Facilities*, to the applicable facilities
- Correlation of the implementing documents to the specific requirements in DOE O 433.1B, attachment 2
- Documentation of the basis for applying a graded approach, if applicable

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

The following is taken from DOE G 433.1-1A.

According to DOE O 433.1B, and using a graded approach as applicable, the NMMP must be integrated with applicable programs (e.g., safety management programs) and requirements identified by Federal regulations and other DOE Orders, manuals, and CFRs to include:

- DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*
- DOE O 414.1D, *Quality Assurance*
- DOE O 420.1B, chg 1, *Facility Safety*
- DOE O 430.1B, chg 2, *Real Property Asset Management*
- DOE O 440.1B, *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*
- DOE O 422.1, *Conduct of Operations*
- DOE O 426.2, *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*
- DOE O 436.1, *Departmental Sustainability*
- DOE O 458.1, chg 2, *Radiation Protection of the Public and the Environment*
- DOE O 450.2, *Integrated Safety Management*
- 10 CFR 830, "Nuclear Safety Management," subpart A, "Quality Assurance Requirements"
- 10 CFR 830, "Nuclear Safety Management," subpart B, "Safety Basis Requirements"
- 48 CFR 970.5223-1, "Integration of Environment, Safety, and Health into Work Planning and Execution"
- 10 CFR 835, "Occupational Radiation Protection"
- 10 CFR 850, "Chronic Beryllium Disease Prevention Program"
- 10 CFR 851, "Worker Safety and Health Program"

The NMMP should address the following:

- Implementation of the requirements, policies, processes, and procedures contained in each of the above directives and regulations; including integration with the processes and procedures that implement the requirements of DOE O 433.1B
- How the NMMP is the safety management system for defining the maintenance of SSCs consistent with the expectations outlined in the documented safety analysis (DSA)

The description document should address such items as how maintenance supports the safe operation and is integrated with the following safety basis-related elements: DSA, including technical safety requirements, the unreviewed safety question process, QA program, CM, and ISM.

According to DOE O 433.1B, the NMMP must include incorporation of the CM program to control approved modifications and to prevent unauthorized modifications to safety SSCs. Implementation of CM programs are according to requirements of DOE O 420.1B.

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

The following is taken from DOE G 433.1-1A.

Material and equipment should be stored in a manner that provides adequate protection and accessibility with due consideration for environmental conditions such as temperature, humidity, and particulates. Items requiring periodic maintenance or checks, such as checking energized heaters, changing desiccant, meggering motors, rotating shafts, or changing cover gas, should be located to simplify this work. A method of tracking the requirements and documenting completion should be used. Consideration should be given to use of the PM process for this purpose versus using another stand-alone method.

The receipt and issue of items from stores should be documented promptly so that the inventory record accurately reflects the current inventory. The record system should indicate the location of items in the warehouse or other designated storage areas. A method should be used to control access to storage areas.

Shelf life control should be provided for items that degrade over time. Various items with finite storage lifetimes should be tracked so that stock that has exceeded its shelf life is not issued. Any material reaching the end of its shelf life should receive proper engineering analysis with appropriate vendor input to extend its storage life, or the material should be disposed and new material ordered. Reordering/restocking programs should incorporate appropriate lead times to ensure sufficient material with good shelf life is available for issue.

Material and equipment subject to restricted use and distribution such as safety class items, critical spare parts, certain sealants and compounds, precious metals, etc., should have clearly defined instructions that provide for the following:

- Unique identification
- Segregation from normal stock
- Access control
- Issue only to those on authorized signature lists
- Purchase order tracking and ready traceability from design drawing through purchasing, receipt, storage, handling, and installation

Safety material and equipment should be segregated from non-safety related material and equipment to prevent inadvertent use of the wrong category of item. If segregation is not practical, marking and tagging techniques should be developed to preclude use of the wrong material or equipment.

A system should be established to ensure the proper storage, segregation, and control of hazardous materials such as chemicals, radioactive/reactive organics, reagents, explosives, flammables/combustibles, corrosives, and pesticides/herbicides; specialty equipment and tools; and general materials, equipment, and tools. Controls should be established for field storage of such consumables to ensure that they are properly stored, identified, and used.

A process for periodic general inspections of storage areas should exist. Typical storage control observations should document the following:

- Reactive chemicals are segregated and secured, as required.
- Flammables are marked and stored in proper containers.

- Radioactive substances are properly shielded and marked.
- Carcinogens are segregated from other materials and equipment.
- Stainless steel and other pedigree metals are segregated from other metals (particularly carbon steel).
- Motors, pumps, relief valves, and other items are stored on their bases.
- Stacking of items, crates, boxes, barrels; etc., does not exceed stacking recommendations.
- Packaging and seals have not been violated leaving contents exposed to degradation caused by the intrusion of foreign materials or environmental conditions.
- Machined and threaded surfaces are left adequately protected.
- Applicable insect and rodent controls are in effect.
- Applicable shelf life conditions are in effect.
- The building structure and support systems are adequate and in working order.
- Environmental controls that control moisture, dust, sun exposure, etc., are in effect.

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

The following is taken from DOE G 433.1-1A

Temporary repairs are recorded and controlled by the facility temporary modification program. Permanent repairs are scheduled when facility conditions permit.

A modification is a planned and controlled change to a facility SSC that is accomplished according to the requirements and limitations of applicable procedures, codes, standards, specifications, licenses, and predetermined safety restrictions identical to or commensurate with those of the item being modified. The maintenance process should address installation and verification of facility modifications based on the complexity of the task, the extent of the modification, and the importance of the equipment, just as is done for normal maintenance activities.

Temporary modifications allow equipment to remain in or be returned to service in a condition that is not the same as the currently approved design. They may result in short-term alterations to facility SSCs that do not conform to permanent drawings or other design documents. Temporary modifications should be reviewed, approved, documented, and periodically reassessed. This ensures that temporary alterations made to facility SSCs do not unacceptably alter or degrade the original design, facility safety, or reliability. The number and duration of temporary modifications should be minimized. Temporary and non-standard repairs should be approved and tracked as temporary modifications.

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.

The following is taken from DOE G 414.1-2B.

Design Inputs

Design inputs should be based upon contractual requirements and customer expectations and should be complete and technically correct. 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, and maintenance. Design processes should be considered for any engineering/design requirements during the deactivation and decommissioning of excess facilities. 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 configurations. The administrative interface process should clearly indicate responsibilities for design output documents, including the requirements for document control, CM, and records management.

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

The following is taken from DOE G 414.1-2B.

Design changes should be controlled by measures commensurate with those applied to the original design. Design changes include field changes and nonconforming items dispositioned for "use-as-is" or "repair." Temporary modifications should receive the same levels of control as the designs of permanent modifications.

Design records should include documentation such as design inputs; calculations; design analyses; engineering reports; design outputs; design changes; design verification activities; a list of approved and controlled computer codes; and other documents that provide evidence that the design process was completed satisfactorily. Design documents should be updated to include all design changes, including field changes, to maintain configuration control.

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

The following is taken from DOE G 414.1-2B.

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 independent of those who developed 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 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, including preoperational testing, before relying on the SSC to perform its function.

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

The following is taken from DOE G 414.1-2A (archived).

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

The following is taken from DOE N 203.1 (canceled).

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 QA;
- all DOE software engineering follows identified standards and best practices throughout the project and product life cycle;
- 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 CRD, DOE N 203.1, attachment 1, *Contractor Requirements Document DOE N 203.1 Software Quality Assurance*, 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 CRD will be required to the extent set forth in the contract.

The provisions of DOE N 203.1 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, 1) administrative/business-oriented software, 2) scientific/engineering software, 3) manufacturing-oriented software, and 4) process control (e.g., programmable logic control instructions).

The requirements of DOE N 203.1 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 DOE N 203.1 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 DOE N 203.1 requirements.

EO 12344, *Naval Nuclear Propulsion Program*, (set forth in Public Law PL 106-65, *National Defense Authorization Act for Fiscal Year 2000* [50 U.S.C. 2406, *Deputy Administrator for Naval Reactors*]) 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 QA requirements implemented within the program. Accordingly, DOE N 203.1 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 life-cycle 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 (V&V), 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 DOE G 414.1-2B and DOE O 414.1D 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 O 226.1B 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 450.4A, 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 the 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 (ESH&Q) organizations; and the receiving/storage organization.

The following is taken from DOE G 414.1-3 (archived).

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 QA 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 QAPs 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 the following:

- 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.

The following is taken from DOE G 414.1-2B.

Procurement documents should clearly state or reference requirements and acceptance criteria for purchased items and services. Procurement documents should include any specifications, standards, QAP requirements, and other applicable documents referenced in the design documents. Parameters and requirements should be specified, such as document submittals, product-related documentation, problem reporting, administrative documentation, personnel or materials qualifications, tests, inspections, performance expectations for services, and reviews. A graded approach should be applied based on the significance of the item or service procured.

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

The following is taken from DOE G 414.1-2B.

The objective of evaluating suppliers is two-fold: 1) to verify the supplier has implemented a QAP that conforms to contractual requirements, and 2) to verify that the supplier is capable of providing the items or services identified in the contract. An effective evaluation method is to conduct an assessment of the supplier's facility. The assessment may include an evaluation of personnel, technical and equipment capabilities, and processes.

Supplier qualification can include some of the following:
- A review of the supplier's history of providing identical or similar items or services
- A review of shared supplier quality information
- An evaluation of certifications or registrations awarded by nationally/internationally accredited third parties
- An evaluation of documented qualitative and quantitative performance information provided by the supplier

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

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 following is taken from DOE G 414.1-2B.

The qualified supplier's performance should be evaluated periodically to confirm continuing capabilities. Qualified supplier's performance should be reviewed annually and audited every third year unless events warrant more frequent assessment. Such evaluation should include monitoring of the supplier's work processes to ensure conformance to those requirements that cannot be readily determined by inspection or test of the product. In some cases, due to the importance of the items being procured or for known quality problems with the supplier, a full-time resident inspector may be assigned to monitor the supplier's performance. Monitoring may include the following:

- Surveillance of in-process work activities and review of work package documentation
- Inspection of facilities and processes
- Review of plans and progress reports
- 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.

The following is taken from DOE G 414.1-2B.

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

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

- Inspections of materials or equipment at the supplier's facility
- Receipt inspection of the shipped items using established item-critical characteristics
- Review of objective evidence such as certifications and reports
- Verification or testing of items before or following shipment

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

The following is taken from DOE G 414.1-2B.

The specified inspections and tests for items, services, and processes should be performed with calibrated equipment using established acceptance and performance criteria. Inspections and tests verify that the physical and functional aspects of items, services, and processes meet requirements and that they are fit for acceptance and use. Performance expectations, inspections, and tests should be identified or considered early in the design process and/or specified in the design output and procurement documents. Before performing inspections or tests, workers should check the materials and equipment used to perform such inspections and tests to ensure adequate calibration and acceptability.

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

The following is taken from DOE G 414.1-2A (archived).

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, certified material test reports, maintenance data, nonconformance documentation, corrective actions, approved changes, waivers, and deviations. Supplier-issued certificates of conformance should not be accepted without an accompanying test report that provides the results of inspection and tests required by the governing product specification or the manufacturer's specifications.

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

The following is taken from Electric Power Research Institute (EPRI) NP-5652, *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07).*

The action taken to utilize a commercial-grade item in a safety-related application has commonly been called dedication by the nuclear industry. The June 15, 2012 edition of 10 CFR 21, "Reporting of Defects and Noncompliance," requires an item to be dedicated before it could be used as a basic component. The term dedication defines the point in time when the commercial-grade item becomes subject to 10 CFR 21 reporting requirements.

Commercial-grade items used in safety-related applications can be shown to be equivalent in quality to a safety-related item purchased as a basic component. The utilization of commercial-grade items intended for safety-related applications involves two distinct processes:

- A technical evaluation to ensure that requirements for an acceptable item are specified in the procurement document
- Acceptance methods to reasonably ensure the item received is the item that was specified

The technical evaluation process provides a means to specify the correct requirements for an item in a procurement document. If a supplier can furnish a like-for-like replacement, only a minimal technical evaluation can be required in developing procurement specifications. If a

supplier can only offer an alternative item, a technical evaluation should be conducted to assure equivalency.

The acceptance methods for commercial-grade items provide reasonable assurance that the item received is the item that was specified. This guideline concentrates on the acceptance process consisting of measures that ensure the correct item has been supplied.

To utilize a commercial-grade item in a safety-related application, reasonable actions must be taken to ensure the item is appropriate for its intended application. The technical evaluation in combination with an appropriate acceptance process provides the assurance that the specified item is adequate to meet 10 CFR 50, appendix B, requirements.

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.

[Note: DOE O 440.1 has been superseded by DOE O 440.1B; however, S/CI is now covered in DOE G 414.1-2B, from which the following is taken.]

Suspect/counterfeit items are reported according to DOE O 232.2.

DOE O 232.2 requires prompt reporting of all S/CIs, regardless of their location/application. S/CIs should be reported to the responsible DOE operations office manager and program manager by means of ORPS, and to the Office of Inspector General (OIG). The use of ORPS and the S/CI notification process will facilitate the contractor's reporting obligation. Reporting an S/CI in ORPS does not substitute for reporting to the OIG.

For each potential S/CI identified, HSS prepares a data collection sheet (DCS) and assigns a tracking number. The DCS is used to facilitate review of the S/CI or DI and to document actions taken to resolve the issue. After appropriate review, the DCS is published by HSS.

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 O 440.1 has been superseded by DOE O 440.1B; however, S/CI is now covered in DOE G 414.1-2B. DOE G 440.1-6 has been cancelled and replaced by DOE G 414.1-3 which has been cancelled. 10 CFR 830.120, "Nuclear Safety Management," dated May 18, 2012, does not cover S/CI. DOE O 232.1 has been replaced by DOE O 232.2. DOE O 414.1A has been superseded by DOE O 414.1D.]

The following is taken from DOE O 414.1D.

Contact the DOE Inspector General (IG), before destroying or disposing of S/CIs and corresponding documentation, to allow the IG to determine whether the items and documentation need to be retained for criminal investigation or litigation. S/CIs must be reported according to DOE O 232.2.

The following is taken from DOE O 232.2.

Notification, update, and final reports must be written clearly and concisely so the general reader can understand the basic who, what, when, where, and how of the event; the safety issues involved; and the actions taken.

Reports on S/CI and DI or material, must provide the manufacturer/ supplier/vendor (including a contact, phone number, and website), the model and part numbers, the quantity found, why the item/material is S/CI or defective, and how the item/material is being used. The report must include the method of detection (i.e., receipt inspection, craft inspection prior to installation, in-service inspection, or failure) and identify any resulting consequences, along with any photos via hyperlink, as appropriate.

Photos, sketches, drawings, and witness statement interview notes must be maintained with the occurrence report record when appropriate for clarification. In addition, sites are encouraged, but not required, to make photos, sketches, and drawings available via a webpage, with the webpage address included in the ORPs report.

The following is taken from Hanford Site, Pacific Northwest National Laboratory, TFC-ESHQ-Q_C-C-03, rev C-9, *Control of Suspect/Counterfeit Items*.

Notify the DOE S/CI point of contact of all occurrence reports associated with S/CIs. As appropriate, transmit copies of nonconformance reports (NCRs) and applicable documentation:

- NCR number
- Date NCR was written
- Purchase order/job control number (if known)
- End use of product
- Name of manufacturer, distributor, supplier
- Safety class (if known)
- Occurrence report number
- Value of item(s)
- Point(s) of contact
- Description of item(s)
- Quantity
- Description of nonconformance
- Any of pertinent information that would help the DOE IG

Notify the DOE IG of all S/CIs, providing the information provided by the S/CI coordinator for investigation as appropriate.

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).

The following is taken from GlobalSpec, The Engineering Search Engine, *Dimensional Measurement and Metrology Service Information.*

Dimensional measurement and metrology services use mechanical gauging, 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 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 gauging 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 direct current (DC) electricity.

The following is taken from DOE G 414.1-2B.

Measuring and testing 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 is uniquely identified and traceable to its calibration data. Procedures should be established for testing, retesting, adjusting, and recalibrating M&TE. M&TE should be calibrated to standards traceable to the 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, computer programs/software that are part of M&TE should be checked to ensure V&V have been performed for the computer programs/software, and that the V&V is current.

The use of M&TE should be traceable to the item inspected because measurements and tests performed with the M&TE may need to be reevaluated if the 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 review of all work packages to identify

each use of a particular M&TE is almost impossible. A process to provide traceability from the M&TE to the item inspected should be established. ISO/IEC 17025, *General Requirements for the Competence of Calibration and Testing Laboratories*, and ASME NQA-1, requirement 12, *Control of Measuring and Test Equipment*, provide additional information on the control of M&TE.

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

The following is taken from Non-destructive Testing (NDT) Resource Center, *What is NDT?*

The most basic NDT method is visual examination. Visual examiners follow procedures that range from simply looking at a part to see if surface imperfections are visible, to using computer controlled camera systems to automatically recognize and measure features of a component.

Video 14. Visual non-destructive testing
http://www.youtube.com/watch?v=XDV5veKluWk

Radiography

The following is taken from Non-destructive Testing (NDT) Resource Center, *What is NDT?*

Real-time radiography (RTR), or real-time radioscopy, is an NDT method whereby an image is produced electronically, rather than on film, so that very little lag time occurs between the item being exposed to radiation and the resulting image. In most instances, the electronic image that is viewed results from the radiation passing through the object being inspected and interacting with a screen of material that fluoresces or gives off light when the interaction occurs. The fluorescent elements of the screen form the image much as the grains of silver form the image in film radiography. The image formed is a "positive image" since brighter areas on the image indicate where higher levels of transmitted radiation reached the screen. This image is the opposite of the negative image produced in film radiography. In other words, with RTR, the lighter, brighter areas represent thinner sections or less dense sections of the test object.

Real-time radiography is a well-established method of NDT having applications in automotive, aerospace, pressure vessel, electronic, and munitions industries, among others. The use of RTR is increasing due to a reduction in the cost of the equipment and resolution of issues such as protecting and storing digital images.

Video 15. Radiography testing
http://www.youtube.com/watch?v=61uQOJm8Jlg&feature=related

Magnetic particle

The following is taken from Non-destructive Testing Resource Center, *What is NDT?*

Magnetic particle inspection (MPI) is a nondestructive testing method used for defect detection. MPI is fast and relatively easy to apply, and part surface preparation is not as critical as it is for some other NDT methods. These characteristics make MPI one of the most widely utilized nondestructive testing methods.

MPI uses magnetic fields and small magnetic particles (i.e., iron filings) to detect flaws in components. The only requirement from an inspectability standpoint is that the component being inspected must be made of a ferromagnetic material such as iron, nickel, cobalt, or some of their alloys. Ferromagnetic materials are materials that can be magnetized to a level that will allow the inspection to be effective.

The method is used to inspect a variety of product forms including castings, forgings, and weldments. Many different industries use MPI for determining a component's fitness-for-use. Some examples of industries that use MPI are the structural steel, automotive, petrochemical, power generation, and aerospace industries. Underwater inspection is another area where MPI may be used to test items such as offshore structures and underwater pipelines.

Video 16. Magnetic particle testing

http://www.youtube.com/watch?v=tegu7TuxxZI&feature=related

Liquid penetrant

The following is taken from Non-destructive Testing Resource Center, *Introduction and History of Penetrant Inspection.*

Liquid penetrant inspection is a method that is used to reveal surface breaking flaws by bleed-out of a colored or fluorescent dye from the flaw. The technique is based on the ability of a liquid to be drawn into a "clean" surface-breaking flaw by capillary action. After a period of time called the "dwell," excess surface penetrant is removed and a developer applied. This acts as a blotter. It draws the penetrant from the flaw to reveal its presence. Colored (contrast) penetrants require good white light while fluorescent penetrants need to be used in darkened conditions with an ultraviolet "black light."

Video 17. Liquid penetrant inspection

http://www.youtube.com/watch?v=QpU5JyhNVgQ&feature=related

Ultrasonic

The following is taken from Non-destructive Testing Resource Center, *What is NDT?*

Ultrasonic testing (UT) uses high frequency sound energy to conduct examinations and make measurements. Ultrasonic inspection can be used for flaw detection/evaluation, dimensional measurements, material characterization, and more.

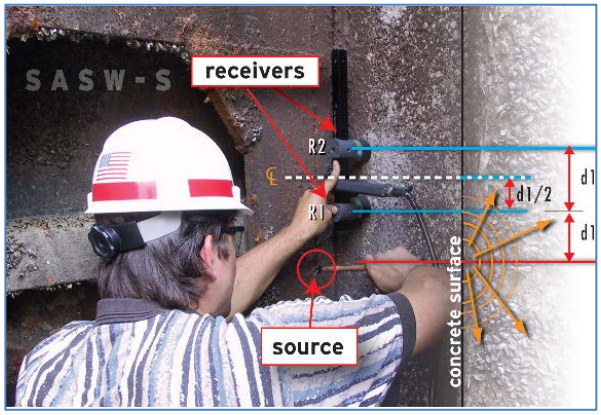
A typical UT inspection system consists of several functional units, such as the pulser/receiver, transducer, and display devices. A pulser/receiver is an electronic device that can produce high voltage electrical pulses. Driven by the pulser, the transducer generates high frequency ultrasonic energy. The sound energy is introduced and propagates through the materials in the form of waves. When there is a discontinuity (such as a crack) in the wave

path, part of the energy will be reflected back from the flaw surface. The reflected wave signal is transformed into an electrical signal by the transducer and is displayed on a screen. Signal travel time can be directly related to the distance that the signal traveled. From the signal, information about the reflector location, size, orientation and other features can sometimes be gained.

Video 18. Ultrasonic testing
http://www.youtube.com/watch?v=TlJTGhFqS28&feature=related

Spectral analysis

The following is taken from American Concrete Institute, ACI 228.2R, *Special Analysis of Surface Waves-S.*



Source: ACI 228.2R

Figure 3. Spectral analysis of surface waves

The spectral analysis of surface waves (SASW) method uses the dispersive characteristics of surface (Rayleigh waves) waves to determine the variation of the shear wave velocity (stiffness) of layered systems with depth. The SASW testing is applied from the surface making it nondestructive and nonintrusive. Once the shear wave velocity profiles are determined, shear and Young's moduli of the materials can be calculated through the use of simple mathematical equations. Shear wave velocity profiles can be determined from experimental dispersion curves and compared to actual SASW measurements through a process called forward modeling or through an inversion process.

This allows the user to find the best thickness and stiffness model for the layered system of interest. The SASW method can be performed on any material provided there is an accessible surface for receiver attachments. SASW is used for geophysical purposes in estimating shear wave velocity of soils and rocks.

Hardness

The following is taken from Non-destruction Testing Resource Center, *NDT Course Material: Materials and Processes, Hardness.*

Hardness is the resistance of a material to localized deformation. The term can apply to deformation from indentation, scratching, cutting, or bending. In metals, ceramics and most polymers, the deformation considered is plastic deformation of the surface. For elastomers and some polymers, hardness is defined as the resistance to elastic deformation of the surface. The lack of a fundamental definition indicates that hardness is not a basic property of a material, but rather a composite one with contributions from the yield strength, work hardening, true tensile strength, modulus, and others factors. Hardness measurements are widely used for the quality control of materials because they are quick and considered to be

nondestructive tests when the marks or indentations produced by the test are in low stress areas.

Video 19. Hardness testing
http://www.youtube.com/watch?v=-eYSQum9VFQ

Eddy current

The following is taken from Non-destruction Testing Resource Center, *Basic Principles of Eddy Current Inspection.*

Eddy current inspection is one of several NDT methods that use the principle of "electromagnetism" as the basis for conducting examinations. Eddy currents are created through a process called electromagnetic induction. When alternating current (AC) is applied to the conductor, such as copper wire, a magnetic field develops in and around the conductor. This magnetic field expands as the AC rises to maximum and collapses as the current is reduced to zero. If another electrical conductor is brought into proximity to this changing magnetic field, current will be induced in this second conductor. Eddy currents are induced electrical currents that flow in a circular path. They get their name from "eddies" that are formed when a liquid or gas flows in a circular path around obstacles when conditions are right.

Video 20. Eddy current testing
http://www.youtube.com/watch?v=_jZqdvSHAwc

Destructive Examination Methods

Source: Wikipedia, Tensile testing
Figure 4. Tensile testing

The following is taken from Wikipedia, *Tensile Testing.*

Tensile testing, also known as tension testing, is a fundamental materials science test where a sample is subjected to uniaxial tension until failure. The results from the test are commonly used to select a material for an application, for quality control, and to predict how a material will react under other types of forces. Properties that are directly measured via a tensile test are ultimate tensile strength, maximum elongation, and reduction in area. From these measurements the following properties can be determined:

- Young's modulus
- Poisson's ratio
- Yield strength
- Strain-hardening characteristics

A tensile specimen is a standardized cross section with two shoulders and a gauge (section) between. The shoulders are large so they can be readily gripped, whereas the gauge section has a smaller cross-section so that the deformation and failure can occur in this area.

The shoulders of the test specimen can be manufactured in various ways to mate to various grips in the testing machine (see figure 4, *Tensile testing*). Each system has advantages and disadvantages; shoulders designed for serrated grips are easy and cheap to manufacture, but the alignment of the specimen is dependent on the skill of the technician. On the hand, a pinned grip ensures good alignment. Threaded shoulders and grips ensure good alignment, but the technician must know to thread each shoulder into the grip at least one diameter's length or the threads can strip before the specimen fractures.

A standard specimen is prepared in a round or a square section along the gauge length, depending on the standard set. Both ends of the specimens should have sufficient length and a surface condition such that they are firmly gripped during the testing. The initial gauge length is standardized and varies with the diameter or the cross-sectional area of the specimen.

Equipment

The most common testing machine used in tensile testing is the universal testing machine. This type of machine has two crossheads; one is adjusted for the length of the specimen and the other is driven to apply tension to the test specimen. There are two types: hydraulic powered and electromagnetically powered machines.

The machine must have the proper capabilities for the test specimen being tested. There are three main parameters: force capacity, speed, and precision and accuracy. Force capacity refers to the fact that the machine must be able to generate enough force to fracture the specimen. The machine must be able to apply the force quickly or slowly enough to properly mimic the actual application. Finally, the machine must be able to accurately and precisely measure the gauge length and forces applied; a large machine that is designed to measure long elongations may not work with a brittle material that experiences short elongations prior to fracturing.

Alignment of the test specimen in the testing machine is critical, because if the specimen is misaligned, either at an angle or offset to one side, the machine will exert a bending force on the specimen. This is especially bad for brittle materials because it will dramatically skew the results. This situation can be minimized by using spherical seats or U-joints between the grips and the test machine. A misalignment is indicated when running the test if the initial portion of the stress-strain curve is curved and not linear.

The strain measurements are most commonly measured with an extensometer, but strain gauges are frequently used on small test specimen or when Poisson's ratio is being measured. New test machines have digital time, force, and elongation measurement systems consisting of electronic sensors connected to a data collection device and software to manipulate and output the data. Analog machines continue to meet and exceed American Society for Testing and Materials International (ASTM), NIST, and the American Society for Metals tensile testing accuracy requirements, continuing to be used today.

The Process

The test process involves placing the test specimen in the testing machine and applying tension to it until it fractures. During the application of tension, the elongation of the gauge section is recorded against the applied force. The data is manipulated so that it is not specific

to the geometry of the test sample. The elongation measurement is used to calculate the engineering strain, ε, using the following equation:

$$\varepsilon = \frac{\Delta L}{L_0} = \frac{L - L_0}{L_0}$$

where ΔL is the change in gauge length, L_0 is the initial gauge length, and L is the final length. The force measurement is used to calculate the engineering stress, σ, using the following equation.

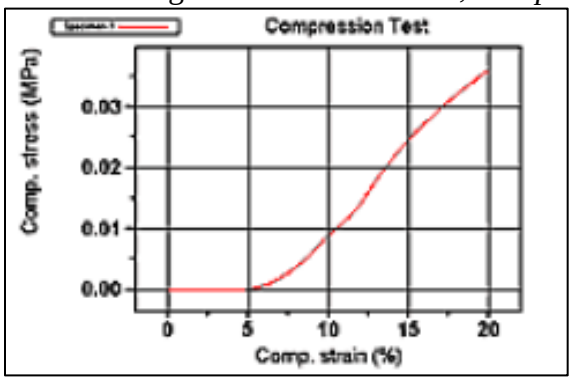
$$\sigma = \frac{F_n}{A}$$

where F is the force and A is the cross section of the gauge section. The machine does its calculations as the force increases, so that the data points can be graphed into a stress-strain curve.

Video 21. Tensile testing
http://www.youtube.com/watch?v=67fSwIjYJ-E&feature=related

Compression Test

The following is taken from Instron, *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 that is used to determine elastic limit, proportional limit, yield point, yield strength, and for some materials, compressive strength.

Source: Instron, Compression Test

Figure 5. Compression test

Fatigue Test

The following is taken from Instron, *Fatigue Test*.

The fatigue test is a method for determining the behavior of materials under fluctuating loads. A specified mean load and an alternating load are applied to a specimen and the number of cycles required to produce failure is recorded. Generally, the test is repeated with identical specimens and various fluctuating loads. Loads may be applied axially, in torsion, or in flexure. Depending on amplitude of the mean and cycle load, net stress in the specimen may be in one direction through the loading cycle, or may reverse direction. Data from fatigue testing often are presented in an S-N diagram that is a plot of the number of cycles required to cause failure in a specimen against the amplitude of the cyclical stress developed. The cyclical stress represented may be stress amplitude, maximum stress, or minimum stress.

Each curve in the diagram represents a constant mean stress. Most fatigue tests are conducted in flexure, rotating beam, or vibratory type machines.

Video 22. Fatigue testing of a Boeing 787

http://www.youtube.com/watch?v=TH9k9fWaFrs

The following is taken from TWI, Ltd., *Bend Testing*.

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.

Source: TWI, Ltd., Bend Test

Figure 6. Bend test

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.

Video 23. Bend testing

http://www.youtube.com/watch?v=DYZFZ7ug5YA&feature=related

The following is taken from for American Society for Testing and Materials ASTM STP 640, *Adhesion Measurement of Thin Films, Thick Films, and Bulk Coatings*.

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

The following is taken from DOE G 433.1-1A.

Engineering personnel should approve any deviation from design specifications of material or equipment received before the item is considered for issue. Personnel should approve any upgrade of material or equipment from a non-safety to a safety category. Nonconforming items should be clearly identified; segregated from normal items to prevent inadvertent use; documented on a nonconformance report and/or a defective or substandard material report; and tracked and resolved as soon as practical by the applicable authority.

Procurement controls should be developed and maintained to help maintenance obtain parts, materials, and services promptly. Consideration should be given to the segregation and status

resolution of damaged, nonconforming, or otherwise deficient items. Technical reviews should be initiated promptly to aid in the resolution of these items.

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

The following is taken from Ramaswamy Viswanathan, *Damage Mechanisms and Life Assessment of High-temperature Components.*

A major advantage of destructive tests is that they eliminate the need to know or to estimate the past operating history. By intelligent selection of an accelerated test scheme, the need to assume any time-of-damage rule is precluded. Destructive tests thus offer the advantage that they characterize the current condition of the material, eliminating many uncertainties arising from lack of knowledge of virgin-material properties, operating conditions, and appropriate damage rules.

The following is taken from Engineers Edge, Solutions from Design, *Advantages and Disadvantages of Selected Non-Destructive Inspection Methods (NDI).*

Table 1, *Advantages and disadvantages of non-destructive testing*, is taken from Engineers Edge and lists some advantages and disadvantages of destructive and NDT.

Table 1. Advantages and disadvantages of NDT

Method	Advantages	Disadvantages
Visual	▪ Inexpensive ▪ Highly portable ▪ Immediate results ▪ Minimum training ▪ Minimum part preparation	▪ Surface discontinuities only ▪ Generally only large discontinuities ▪ Misinterpretation of scratches
Dye Penetrant	▪ Portable ▪ Inexpensive ▪ Sensitive to very small discontinuities ▪ 30 minutes or less to accomplish ▪ Minimum skill required	▪ Locate surface defects only ▪ Rough or porous surfaces interfere with test ▪ Part preparation required (removal of finishes and sealant, etc.) ▪ High degree of cleanliness required ▪ Direct visual detection of results required
Magnetic Particle	▪ Can be portable ▪ Inexpensive ▪ Sensitive to small discontinuities ▪ Moderate skill required ▪ Detects surface and subsurface discontinuities ▪ Relatively fast	▪ Surface must be accessible ▪ Rough surfaces interfere with test ▪ Part preparation required (removal of finishes and sealant, etc.) ▪ Semi-directional required general orientation of field to discontinuity ▪ Ferro-magnetic materials only ▪ Part must be demagnetized after test
Eddy Current	▪ Portable ▪ Detects surface and subsurface discontinuities ▪ Moderate speed ▪ Immediate results ▪ Sensitive to small discontinuities ▪ Thickness sensitive	▪ Surface must be accessible to probe ▪ Rough surfaces interfere with test ▪ Electrically conductive materials ▪ Skill and training required ▪ Time consuming for large areas
Ultrasonic	▪ Portable ▪ Inexpensive ▪ Sensitive to very small discontinuities ▪ Immediate results ▪ Little part preparation ▪ Wide range of materials and thickness can be inspected	▪ Surface must be accessible to probe ▪ Rough surfaces interfere with test ▪ Highly sensitive to sound beam discontinuity orientation ▪ High degree of skill required to set up and interpret ▪ Couplant usually required
X-ray Radiography	▪ Detects surface and internal flaws ▪ Can inspect hidden areas ▪ Permanent test record obtained ▪ Minimum part preparation	▪ Safety hazard ▪ Very expensive (slow process) ▪ Highly directional, sensitive to flaw orientation ▪ High degree of skill and experience required for exposure and interpretation ▪ Depth of discontinuity not indicated

Source: Engineers Edge, Solutions by Design, Advantages and Disadvantages of Selected Non-Destructive Inspection Methods (NDI)

d. Describe testing and inspection methods commonly used in the following areas:

- **Electrical**
- **Mechanical**
- **Chemical**
- **Soil and concrete**
- **Welding/fabrication**
- **Computer software**

Electrical

Information on the following electrical devices is taken from DOE-HDBK-1011/4-92.

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

Voltmeter

Source: ebay.prnc.net

Figure 7. 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.

Video 24. How to use a voltmeter

http://www.youtube.com/watch?v=wq2x5WqShuI

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.

Source: Wikipedia, Ammeter

Figure 8. Ammeter

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.

Video 25. How to use an ammeter

http://www.bing.com/videos/search?q=ammeter&view=detail&mid=0F7918DD0AE061EA60D70F7918DD0AE061EA60D7&first=0

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.

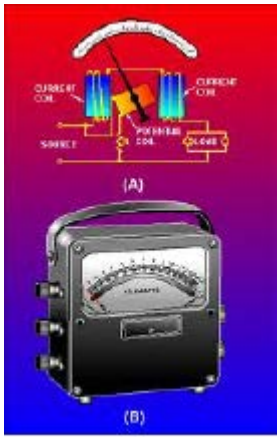
Source: Wikipedia, Ohmmeter

Figure 9. Ohmmeter

Video 26. How to use an ohmmeter

http://www.bing.com/videos/search?q=how+to+use+a+ohmmeter&view=detail&mid=5460D019125DF38A0EE95460D019125DF38A0EE9&first=0

Wattmeter



The wattmeter is an instrument that measures DC power or true 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.

Source: Integrated Publishing

Figure 10. Wattmeter

Video 27. How to use a wattmeter

http://www.bing.com/videos/search?q=how+to+use+a+wattmeter&view=detail&mid=30FF98AFDBE23342DA0230FF98AFDBE23342DA02&first=21

Ampere-Hour Meter

Source: Countronics

Figure 11. 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 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

Source: Mahesh Electrical Instruments

Figure 12. 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.

Video 28. Power factor meters

http://www.youtube.com/watch?v=Zg3dSDjQPDM

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.

Source: Direct Industry

Figure 13. Ground detector

Synchroscope

Source: Wikipedia, Synchroscope

Figure 14. 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.

Megger

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.

Source: Wikipedia, Megger
Figure 15. Megger

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 counterclockwise position, which is marked as infinite resistance.

Video 29. How to use a megger
http://www.youtube.com/watch?v=vJlcKhc8tJo

Power Quality Monitors

Source: Weschler Instruments
Figure 16. 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.

Video 30. Power quality monitoring demonstration
http://www.automationworld.com/automation-team/ni-week-2011-power-quality-monitoring-demo

Mechanical

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

Brinell Hardness Test

The following is taken from Surface Engineering Forum, *The Brinell Hardness Test*.

The Brinell hardness test method consists of indenting the test material with a 10 millimeters diameter hardened steel or carbide ball subjected to a load of 3000 kilogram (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.

Video 31. Brinell hardness test
http://www.youtube.com/watch?v=3K4kPjRYQmE

Rockwell Hardness Test

The following is taken from Surface Engineering Forum, *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 kg force. 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.

Video 32. Rockwell hardness test
http://www.youtube.com/watch?v=eF5943tlbBs

Charpy V-Notch Test

The following is taken from Wikipedia, *Charpy Impact Test*.

The Charpy impact test, known as the Charpy v-notch test, is a standardized high strain-rate test that determines the amount of energy absorbed by a material during fracture. This absorbed energy is a measure of a given material's toughness and acts as a tool to study temperature-dependent ductile-brittle transition. It is widely applied in industry, since it is easy to prepare and conduct and results can be obtained quickly and cheaply. A major disadvantage is that all results are only comparative.

Drop-Weight Test

The following is taken from TWI Ltd., *What is the Drop-Weight Test (or Pellini Test).*

The drop-weight test (often referred to as Pellini test) was developed at the Naval Research Laboratory in Washington DC, as a simple method to determine the nil-ductility transition temperature (NDTT). The NDTT was defined in the 1950s as the test temperature in explosion bulge tests at which the place remained flat at fracture, that is crack propagation occurred in the presence of elastic strains only. The drop-weight test was developed to simplify the determination of the NDTT, it is standardized in ASTM E208-06, *Standard Test Method for Conducting Drop-Weight Test to Determine Nil-Ductility Transition Temperature of Ferritic Steels*.

Creep Test

The following is taken from Instron, *Creep Test.*

The creep test is a method of determining creep or stress relaxation behavior. To determine creep properties, material is subjected to prolonged constant tension or compression loading at constant temperature. Deformation is recorded at specified time intervals and a creep versus time diagram is plotted. Slope of curve at any point is the creep rate. If failure occurs, it terminates test and time for rupture is recorded. If the specimen does not fracture within test period, creep recovery may be measured. To determine stress relaxation of material, the specimen is deformed a given amount and decrease in stress over a prolonged period of exposure at constant temperature is recorded.

Corrosion Test

The following is taken from the NACE International Recourse Center, *Corrosion Testing Basics.*

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 hoping to accelerate 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.

[Note: Two additional tests—tension and fatigue—are discussed in competency B8b.]

Chemical

The following is taken from the CITAC/EURACHEM (The Cooperation on International Traceability in Analytic Chemistry/A Focus for Analytical Chemistry in Europe) Guide, *Guide to Quality in Analytical Chemistry.*

The value of chemical measurements depends upon the level of confidence that can be placed in the results. Increasingly, the chemical testing community is adopting QA principles which, while not actually guaranteeing the quality of the data produced, increases the likelihood of it being soundly based and fit for its intended purpose.

Appropriate QA can enable a laboratory to show that it has adequate facilities and equipment for carrying out chemical analysis and that the work was carried out by competent staff in a controlled manner, following a documented validated method. QA should focus on the key issues which determine quality results, costs and timeliness, and avoid diversion of energies into less important issues.

Good QA practice, including its formal recognition by accreditation, certification etc., helps to ensure that results are valid and fit for purpose. However, it is important for both laboratories and their customers to realize that QA cannot guarantee that 100 percent of the individual results will be reliable. There are two reasons for this:

- Mistakes/gross errors can occur, where, for example, the results for two samples are mixed-up. In a well-run laboratory, the frequency of mistakes will be small, but not zero.
- Random and systematic errors also occur, leading to uncertainty in a measured result. The probability of a result lying within the stated uncertainty range depends on the level of confidence employed, but again, even in a well ordered laboratory, deviant results will occasionally occur and very occasionally the deviation will be large.

The business of QA is to manage the frequency of quality failures. The greater the effort taken, the smaller the number of quality failures that can be expected. It is necessary to balance the cost of QA against the benefit in reducing quality failures to an acceptable (non-zero) level.

The principles of QA have been formalized in a number of published protocols or standards. Those most widely recognized and used in chemical testing fall into three groups and are applied according to a laboratory's individual needs. The three groups are:

- ISO/IEC 17025:2005. This standard addresses the technical competence of laboratories to carry out specific tests and calibrations and is used by laboratory accreditation bodies world-wide as the core requirements for the accreditation of laboratories.
- ISO 9001:2000 and its national and international equivalents. This standard relates primarily to quality management, for facilities carrying out production, or providing services, including chemical analysis.
- Organization for Economic Cooperation and Development, OECD Principles of Good Laboratory Practice, 1998 and its national and sectorial equivalents. These guidelines are concerned with the organizational processes and conditions under which laboratory studies related to certain regulatory work are carried out.

In addition, there are total quality management approaches to QA which place emphasis on continuous improvement (the new ISO 9001:2000 gives more emphasis here). Central to this guide is the contention that, at the technical level, good practice in analytical QA is independent of the formal QA system adopted.

A laboratory may decide to design its own QA procedures or it may follow one of the established protocols. In the latter case it may claim informal compliance against the protocol or ideally may undergo independent assessment from an official expert body, with the aim of gaining independent endorsement of its quality system. Such independent assessment/ endorsement is variously known as accreditation, registration, or certification depending on

which standard the assessment is made against. In particular areas of analysis, accreditation is sometimes mandatory, however in most cases, the laboratory is free to decide what sort of QA measures it wishes to adopt. The independent assessment route has recognized advantages, particularly where the laboratory's customers require objective evidence of the technical competence of the laboratory.

Soil and Concrete

The following is taken from DOE-STD-1022-94.

For evaluation and design of DOE facilities with SSCs in performance category (PC)-3 or PC-4, laboratory tests for 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. 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. These measurements are shown in table 2.

Table 2. Examples of soil dynamic property and strength tests

D 3999-91	Standard test method for the determination of the modulus and damping properties of soils using the cyclic triaxial apparatus
D 4015-92	Standard test methods for modulus and damping of soils by the resonant-column method
D 5311-92	Standard test method for load controlled cyclic triaxial strength of soil

Source: DOE-STD-1022-94

For coarse geological materials such as coarse gravels and sand-gravel mixtures, special testing equipment and a testing facility should be used. 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 gravelly 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 gravelly soils.

Video 33. Cyclic triaxial testing
http://www.youtube.com/watch?v=1Vo8sXU4wVA

Video 34. Cyclic torsional shear tests
http://www.youtube.com/watch?v=5UPJ3waHtp4&feature=related

Site Response Analysis

The following is taken from DOE-STD-1022-94.

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

The following is taken from Wikipedia, *Soil Compaction*.

Soil compaction is the process in which a stress applied to a soil causes densification as air is displaced from the pores between the soil grains. Normally, compaction is the result of heavy machinery compressing the soil, but it can occur due to the passage of animal feet.

There are several means of achieving compaction of a material. The available techniques can be classified:

- Static—a large stress is slowly applied to the soil and then released.
- Impact—the stress is applied by dropping a large mass onto the surface of the soil.
- Vibrating—a stress is applied repeatedly and rapidly via a mechanically driven plate or hammer. Often combined with rolling compaction.
- Gyrating—a static stress is applied and maintained in one direction while the soil is subjected to a gyratory motion about the axis of static loading. Limited to laboratory applications.
- Rolling—a heavy cylinder is rolled over the surface of the soil. Commonly used on sports pitches. Roller-compactors are often fitted with vibratory devices to enhance their ability.
- Kneading—shear is applied by alternating movement in adjacent positions. An example, combined with rolling compaction, is the “sheepsfoot” roller used in waste compaction at landfills.

Soil compaction is a vital part of the construction process. It is used for support of structural entities such as building foundations, roadways, walkways, and earth retaining structures.

Video 35. Soil compaction in construction
http://www.bing.com/videos/search?q=soil+compaction+in+construction&view=detail&mid=1A55D7253DD652617EE61A55D7253DD652617EE6&first=0

Shear Testing

The following is taken from Wikipedia, *Shear Strength (Soil)*.

Shear tests measure the shear strength of soils. The shear strength is a term used in soil mechanics to describe the magnitude of the shear stress that a soil can sustain. The shear strength of soil depends on the effective stress, the drainage conditions, the density of the particles, the rate of strain, and the direction of the strain.

The triaxial shear test is a common method to measure the mechanical properties of many deformable solids, especially soil and rock, and other granular materials or powders. For loose granular materials like sand or gravel, the material is contained in a cylindrical latex sleeve with a flat, circular metal plate or platen closing off the top and bottom ends. This cylinder is placed into a bath of water to provide pressure along the sides of the cylinder. The top platen can then be mechanically driven up or down along the axis of the cylinder to squeeze the material. The distance that the upper platen travels is measured as a function of the force required to move it, as the pressure of the surrounding water is carefully controlled. The net change in volume of the material is measured by how much water moves in or out of the surrounding bath.

Concrete Testing

The following is taken from the U.S. Department of Transportation 5-694-503, *Concrete Manual*.

Strength tests are required for one or both of the following purposes:

- To check the potential strength of the concrete under controlled conditions against the desired strength
- To establish a strength-age relationship for the concrete under job conditions as a control for construction operations or the opening of the work

Tests made for the first purpose are referred to as standard tests and those for the second purpose are referred to as control tests. For uniform and comparable results, follow a standard and consistent procedure in making all of the test specimens whether they are used either for standard or for control tests.

Welding/Fabrication

The following is taken from American Testing Services, Ltd., *Fabricating/Welding*.

Fabricating as an industrial term refers to building metal structures by cutting, bending, and assembling. These processes can cause breakdown in the materials used and, in some cases, defects or failures in finished product. Welding is one of the most common processes used in assembling and is usually the focal point of NDT. Common inspections would include

radiograph (x-ray), magnetic particle, liquid penetrant, visual, and ultrasonic. (See B8b for a discussion of common inspection methods for welding.)

Computer Software

The following is taken from DOE G 414.1-4.

During implementation, static analysis, clean room inspections, and reviews are common techniques to ensure the implementation remains consistent with the design and does not add complexity or functions that could decrease the safe operation of the 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 V&V 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.

Video 36. Software testing
http://www.youtube.com/watch?v=4ySF7c_ndwU&feature=related

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.

The following is taken from DOE G 414.1-2B.

Commercial grade items that affect the safety function of the application in which they are intended for use should be accepted according to the commercial grade dedication (CGD) process. A documented technical evaluation should be performed by the responsible design organization for acceptance of the commercial grade items. This evaluation should include: determining the safety function(s); verifying performance requirements and applicable service conditions; and verifying critical characteristics including acceptance criteria. Additional guidance for the CGD process can be found in ASME NQA-1, subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, the EPRI Guideline NP-5652 and EPRI Guideline TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items*.

Methods used to verify critical design characteristics and appropriateness of the item for use include processes such as the following:

- Special test(s), inspection(s), and/or analysis
- Commercial grade survey of the supplier
- Source verification
- Acceptable supplier item or service performance record

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

The following is taken from DOE G 414.1-2B.

The procurement process should provide for identifying inspections and tests to ensure conformance with purpose 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. Inspections may include the following methods:

- Inspections of materials or equipment at the supplier's facility
- Receipt inspection of the shipped items using established item-critical characteristics
- Review of objective evidence such as certifications and reports
- Verification or testing of items before or following shipment

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

The following is taken from IT Project Management, *Statistical Sampling Method for Project Quality Control*.

Attributes sampling defines what exactly will be measured for quality control. This is often based upon past sample failure experience or customer feedback. The quality inspector merely checks the individual sample against the quality criteria. The attribute is measured by a simple "yes" or "no" that the item is acceptable. This method is often used in inspecting for size, color, finishing, marking, and packing. Data is recorded on a simple checklist sheet.

The use of attributes sampling has some advantages and disadvantages Attributes testing is simpler and less expensive than inspection by variables. Recordkeeping is simplified by having one quality level for a group of like attributes. However, attributes sampling requires a large sample size to determine the acceptability of the parent lot that makes the process time consuming and expensive.

Variable sampling collects data on possible variable items. When the error rate exceeds a combined level for several of the variables, the lot is rejected. The sample is rated on a scale against such criteria as time, distance, weight, strength, or purity.

Instead of being tested as "acceptable" or "unacceptable," the sample is compared against historic values to determine problems. Variable sampling is used when the quality characteristic is measurable or quantifiable.

The advantages include more data to compare to quality conformance criteria. It requires smaller sample sizes, reducing cost while ensuring high quality. The disadvantages are the quality inspectors need more training and more sophisticated analysis is required to determine quality conformance.

Video 37. Attribute versus variable sampling
http://www.youtube.com/watch?v=4JtQLaV26p0

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

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

[Note: The National Institute of Standards and Technology (NIST) refers to "primary," "secondary," and "working" standards as "primary measurement standards," "secondary measurement standards," and "working measurement standards." NIST ascribes to the International Vocabulary of Metrology for their definitions. The following is taken from Joint Committee for Guides in Metrology, JCGM 200:2008.]

A primary standard is a measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention.

A secondary standard is a measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind. Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard. A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

A working standard is a measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems. A working measurement standard is usually calibrated with respect to a reference measurement standard. In relation to verification, the terms "check standard" or "control standard" are also sometimes used.

b. Discuss the purpose and application of calibration systems with respect to:

- **Process/product quality**
- **Accuracy**
- **Precision**

The following is taken from DOE-STD-1054-93 (archived).

DOE-STD-1054-93, *Guideline to Good Practices for Control and Calibration of Measuring and Test Equipment (M&TE) at DOE Nuclear Facilities,* is intended to assist facility maintenance operations in the review of existing and in developing new programs to ensure the accuracy and integrity of performance data derived from plant process and control instrumentation is verified by controlled application of properly calibrated/certified M&TE having the appropriate precision, design accuracy, and durability for their intended use.

M&TE should be calibrated using reference standards (secondary or working) whose calibration has a known valid relationship to nationally recognized standards or accepted values of natural physical constants. If national standards do not exist, the basis for calibration should be documented. The reference standard used should have accuracy at least four times greater than the device under test. If this accuracy ratio cannot be met, analysis of the errors should be estimated to provide a valid uncertainty of the calibration process.

The following is taken from National Institute of Standards and Technology, NIST *Engineering Statistics Handbook*.

Instrument calibration is intended to eliminate or reduce bias in an instrument's readings over a range for all continuous values. For this purpose, reference standards with known values for selected points covering the range of interest are measured with the instrument in question. Then a functional relationship is established between the values of the standards and the corresponding measurements. There are two basic situations.

Instruments which require correction for bias

The instrument reads in the same units as the reference standards. The purpose of the calibration is to identify and eliminate any bias in the instrument relative to the defined unit of measurement. For example, optical imaging systems that measure the width of lines on semiconductors read in micrometers, the unit of interest. Nonetheless, these instruments must be calibrated to values of reference standards if line-width measurements across the industry are to agree with each other.

Instruments whose measurements act as surrogates for other measurements

The instrument reads in different units than the reference standards. The purpose of the calibration is to convert the instrument readings to the units of interest. An example is densitometer measurements that act as surrogates for measurements of radiation dosage. For this purpose, reference standards are irradiated at several dosage levels and then measured by radiometry. The same reference standards are measured by densitometer. The calibrated results of future densitometer readings on medical devices are the basis for deciding if the devices have been sterilized at the proper radiation level.

Accuracy

Accuracy is a qualitative term referring to whether there is agreement between a measurement made on an object and its true (target or reference) value.

The following is taken from ASTM vol. 14.02, *General Test Methods; Forensic Psychophysiology; Forensic Sciences; Terminology; Conformity Assessment; Statistical Methods; Nanotechnology; Forensic Engineering; Manufacture of Pharmaceutical Products*.

The accuracy of a measurement is the closeness of agreement between the test result and the true value. This is straightforward. The accuracy of a measurement process is the degree of agreement of a set of measurements with the true value of the quantity being measured. This is not so straightforward. There are two schools of thought regarding accuracy. One school argues that a process is accurate if the average of all measurements is close to the truth, regardless of the closeness of each individual measurement. The second school insists that accuracy should imply that any given measurement is very likely to be close to the true value. The first school disregards any process precision and asks for low bias. The second requires both low bias and high precision. To avoid confusion the ASTM asks for description of processes in terms of precision and bias only.

Precision

The precision of a measurement process is the degree of agreement among measurements obtained from the measurement process being evaluated under prescribed conditions. The process must be in a state of statistical control, otherwise the precision of the process has no meaning. There is no implication of closeness to the true value. Repeated observation is

fundamental to determining precision. No information can be gained from a single measurement. A measurement method cannot be described as precise because the method can only realized in the context of a measurement process and as process parameters change precision may change.

Video 38. Calibration
http://www.youtube.com/watch?v=sOGKEnB2RJE

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**

[Note: DOE O 414.1A has been superseded by DOE O 414.1D and ASME NQA-1-2000 has been superseded by ASME NQA-1-2008.]

10 CFR 830.122

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

Criterion 8, Performance/Inspection and Acceptance Testing, in 10 CFR 830.122 states, "Calibrate and maintain equipment used for inspections and tests."

DOE O 414.1D

DOE O 414.1D contains the same information as 10 CFR 830.122.

The following is taken from DOE G 414.1-2B.

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, computer programs/software that are part of M&TE should be checked to ensure V&V has been performed for the computer programs/software, and that the V&V is current.

The use of M&TE should be traceable to the item inspected because measurements and tests performed with the M&TE may need to be reevaluated if the 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 review of all work packages to identify each use of a particular M&TE is almost impossible. A process to provide traceability from the M&TE to the item inspected should be established. ISO/IEC 17025 and ASME NQA-1, requirement 12 provide additional information on the control of M&TE.

ASME NQA-1-2000

ASME NQA-1-2008 requires the organization to calibrate M&TE using reference standards and control procedures.

ASME NQ-1-2008 requires the organization to establish and maintain calibration records, including calibration reports and certificates that include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

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

The following is taken from QC Inspection Services, *Calibration Tip: Frequency of Calibration*.

The ISO 10012:2003, *Measurement Management Systems—Requirements for Measurement Processes and Measuring Equipment*, suggests two items are considered when deciding on recall frequencies:

- Risk of failure
- Cost of calibration
  - The initial choice for setting a recall can be based on several factors including the following:
    - Engineering intuition
      - Experience of gauge use
      - Knowledge of other users intervals
    - Manufacturer's recommendation
    - Severity of use
    - Environment
    - Accuracy
    - Gauge repeatability and reproducibility (R&R) studies
    - Cost
    - History of calibrations
      - Frequencies can be set using various options:
        - ✓ Calibrate after use
        - ✓ Calibrate before use
        - ✓ Number of uses
        - ✓ Hours
        - ✓ Days
        - ✓ Weeks
        - ✓ Months
        - ✓ Years
        - ✓ Etc.

When sending gauges to a calibration laboratory it is important to specify what recall dates are wanted on the gauges. The laboratory will most likely default to one year. This has been spelled out in their quality manual. If different than one year, this should be noted in writing; the purchase order is the best place to do this. Also, frequencies can be adjusted based on calibration histories and gauge R&R studies.

e. Discuss the importance of calibration traceability.

The following is taken from DOE G 433.1-1A.

The individual identifying a deficiency should initiate a work request/work order (WR/WO) according to the following steps:

- Enter the deficiency identification tag or sticker number in the WR/WO index, if applicable. Because the date on the deficiency tag is the date of the WR/WO, the index provides a cross-reference.
- Use the duplicate portion of the deficiency identification tag to enter key information on the WR/WO.
- Record the tag or sticker serial number, date, and description of deficiency on the WR/WO.
- Note whether it was possible to place the deficiency identification tag in proximity to the deficiency.

The duplicate may be affixed to the WR/WO or discarded. The system now provides complete traceability from a deficiency, using the tag number and date, to the WR/WO index and then to the WR/WO. The age of the deficiency may be determined in the field from the date on the tag and the status of its repair determined from the work-control system.

Post maintenance testing (PMT) integrates with the work-control system, and the health and safety permit system. PMTs may be a part of the facility work-control system that uses the facility WR, or work package to specify testing, assign responsibility, and document acceptance of all PMTs. The WR should provide specific instructions or cross-reference a test procedure and should provide traceability to PMT data by recording the PMT data directly on the WR or by referencing data recorded on PMT data sheets or documents.

The following is taken from National Metrology Laboratory, *About Metrology.*

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 United States., industry ensures traceability to the highest international level direct from NIST.

f. Discuss methods for determining a proper calibration interval.

The following is taken from NIST, *Recommended Calibration Interval*.

NIST does not require or recommend any set recalibration interval for measuring instruments, devices, or standards. Specific recalibration intervals depend on a number of factors including

- accuracy requirements set by customers
- requirements set by contract or regulation
- inherent stability of the specific instrument or device
- environmental factors that may affect the stability

In the absence of other external requirements for specific intervals, NIST recommends that calibration and measurement laboratories adopt internal measurement assurance programs that include cross-comparisons of primary and secondary measurement standards. Recording and analyzing the resulting data in control charts can be used to characterize the short- and long-term behavior of specific devices. This time-dependent behavior can be compared to the accuracy requirements of the particular application to determine an initial recalibration interval. Subsequently, recalibration reports should include "as submitted" and "post calibration" accuracy and precision data to validate and/or refine the interval.

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**

The following is taken from DOE-HDBK-1122-2009.

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

Video 39. Mean, median, and mode functions
http://www.youtube.com/watch?v=uydzT_WiRz4&feature=related

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:

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

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

The following is taken from DOE-HDBK-1014/2-92.

The mean variance is the average value of the variances of a set of data. The mean variance is calculated as follows:

$$\frac{1}{n}\sum_{i=1}^{n}\left|x_i - \bar{x}\right|$$

The mean variance, or mean deviation, can be calculated and used to make judgments by providing information on the quality of the data.

Video 40. Calculating the variance

http://www.youtube.com/watch?v=VgKHjVDK0uM&feature=related

Standard Deviation

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

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

Example:

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

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

Video 41. How to calculate standard deviation

http://www.youtube.com/watch?v=klP8ElkVxJk&feature=related

b. Discuss in general, the following sampling procedures:

- **Simple random sampling**
- **Stratified sampling**
- **Cluster sampling**
- **Systematic sampling**
- **Acceptance sampling**

Simple Random Sampling

The following is taken from DOE-STD-1153-2002.

The validity of most statistical methods requires that samples be collected randomly from within the population of interest. Random sampling uses the concept of uniform probabilities to choose representative sample locations. The objective of this sampling approach is to give each sampling unit in the population an equal probability of being included in the sample. Random sampling generally is employed when little information exists concerning the

contamination or site. It is most effective when the number of available sampling locations is large enough to lend statistical validity to the random selection process.

Video 42. Simple random sampling
http://www.youtube.com/watch?v=yx5KZi5QArQ

Stratified Sampling

The following is taken from DOE-STD-1153-2002.

Stratified random sampling involves the division of the sample population into strata based on knowledge of certain characteristics within the strata. Random samples are then taken from within these strata. This approach is used to increase the precision of the estimates made by sampling; it is most applicable when the contaminant distribution is heterogeneous and clumped or associated with distinct habitats. Stratified random sampling is advantageous when contaminant concentration distributions within the strata are more homogeneous than they are between divisions.

Video 43. Stratified sampling
http://www.youtube.com/watch?v=sYRUYJYOpG0

Cluster Sampling

The following is taken from the University of Wisconsin-La Crosse, *Traffic Fatalities*.

In contrast to simple random sampling and stratified sampling, where single subjects are selected from the population, 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. To conduct interviews with hotel managers in a major city about their training needs, each hotel in the city could represent one cluster. A small number (e.g., ten) of hotels from this cluster are randomly selected and the managers of this selected group are contacted for interviews.

Cluster sampling can also be combined with stratified sampling. For instance, in the above example of wanting to interview employees in randomly selected clusters, stratify the employees based on some characteristic deemed most relevant to the 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.”

Video 44. Cluster sampling
http://www.youtube.com/watch?v=QOxXy-I6ogs

Systematic Sampling

The following is taken from DOE-STD-1153-2002.

Systematic sampling involves the collection of samples at predetermined, regular spatial, or temporal intervals. It is the most often employed sampling scheme. However, care must be used to avoid bias. If, for example, there are periodic variations in the material to be sampled, the systematic plan may become phased with these variations (Krebs, 1989). A systematic plan often results from approaches that are intended to be random. This is because investigators tend to subdivide a large sample area into increments prior to randomization (Green, 1979). Studies performed comparing results from systematic and random sampling in

ecological systems found no significant difference (Krebs, 1989). Consequently, Krebs (1989) suggests that systematic sampling be employed for ecological applications, with the resulting data treated as if they were the results of random samples.

Video 45. Systematic sampling
http://www.youtube.com/watch?v=QFoisfSZs8I

Acceptance Sampling

The following is taken from SQC Online, *About Acceptance Sampling.*

Acceptance sampling is a procedure used for sentencing incoming batches. The most widely used plans are given by the military standard (MIL STD) tables developed during World War II. The original version of the standard, MIL STD 105D, *Sampling Procedures and Tables for Inspection by Attributes* 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).

MIL STD 105D included 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.

Video 46. Acceptance sampling
http://www.youtube.com/watch?v=wULAwQz0md4

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

The following is taken from the Yale University, Department of Statistics, *Confidence Intervals.*

Confidence Interval

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

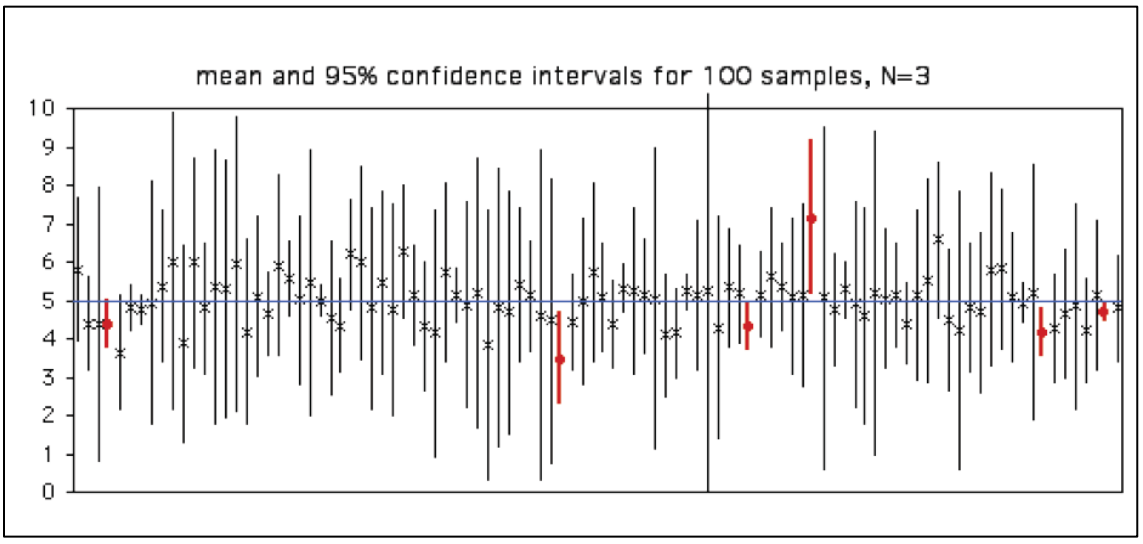
The common notation for the parameter in question is Θ. Often, this parameter is the population mean μ that is estimated through the sample mean $\overline{x}$. The level C of a confidence interval gives the probability that the interval produced by the method employed includes the true value of the parameter Θ.

Confidence Limit

The following is taken from the University of Delaware, *Handbook of Biological Statistics: Confidence Limits.*

After the mean of a set of observations has been calculated, determine how close the estimate is likely to be to the parametric mean. One way to do this is with confidence limits, numbers at the upper and lower end of a confidence interval. Usually, 95 percent confidence limits are used, although other values can be used. Setting 95 percent confidence limits means that if repeated random samples are taken from a population and the mean and confidence limits are calculated for each sample, the confidence interval for 95 percent of the samples would include the parametric mean.

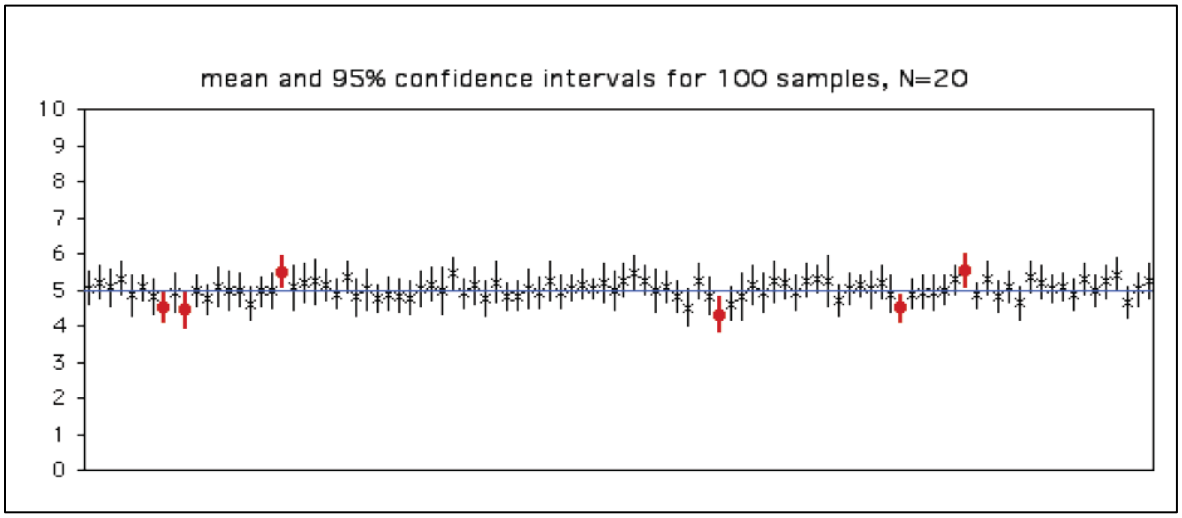
For example:



Source: University of Delaware, Handbook of Biological Statistics: Confidence Limits.

Figure 17. Confidence limit calculations

With larger sample sizes, the 95 percent confidence intervals get smaller:



Source: University of Delaware, Handbook of Biological Statistics: Confidence Limits.

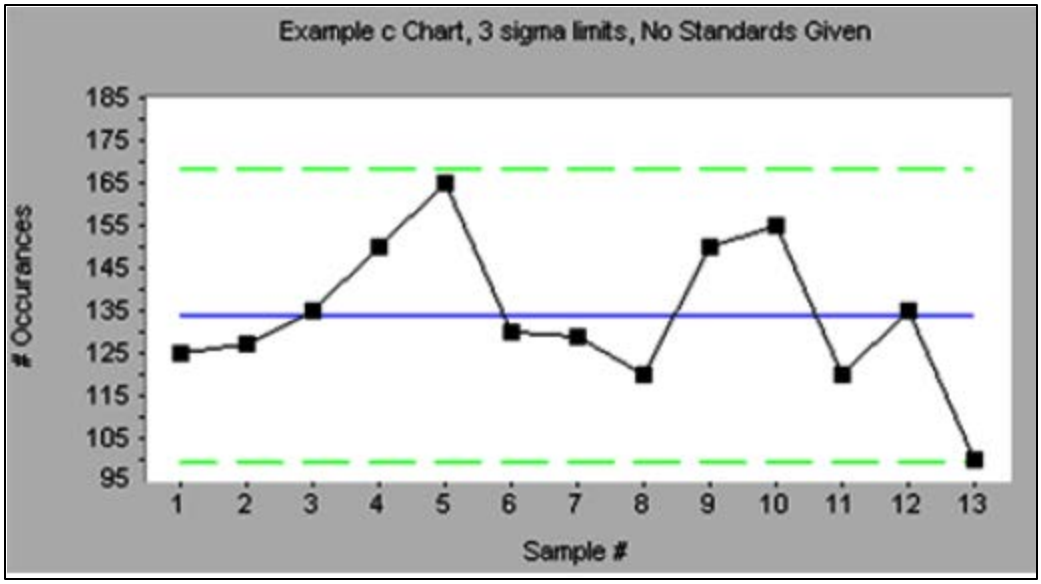
Figure 18. Confidence limit calculation part 2

When calculating the confidence limits for a single sample, it is tempting to say that "there is a 95 percent probability that the confidence interval includes the parametric mean." This is technically incorrect, because it implies that if there are enough collected samples with the same confidence interval, sometimes they would include the parametric mean and sometimes they wouldn't. For example, the first sample in the figure above has confidence limits of 4.59 and 5.51. It would be incorrect to say that 95 percent of the time, the parametric mean for this population would lay between 4.59 and 5.51. If repeated samples from this same population repeatedly got confidence limits of 4.59 and 5.51, the parametric mean (which is 5) would be in this interval 100 percent of the time.

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

The following is taken from U.S. Army, Office of Business Transformation, *Continuous Process Improvement: Lean Six Sigma.*

Every process varies. Writing a name ten times, the 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, there is an unusual variation due to what is called a special cause. If 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.



Source: U.S. Army, Office of Business Transformation, Continuous Process Improvement: Lean Six Sigma

Figure 19. Control chart

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

Video 47. What are control charts?

http://www.youtube.com/watch?v=gTxaQkuv6sU&feature=related

The following is taken from Skymark Management Resources, *Control Charts*.

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, 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 one applies more tests, 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 adjustments. This tampering usually distorts a stable process and wastes time and energy.

Type II or beta errors occur when a special cause is missed because the chart isn't sensitive enough to detect it. In this case, there is no awareness that a problem exists.

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 percent 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*.**

[Note: DOE G 414.1-1 has been superseded by DOE G 414.1-1B.]

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

The following is taken from DOE G 414.1-1B.

Source: iter.org

Figure 20. Daniel Lehman and DOE's Office of Project Assessment

All DOE products and services, and the programs, systems, and processes that deliver them can be assessed over their entire life cycles. DOE directives require integration of ES&H, S&S, and emergency management assessments to ensure that DOE and its contractors perform assessments as stated in 10 CFR 830, subpart A; DOE O 414.1D; and DOE O 226.1B.

Examples of functional areas for assessments are listed in DOE G 414.1-1B, appendix B, *Assessment Functional Areas*.

DOE line managers fulfill their safety responsibilities in part through line management ES&H oversight and have unfettered access to information and facilities according to safety and security requirements. Contractor line managers fulfill safety responsibilities in part through the implementation of their assessment programs. Contractors are responsible for establishing robust, rigorous, and credible ES&H, S&S, and emergency management assessment programs, integrated with their safety management systems.

Assessment programs conducted according to DOE G 414.1-1B, and appropriately adopted standards will satisfy the assessment requirements of 10 CFR 830, subpart A; DOE O 414.1D; and DOE O 226.1B. DOE G 414.1-1B, however, does not lessen the requirements to comply with DOE O 414.1D or 10 CFR 830, subpart A, including those requirements related to management and independent assessments. Alternative methods demonstrated to achieve adequate levels of safety and quality may be acceptable to DOE. DOE G 414.1-1B provides a basis for determining the adequacy of QA programs and ISMS descriptions.

DOE and its contractors are required to perform management and independent assessments according to

- 10 CFR 830, subpart A
- DOE O 414.1D
- 48 CFR 970.5223-1
- DOE O 226.1B
- DOE/NNSA QC-1, revision 10

DOE O 226.1B refers to contractor self-assessments for management and independent assessments. In this context, the assessments are those that a contractor conducts on its own ES&H performance. Management and independent assessments as described in DOE G 414.1-1B will satisfy the requirements of DOE O 226.1B.

Management and independent assessments may be performed on the same functions or organizations; however, each has a specific focus defined by 10 CFR 830, subpart A and DOE O 414.1D. Contractors should clearly describe in writing how their self-assessment programs satisfy the requirements for management and/or independent assessment.

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.

The following is taken from DOE G 414.1-1B.

Assessment Elements

An assessment program should have the following elements:

- Defined roles, responsibilities, authorities, and accountabilities for the staff performing and responding to assessments
- Documented description, defining the purpose and the processes that will be used to plan, perform, and follow up on assessments
- Use of safety information programs to plan and direct assessment resources on ES&H issues
- Both management and independent assessments
- Performance metrics that reflect the assessment process
- A process to periodically evaluate the effectiveness of site assessment programs in meeting regulatory and management objectives
- Clear links to measurable organizational goals and directives
- Inclusion of appropriate technical expertise within the assessment team
- A training program to ensure that assessment participants have the proper skills to perform assessments
- Assessment results that feed the corrective action system

Relationship and Differences Between Management and Independent Assessments

Managers must perform management assessments to comply with 10 CFR 830 and DOE O 414.1D. Management assessments look at the total picture.

- How well the management system and processes meet the customer's requirements
- Compliance with standards and requirements
- Meeting the expectations for safely performing work
- Clarity of the organizational mission, goals, and objectives
- Identifying and correcting problems that hinder the organization from achieving its 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.

Management assessment is a periodic introspective self-analysis to determine whether the management infrastructure is properly focused on achieving desired results. This includes reviewing the processes, systems, and programs that are important to the organization's mission and objectives.

An independent assessment may be an audit, surveillance, "for cause" review, or inspection conducted by individuals within the organization or company but independent from the work or process being evaluated, or by individuals from an external organization or company. In general, the purpose of this assessment is to perform the following:

- Evaluate compliance with standards and requirements

- Evaluate the performance of work
- Measure the quality of the item or service
- Examine process effectiveness/adequacy
- Promote improvement

The organization or staff performing independent assessments should have sufficient authority and freedom from the line organization to carry out its responsibilities. Individuals should be technically qualified and knowledgeable in assessment techniques and in the areas being assessed.

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. 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, subpart A and DOE O 414.1D.

Role of QA Personnel Relative to Management and Independent Assessments

Assessment personnel facilitate continuous process improvement by identifying ways programs, systems, and processes can be improved and by providing information to management and process owners. The assessor should be able to collect performance data through interviews, document reviews, observations, and inspections. It is very important that the assessor be able to communicate effectively, orally and in writing, and demonstrate effective interpersonal skills.

Management and independent assessments should be performed by qualified individuals who are knowledgeable about the program, system, or process being assessed and have been trained to ensure full understanding of the assessment processes, including reporting.

Individuals performing independent assessments should not currently perform, supervise, or be directly responsible for performing the activities being assessed. Independence is determined based on an individual not having bias, rather than on organizational affiliation. The independent assessor should have the personal and organizational freedom to communicate with the management of the assessed organizations.

Effective assessments may be accomplished through the 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.

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

The following is taken from DOE G 414.1-1B.

The emphasis of management assessment is on issues that affect performance, strategic planning, personnel qualification and training, staffing and skills mix, communication, cost control, organizational interfaces, and mission objectives.

Management assessment is a periodic introspective self-analysis to determine whether the organization's activities are properly focused on achieving desired results. This includes reviewing the processes, systems, and programs that are important to the organization's mission and objectives. Results of management as well as independent assessments can be used, in addition to formulating approaches and corrective actions for improvements, to develop plans for the subsequent management assessments. Additionally, independent assessment results may be used as the basis for determining the focus and frequency of management assessments. It should be noted that effective management assessments could result in less frequent independent assessments, and independent assessment findings could affect the frequency and rigor of management assessments.

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

The following is taken from DOE G 414.1-1B.

The information listed in KSA B1c, plus the following information, applies to this KSA.

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. 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 assessments share procedural and protocol commonalities with independent assessments. Because of this, the organization should ensure that assessment procedures are well defined and integrated, while maintaining the separate and unique focuses of the two types of assessments. Management and independent assessments look at the results of internal and external assessments to determine compliance with defined system requirements. Management assessments; however, need to focus on how well the system is meeting organizational objectives and achieving improvement goals.

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

The following is taken from DOE G 414.1-1B.

There are two different methods commonly used for accomplishing assessments. These are usually known as compliance assessment and performance-based assessment. While each method has distinct characteristics, a good assessment will usually gauge, at some level, effectiveness of the processes, systems, and programs in meeting the mission and objectives of the organization.

Compliance assessments focus on verifying compliance with requirements through the implementation of procedures, and begin with a determination of the contractual and regulatory requirements governing the assessed organization. Assessors should become familiar with requirements and procedures and 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. For example, an organization may have written procedures that appear to implement the requirements, however, in practice the intent of those requirements may not be fully achieved because of variables such as poorly executed procedures.

Performance-based assessments take 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, the assessor evaluates the methods and procedures used to implement the applicable requirements in an effort to find the failure that led to the problems. The assessor is expected to determine whether a non-compliance or series of non-compliances with procedures could result in a failure to satisfy top-level requirements. Results of prior compliance assessments may help the assessor in determining the focus areas for planning performance-based assessments.

In performance-based assessments, 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, the next step 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 a problem such as engineering or procurement?

While the assessor should be familiar with requirements and procedures, in performance-based assessments the assessor's experience and knowledge play an integral part in determining whether requirements are satisfied. Therefore, participants in performance-based assessments should 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 just verifying simple procedure compliance.

Performance-based assessments usually provide the most useful information to management; however, it requires a much higher level of competence on the part of the assessment team. Results of performance-based assessments may provide useful insight for management's pursuit of excellence.

Video 48. Performance-based assessment
http://www.youtube.com/watch?v=VBpXExOoSKM&feature=related

Video 49. Compliance assessment
http://www.bing.com/videos/search?q=Evaluation+of+Compliance+in+ISO+14001+Standards&view=detail&mid=BDB2E0EA7145E5079A6DBDB2E0EA7145E5079A6D&first=0

f. Describe the contents of a typical assessment report.

The following is taken from DOE G 414.1-1B.

Assessment reports are required for documentation of assessment results. Assessment team leaders have the overall responsibility for preparing the report and obtaining appropriate approval for its release as applicable. The report may be formal (e.g., distributed by memorandum) or informal (e.g., letter to file or email), 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 assessment report should be clear, concise, accurate, 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 develop and implement appropriate improvement plans.

Specific report formats may vary considerably from one organization to the next. An independent assessment report usually includes the sections described below. (Note: A management assessment report may not require all of the content listed below and may only require an executive summary.) Assessment report content includes the following:

- Executive summary
- Assessment scope
- Identification of team members
- Identification of personnel contacted
- Documents reviewed
- Work performance observed; assessment process and criteria (e.g., criteria review and approach documents)
- Results of the assessment including identification of areas for improvement, and/or strengths

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

The following is taken from DOE G 414.1-1B.

Management assessments should be planned in a systematic manner by the individual managers at each level of management, to evaluate the effectiveness and adequacy of their management systems. Assessments should be planned with appropriate consideration for other management and/or independent assessments that could conflict with or duplicate their efforts (see DOE G 414.1-1B, section 4.3, *Assessment Integration*). Management should

retain overall responsibility for the planning and performance of management assessments, and the results of the planning process should be documented in an assessment plan. The following items should be evaluated:

- How well management is providing the leadership to enable an organization to continuously meet internal and external customer requirements and expectations
- Processes and their effectiveness, internally and across organizational boundaries, including ensuring that the staff is receiving the support to do their work (training, procedures, tools, and cooperation from others)
- Performance information from other assessments (independent, self, and external assessments including financial, employee feedback systems, customer surveys, etc.)

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

Schedules for management assessments need to be established with the expected frequency of assessment performance specified. However, scheduling of management assessments should be as flexible as possible to meet operational and management needs.

The organization should review and update its management assessment schedule on a regular basis, either bi-monthly or quarterly, to ensure relevance. The review should consider the current conditions, conclusions of recent management assessments, inputs for independent assessments, and organizational performance.

Management of the Assessment Team

The following is taken from DOE-HDBK-3027-99.

The team leader should establish report requirements to the team members early in the review process. Team leader preparation of the final report should begin as soon as the team leader determines that sufficient information has been developed to identify issues and concerns. As new information is developed, it should be entered into the report draft.

The qualified team leader is a person selected from a list of senior technical safety managers who has been approved by the Director, Safety Management Implementation Team. Additional team leaders may be added to the approved team leader list after the member has successfully served on at least one team and was recommended by an approved team leader.

The following is taken from DOE G 414.1-1B.

Assessments should be performed by qualified individuals who are knowledgeable about the program, system, or process being assessed and have been trained to ensure full understanding of the assessment processes, including reporting. Individuals performing assessments should not currently perform, supervise, or be directly responsible for performing the activities being assessed. Independence is determined based on an individual not having bias, rather than on organizational affiliation.

Organizations should establish formal training and qualification programs for assessors, including assessment team leaders and team members, that reflect regulatory and customer requirements. Organizations may adopt third-party personnel qualification programs such as the ASQ quality auditor certification (http://www.asq.org/certification/index.html) or the

registrar accreditation board's certification program (http://www.rabqsa.com/). The ISO and the ASME provide additional guidance for training and qualification of assessors (ISO-1911:2002, *Structures*, and ASME NQA-1). For assessments of nuclear facilities and activities, ASME NQA-1 is the appropriate national standard to be used by DOE and contractor organizations for guidance on training of assessment personnel. At a minimum, training and qualification programs should be based on a recognized, relevant standard such as DOE-STD-1150-2002.

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 competency statement C1, element "f" for a discussion of communicating team findings.

The following is taken from DOE G 414.1-1B.

The assessor should be able to collect performance data through interviews, document reviews, observation, and inspection. It is very important that the assessor be able to communicate effectively, orally and in writing, and demonstrate effective interpersonal skills.

Analyzing Data and Determination of Overall Performance

The following is taken from DOE G 414.1-1B.

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. Assessments should be thorough and information gathered with sufficient diligence such that accurate, detailed conclusions can be provided to the organizations that will receive the final report.

When 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 be valuable 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.

Interviews

Interviews provide the means of verifying the results of observation, document review, inspection, and performance testing; allow the responsible person to explain and clarify those results; help to eliminate misunderstandings about program implementation; and provide a venue where apparent conflicts or recent changes can be discussed and organization and program expectations can be described.

Document Review

Document reviews provide the objective evidence to substantiate compliance with applicable requirements. A drawback 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 performance picture. Records and documents should be selected carefully to ensure that they adequately characterize the program, system, or process being assessed.

Observation

Observation, the viewing of actual work activities is often considered the most effective technique for determining whether performance is in accordance with requirements. 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.

Inspection

Inspections are performed in accordance with acceptance criteria to verify the condition of physical facilities, systems, equipment, and components.

Performance Testing

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

Much information about performance and additional performance requirements may be available to assessors in existing documents and reports, such as

- reports from outside regulators;
- facility operations/activity/metrics reports;
- performance reviews;
- previous assessment reports, including self-assessment reports;
- internal inspections, reviews, and reports;
- CAPs and status reports;
- concerns and occurrence reports;
- performance indicators;
- monitoring and survey data, and modeling data and analyses; and
- PAAA nonconformance tracking system reports.

Requirements contained in these documents are selected based upon impact on the assessed organization's mission and the relationship to the scope of the assessment. From selected requirements, objective statements (performance measures) are developed for determining whether a program, system, or process is working efficiently and effectively. From these measures, the specific performance criteria (based on written programs, DOE orders, rules, etc.) are developed and tools selected for conducting the assessments. In developing performance criteria, assessment personnel should not reinterpret or redefine requirements specified in the source documents.

The Exit Meeting

The following is taken from DOE G 414.1-1B.

This meeting is used primarily by the assessment team to present the assessment summary. Reasonable time should be allowed to discuss any concerns, but this meeting should not be used to argue the assessment findings or methodology. There should be no surprises during the exit meeting since the assessment team should have taken every effort possible during the conduct of the assessment to ensure that the assessed organization was aware of the team's findings and concerns. Prior to the exit meeting the assessment team should consider combining related findings into a small number of well-supported findings to help focus management's opportunities for improvement.

Closure Process, Tracking to Closure, and Follow up

The following is taken from DOE G 414.1-1B.

At a minimum, the final report should be distributed to the management of the assessed and assessing organizations. Distribution to other organizations should be defined during the planning phase and communicated in advance to the assessed group.

Because the true value of an assessment is the improvement opportunities it identifies, and its value typically diminishes over time, the best time to release a report is immediately after the post-assessment meeting, which allows the assessed organization to begin improvement actions, yielding the maximum return for those actions. The assessment report or transmittal correspondence should clearly indicate what response is expected from the assessed organization and a reasonable response date.

Assessment reports should include a concise summary of the topics or areas assessed, the conclusions reached, and any follow up actions that may be required. Reports should be available for use by others and for future planning. Special provisions may be required for reports dealing with sensitive areas, proprietary information, or classified information. Assessments identifying potential regulatory compliance issues should be communicated directly to the appropriate managers for any necessary action as well as in the final assessment report.

Corrective Action Implementation

The following is taken from DOE G 414.1-1B.

Managers responsible for the activities assessed are responsible for the development of effective corrective actions for the problem areas/deficiencies discovered during the assessment. At a minimum, these 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 or underlying causes
- Actions to preclude recurrence of like or similar deficiencies
- Assignment of corrective action responsibility
- Completion dates for each corrective action

Managers should verify that corrective actions are likely to fully address the identified deficiency and when actions are completed, validate that the actions have corrected the deficiency. Specific, detailed requirements and guidance exist for responding to assessments conducted by the Department's independent oversight organization.

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

The following is taken from DOE G 414.1-1B.

An entrance meeting involving personnel from the assessing organization and the managers of the organization being assessed is held immediately before the assessment fieldwork begins to set the stage for a positive and productive independent assessment. This meeting is usually held at the assessed organization's location/facility and allows the assessment team to meet the assessed organization's managers and answer any questions they may have about the assessment. This meeting is used to establish how concerns involving imminent danger or regulatory non-compliance will be communicated.

The exit meeting is used primarily by the assessment team to present the assessment summary. Reasonable time should be allowed to discuss any concerns, but this meeting should not be used to argue the assessment findings or methodology. There should be no surprises during the exit meeting since the assessment team should have taken every effort possible during the conduct of the assessment to ensure that the assessed organization was aware of the team's findings and concerns. Prior to the exit meeting the assessment team should consider combining related findings into a small number of well-supported findings to help focus management's opportunities for improvement.

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

The following is taken from American Society for Quality Control, Charles Mills, *The Quality Audit: A Management Evaluation Tool.*

In order to uphold and advance the honor, dignity, and status of the quality audit profession, the auditor will

- be honest and impartial, and serve with devotion employers, clients, and the public;
- undertake those audits compatible with the degree of training, experience, and proficiency he or she holds in regard to the technical or systems operations being audited;
- demonstrate a freedom of mind and approach which will ensure objective viewing of the operation being audited;
- be able to document the professional qualifications needed in order to provide clear, objective evidence of the degree of his or her technical and systems training;
- act in professional matters as a faithful agent or trustee of each employer or client;

- inform each client or employer of any business connections, financial interests, employment history, or affiliations which might influence, or appear to influence, his or her judgment or impair the equitable character of his or her services;
- have their independence clearly defined by organizational policies and procedures;
- will issue reports which clearly define the degree of conformance or nonconformance of the operation being audited. In all cases the requirement against which conformance is being measured will be clearly defined.
- indicate to employers or clients the adverse consequences to be expected if their professional judgment is overruled;
- will not disclose information concerning the business affairs or technical processes of any present or future employer or client without obtaining consent to do so.

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.

[Note: DOE G 414.1-2 has been superseded by DOE G 414.1-2B.]

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

Identification of Quality Problems

The following is taken from DOE G 414.1-2B.

Problems affecting quality may be identified by internal organization sources or external sources. Once identified, problems should be documented and evaluated to determine their significance. The method for determining the significance of a problem and the process for handling problems should be documented as part of the QAP.

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

Problems that are not significant, but can be readily corrected, should be identified and documented. These types of problems may be handled in an expedient manner that may not necessarily need to follow the more formal processes for problem documentation, disposition, and corrective action.

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 414.1-2B, section 4.3.2, including

- deficiencies in an activity, product, service, item characteristic, or process parameter;
- noncompliance to a requirement;
- indeterminate/substandard condition, or a S/CI as defined in International Atomic Energy Agency (IAEA)-Technical Document (TECDOC)-1169, *Managing Suspect and Counterfeit Items in the Nuclear Industry*; or
- conditions adverse to quality and/or significant conditions adverse to quality.

b. Resolution of quality problems.

The following is taken from DOE G 414.1-2B.

Problems that affect quality may be referred to as conditions adverse to quality and/or significant conditions adverse to quality, should be identified and corrected as soon as possible. The identification and reporting process should be documented and include a standard categorization of problem findings based on significance, criticality, severity, and potential impact on the safety, security, and mission of the site/organization. A corrective action/resolution process should consist of the appropriate steps, such as

- identifying a condition adverse to quality, and/or significant condition adverse to quality;
- taking appropriate actions as required to mitigate, stabilize, and/or prevent further progression of unsafe conditions or conditions adverse to quality;
- documenting the condition adverse to quality and/or significant 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 personnel as appropriate;
- taking steps to prevent recurrence;
- verifying implementation;
- documenting closure;
- determining the effectiveness of the corrective and preventive actions for significant problems;
- tracking and trending conditions adverse to quality as appropriate; and
- communicating lessons learned as appropriate.

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

The following is taken from DOE G 414.1-4.

Formal procedures for software problem reporting, and corrective action for safety software errors and failures are established, maintained, and controlled.

Criteria:

- Documented practices and procedures for reporting, tracking, and resolving problems or issues are defined and implemented.
- An evaluation process exists for determining if the reported problem is a safety software defect, error, or something else.
- Organizational responsibilities for reporting issues, approving changes, and implementing corrective actions are identified and found to be effective.
- For safety software defects and errors, the defect or error is correlated with the appropriate software engineering elements, identified for potential impact, and all users are notified.

- For acquired safety software, procurement documents identify the requirements to the supplier and purchaser to report problems to each other.

Review documents and interview facility staff for the problem reporting and notification process to determine whether

- a formal procedure exists for software problem reporting and corrective action development that addresses software errors, failures, and resolutions;
- problems that impact the operation of the software are promptly reported to affected organizations;
- corrections and changes are evaluated for impact and approved prior to being implemented;
- corrections and changes are verified for correct operation and to ensure that no side effects were introduced;
- preventive measures and corrective actions are provided to affected organizations in a timely manner; and
- the organizations responsible for problem reporting and resolution are clearly defined.

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

The following is taken from DOE G 414.1-2B.

Preventive action minimizes the occurrence of quality problems through appropriate design, inspection, procurement, and other process controls and assessment activities. 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 safety risks to the environment and human health
- impacting the 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.

The following is taken from DOE G 414.1-2B.

Efforts related to quality improvement are intended to identify, control, and improve items, services, and processes. Improvement processes detect and prevent problems while identifying the causes of problems and work needed to prevent recurrence of problems through corrective actions. The quality improvement process is a disciplined management process based on the premise that all work can be planned, performed, measured, and improved. Management should ensure that the focus is on improving the quality of products, processes, and services by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating lessons learned, and resolving significant management issues and problems that can hinder the organization from achieving its objectives. Management should balance safety and mission priorities when considering improvement actions, and implement safety and ISMS for their operations and work practices, based on the ISM guiding principles.

Management should encourage employees to plan, develop, explore, and implement new ideas for improving products, processes, and services. Management commitment can be demonstrated by empowering employees to

- identify and report problems
- identify opportunities for improvement
- identify best management practices
- develop alternative approaches for addressing problems and recommending improvements
- implement the approved solution
- evaluate the improvement
- provide lessons learned to other organizations

Identified problems and other related information, positive and negative, from internal and external sources should be reviewed and analyzed to identify improvement opportunities. Implemented improvements should be monitored and methods established to verify their effectiveness.

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.

[Note: DOE G 414.1-1 has been superseded by DOE G 414.1-1B; DOE G 450.4-1 has been superseded by DOE G 450.4-1C, *Integrated Safety Management System Guide*; and DOE G 414.1-2 has been superseded by DOE G 414.1-2B.]

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

The following is taken from DOE-NE-STD-1004-92 (archived).

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 the 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 back to the root cause (the fundamental reason that, if corrected, could prevent recurrence of this and similar occurrences throughout the facility and other facilities). 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.

Video 50. Root cause analysis of the Titanic
http://www.youtube.com/watch?v=GOVeO5_0qD0

Causal Factor Analysis

The following is taken from DOE-NE-STD-1004-92 (archived).

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.

Video 51. Causal factor analysis
http://www.bing.com/videos/search?q=causal+factor+analysis&view=detail&mid=688B9B1584793737F29D688B9B1584793737F29D&first=0

Change Analysis

The following is taken from DOE-NE-STD-1004-92 (archived).

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 is relevant to the causes of, or that is the contributor to, the undesirable consequences.

Change analysis is a good technique to use whenever the causes of the condition are obscure, the starting point is unclear, or one suspects 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

The following is taken from DOE-NE-STD-1004-92 (archived).

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

The following is taken from DOE-NE-STD-1004-92 (archived).

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, causal 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)**

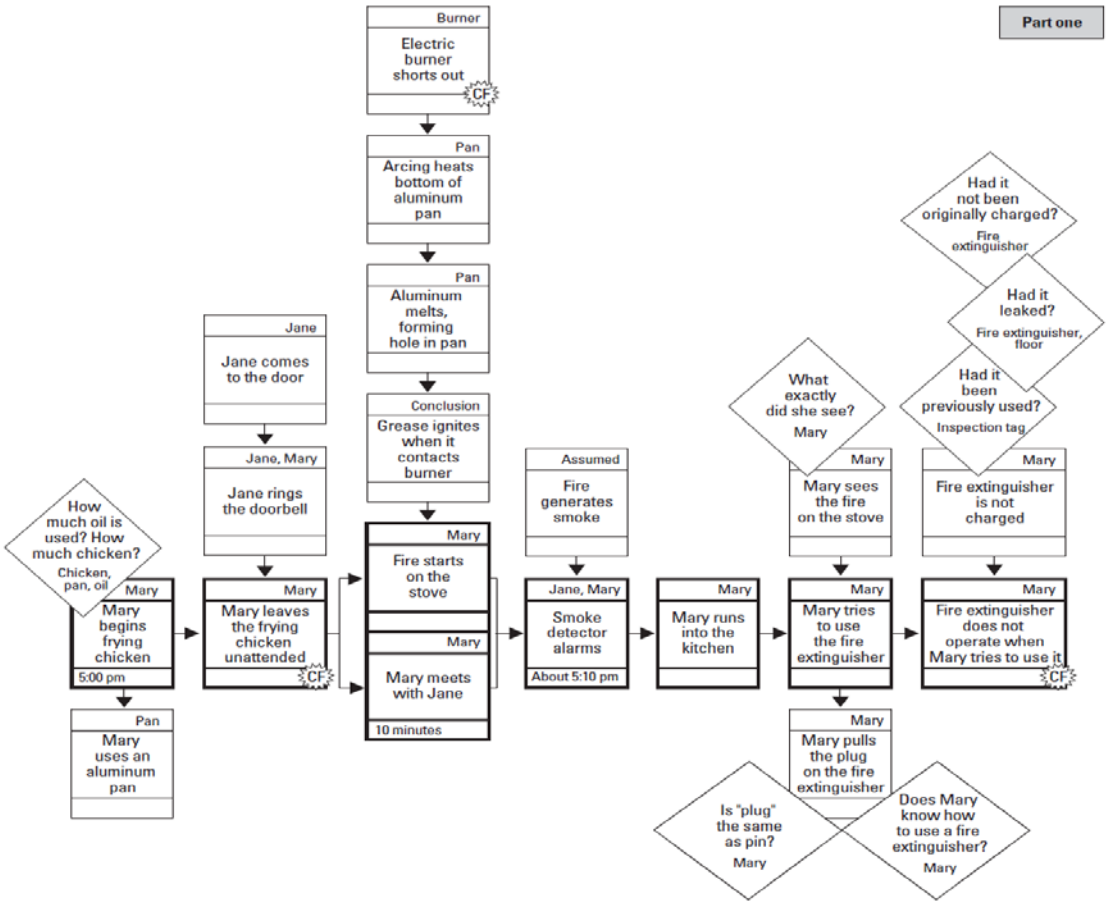
Event and Causal Factor Charting

The following is taken from DOE G 225.1A-1 (cancelled).

Events and causal factors charting is an integral and important part of the DOE accident investigation process. It is used in conjunction with other key tools (such as root cause analysis, change analysis, and barrier analysis) to achieve optimal analytical results in accident investigation.

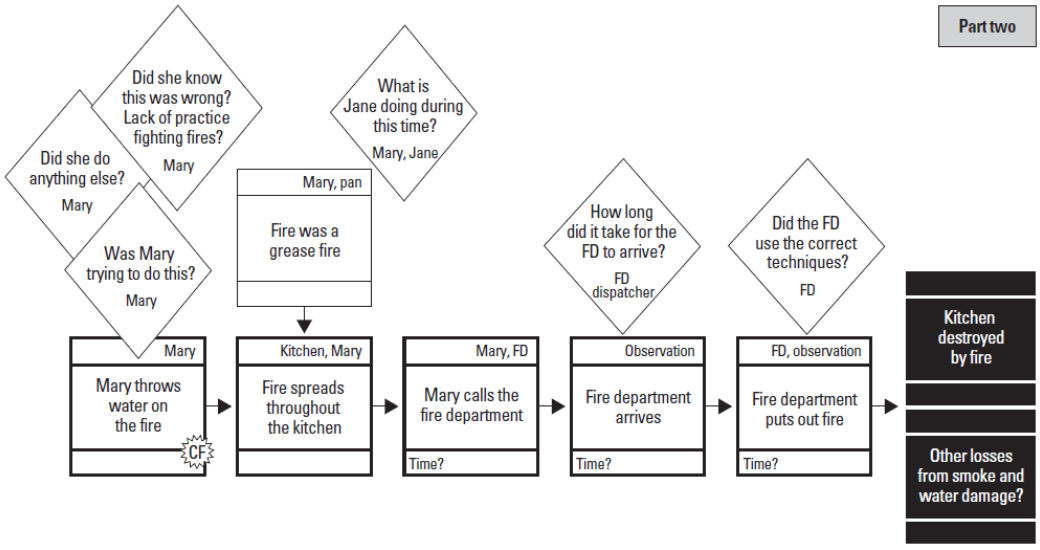
An events and causal factors chart is a graphic representation that produces a picture of the accident: both the sequence of events that led to the accident and the conditions that were causal factors.

Events and causal factors analysis is an effective means of integrating other analytical techniques into a concise and complete investigative summary. Events and causal factors analysis depicts, in logical sequence, the necessary and sufficient events and conditions for accident occurrence. It provides a systematic accident analysis tool to aid in collecting, organizing, and depicting accident information; validating information from other analytical techniques; writing and illustrating the accident investigation report; and briefing management on the results of the investigation. The following figures 22, *Event and causal factor charting, part one*, and 23, *Event and causal factor charting, part two*, show events and causal factors charting.



Source: James J. Rooney and Lee N. Vanden Heuvel, Root Cause Analysis for Beginners

Figure 21. Event and causal factor charting, part one



Source: James J. Rooney and Lee N. Vanden Heuvel, Root Cause Analysis for Beginners

Figure 22. Event and causal factor charting, part two

Root Cause Coding

The following is taken from DOE G 225.1A-1 (cancelled).

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)

Source: Mathews Brand Solutions

Figure 23. Root cause coding

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

Generation of Recommendations

The following is taken from Rooney, James J. and Lee N. Vanden Heuvel, *Root Cause Analysis for Beginners*.

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.

Source: skills-management.blogspot.com

Figure 24. Root cause analysis for beginners

There are four steps to recommendation generation.

- Step one—data collection. The first step is to gather data. Without complete information and an understanding of the event, the causal factors and root causes associated with the event cannot be identified. The majority of time spent analyzing an event is spent in gathering data.
- Step two—causal factor charting. Charting provides a structure for investigators to organize and analyze the information gathered during the investigation and identify gaps and deficiencies in knowledge as the investigation progresses.
- Step three—root cause identification. After all the causal factors have been identified, the investigators begin root cause identification. This step involves the use of a decision diagram called the root cause map.
- Step four—recommendation generation and implementation. Following identification of the root causes for a particular causal factor, achievable recommendations for preventing its recurrence are then generated.

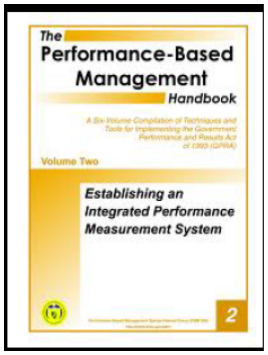
The root cause analyst is often not responsible for the implementation of recommendations generated by the analysis. However, if the recommendations are not implemented, the effort expended in performing the analysis is wasted. In addition, the events that triggered the analysis should be expected to recur.

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

The following is taken from the Performance-Based Management Special Interest Group, Performance-Based Management Handbook, vol. 5, *Analyzing, Reviewing, and Reporting Performance Data*.

Data should be collected from all possible sources. The analysis plan should indicate what data has been collected on these various aspects or where to pull that data.

- Baseline data
- Performance measurements (self-assessments, onsite reviews, etc.)
- Relevant in-depth evaluation studies (expert review, Government Accountability Office studies, etc.)
- Status of assumptions about external influencing factors
- Other parts of the organization, programs, and facilities



Source: aspdf.com

Figure 25. The performance-based handbook

Goals and stretch targets can be numerical or they can be stated in terms of achievement of a significant, improving trend. One way of determining and showing a trend is a statistical process control chart. Another is to use expert opinion about qualitative definitions of success in a peer review. If a control chart is used, the chart becomes the criterion for determination of success. In both cases, numerical targets are not used. With the control chart, the goal or stretch target is stated as to "achieve statistically significant improvement" in certain measures over certain time frames. Goals that are stated in terms of achievement of statistically significant improvements are easy to monitor using a control chart. This methodology eliminates the problem of "we achieved a 49 percent improvement, but the target was 50 percent, so we

failed." It prevents a random, lucky fluctuation in performance from being declared as a success. As part of asking "Is there a trend?" an analyst would ask:

- Is the performance measure improving, degrading, or remaining stable?
- Is the data predictable and is variability in the data predictable and small, or is the process very unpredictable and/or is there large variation in the data?

The goal of trend analysis is to detect trends indicating that a performance measure or indicator is improving, declining, or remaining stable. In the context of this procedure, a trend is a statistically significant change in time-series data. Trend analysis can provide important information that a simple table or bar chart of the raw data cannot provide. Simply reviewing the raw data may cause a person to overreact to random fluctuations (variation) in the process data and wrongly assume that progress is being made towards or away from the goal. If numerical targets are used, the trend analysis gives more information than how far the current data point is from the target. Trend analysis answers these questions:

- Is the target achievable by the current process?
- Is the current process data stable in a range where the target can be achieved?
- Is progress being made to close the gap between actual and the target, or is the gap opening?

It is possible to have goals and meet the Government Performance and Results Act of 1993 requirements without numerical targets. In this case, the trend analysis itself represents the goal. The goal is either stated as 1) maintain current performance without a significant declining trend or 2) achieve an improving trend.

Performance data will rarely remain constant from month to month. The key ability trending provides is determining whether or not the pattern in the data is a random fluctuation (or noise) or is an important signal which must be acted upon. The simplest trending tool that allows for determination of statistical significance is statistical process control, utilizing control charts.

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 KSA. The Qualifying Official will evaluate its completion.

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 following is taken from the Performance-Based Management Special Interest Group, Performance-Based Management Handbook, vol. 5, *Analyzing, Reviewing, and Reporting Performance Data*.

The simplest trending tool that allows for determination of statistical significance is statistical process control, utilizing control charts. A control chart includes

- the performance data
- an average (or center) line set at the mean (arithmetic average) of the data
- an upper control limit set at the mean plus three standard deviations
- a lower control limit set at the mean minus three standard deviations

There are four types of control charts—the p-chart, c-chart, u-chart, and x-chart—that are used when the data being measured meet certain conditions (or attributes). Their characteristics are given in the following table.

Table 3. Type of control charts

Type	Characteristics
p-chart	Used with binomial data such as go/no-go situations. They account for sample size and are effective for small samples as well as large samples.
c-chart	Used for Poisson processes such as counting attributes or random arrival.
u-chart	Used for counting defects when sample size varies for each lot.
x-chart	Generic control chart that is used when the above conditions are not met.

Source: Performance-Based Management Handbook, volume 5

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 KSAs. The Qualifying Official will evaluate their completion.

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.

[Note: DOE G 414.1-1 has been superseded by DOE G 414.1-1B and DOE G 414.1-2 has been superseded by DOE G 414.1-2B.]

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

The following is taken from DOE G 414.1-1B.

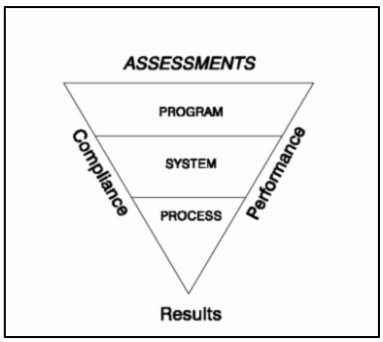
To develop a comprehensive assessment program that optimizes the application of each assessment type, it may be helpful to visualize the organization as having three interlinked levels of activity. For this discussion, these levels are referred to as "process," "system," and

"program." Management and independent assessments can be applied at all three levels, but examine different aspects of each level.

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 to yield a complete product or service.

A program is the most complex level, and consists of multiple interdependent systems that often require several interfaces to provide the desired product or service.



Source: DOE G 414.1-1B

Figure 26. Level of activity

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.

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.

System Level Assessments

A system is made up of two or more processes that may operate independently or interdependently to yield a complete product or service. 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.

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.

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).

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

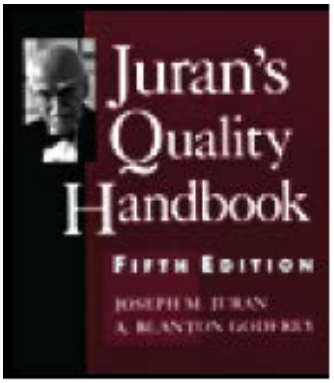
effectiveness of the entire maintenance program. This program assessment could be performed as either a management assessment or an independent assessment. A management assessment might focus on comparing the strategic goals for maintenance with actual performance to determine whether the rewards and 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.

The following is taken from Juran's *Quality Control Handbook,* 5th Edition.



Source: Juran's Quality Handbook

Figure 27. Juran's quality handbook

Formal systems of seriousness classification were originally evolved to serve specialized purposes. However, as the systems came into being, they were found to have application in the entire progression of product from design through usage: in quality specification, manufacturing planning, supplier relations, tooling, production, salvage, product auditing, and executing reporting. Vital qualities could now be identified with greater confidence, and it became feasible to delegate class decisions and actions on a broad scale. For example all class "C" defects could be assigned a common sampling plan, thereby avoiding the need for publishing numerous individual plans. The multiple uses of seriousness classification systems make it desirable that the job of developing such a system be guided by an interdepartmental committee that has the responsibility for drafting a plan, modifying it, and recommending it for adoption. Such a committee has a series of tasks:

- Determining the number of strata or classes of seriousness to use
- Defining each class
- Classifying each defect into one of the classes.

Table 4, *Serious classification of defects (Bell System),* lists the formal system of seriousness classifications evolved to serve specialized purposes.

Table 4. Serious classification of defects (Bell System)

Class A – very serious (demerit value, 100)	
1.	Will surely cause an operating failure of the unit in service that cannot be readily corrected in the field, or
2.	Will surely cause intermittent trouble, difficult to locate in the field, or
3.	Will render unit totally unfit for service, or
4.	Liable to cause personal injury or property damage under normal conditions of use.
Class B – serious (demerit value, 50)	
1.	Will probably cause an operating failure of the unit in service that cannot be readily corrected in the field, or
2.	Will surely cause an operating failure of the unit in service that can be readily corrected in the field, or
3.	Will surely cause trouble of a nature less serious than an operating failure, such as substandard performance, or
4.	Will surely involve increased maintenance or decreased life, or
5.	Will cause a major increase in installation effort by the customer, or
6.	Defects of appearance or finish that are extreme in intensity.
Class C – moderately serious (demerit value, 10)	
1.	May possibly cause an operating failure of the unit in service, or
2.	Likely to cause trouble of a nature less than an operating failure, such as substandard performance, or
3.	Likely to involve increased maintenance or decreased life, or
4.	Will cause a minor increase in installation effort by the customer, or
5.	Major defects of appearance, finish, or workmanship.
Class D – not serious (demerit value, 1)	
1.	Will not affect operation, maintenance, or life of the unit in service (including minor deviations from engineering requirements), or
2.	Minor defects of appearance, finish, or workmanship.

Source: Juran's Quality Control Handbook, 5th Edition.

c. Discuss possible assessment alternatives when actual work activities cannot be observed.

The following is taken from DOE G 414.1-2B.

[Note: The following is excerpted from the Quality Assurance Assessment Plan Template, found in the referenced guide. Each of the items below contains additional recommendations and information that may be used as part of an independent assessment.]

The objective of an independent assessment is to provide feedback for continuous improvement: A process is established and effectively implemented to continuously improve safety and improve the efficiency and quality of operations. Procedures and mechanisms are in place to implement ISM and QAPs through approved program plans.

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

- Review the organization and reporting chain to ensure clear lines of authority are established and utilized.
- Review the graded approach and any criteria for determining what QA management requirements are implemented for various types of work.
- Review and approval of contractor QAPs for selected high-risk activities.
- Evaluate the status of implementation of a training and qualification program that ensures personnel are capable of performing their assigned work.
- Evaluate the status of implementation of a quality improvement process to detect and prevent quality problems.
- Evaluate the approach to identification, control, and correction of items, services, and processes that do not meet established requirements (nonconforming).
- Evaluate the process to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
- Evaluate the process for preparation, review, approval, issue, use, and revision of documents that prescribe processes, requirements, and design.
- Evaluate the process for specification, preparation, review, approval, and maintenance of records.
- Evaluate the implementation of quality management principles in work processes.
- Evaluate the implementation of quality management principles in design.
- Review contract list A/list B requirements for proper flowdown to contractors of DOE O 414.1D and/or 10 CFR 830, subpart A, requirements.
- Evaluate the process for review of proposals and selection of contractors, QA and ISMS requirements flowdown, customer requirements flowdown.
- Evaluate the process for inspections and acceptance testing of items, services, and processes.
- Evaluate the assigned responsibility for implementation of management assessment for selected activities.
- Evaluate the assigned responsibility for implementation of independent assessment for selected activities.
- Evaluate the status of implementation of a software QA program.
- Review the oversight of the S/CI prevention process implementation.

- Review the integration of ISMS into the overall QA program for selected high-risk activities.

The following is a suggested list of documents and interviews that may be useful in the independent assessment process.

Record Review:

- Functions, responsibilities, authorities manual
- QAP
- ISMS description
- Contract list A/list B requirements
- Contractor QAP approval
- List of current projects and activities
- Management assessment schedule
- Independent assessment schedule

For ISMS:

- Oversight assessment plan for current fiscal year (FY)
- Current FY safety performance objectives
- Current ISMS description
- Contractor ISMS description
- Contract section I DEAR clauses 10 CFR 970.5223-1 and 10 CFR 970.5204-2

Interviews:

- Senior management (closeout)
- Facility and operations team leader
- Quality and safety division director
- Quality assurance and process management team leader
- Quality assurance subject matter expert
- Facility and materials disposition division acting director
- Waste disposition division acting director
- Lead facility representative
- Facility engineers
- Others as needed

d. Discuss conventional assessment team member qualification requirements.

The following is taken from DOE G 414.1-2B.

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.

Source: www.1strecruitaustralia.com

Figure 28. Qualification and training

The following is taken from DOE G 414.1-1B.

Organizations should establish formal training and qualification programs for assessors, including assessment team leaders and team members, that reflect regulatory and customer requirements. Organizations may adopt third-party personnel qualification programs such as the ASQ quality auditor certification or the registrar accreditation board's certification program. The ISO and the ASME provides additional guidance for training and qualification of assessors. For assessments of nuclear facilities and activities, ASME NQA-1 is the appropriate national standard to be used by DOE and contractor organizations for guidance on training of assessment personnel. At a minimum, training and qualification programs should be based on a recognized, relevant standard such as DOE-STD-1150-2002.

Effective assessments may be accomplished through the 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. Further guidance on assessor training and qualification is provided by DOE Orders and guides, and the standards listed in DOE G 414.1-2B, appendix A, *Quality Assurance Program Review and Approval Template*.

e. Describe the benefits of monitoring or surveillance of contractor activities.

The following is taken from DOE G 414.1-2B.

Source: www.palmerbros.com
Figure 29. Monitoring of contractors

The qualified supplier's performance should be evaluated periodically to confirm continuing capabilities. Qualified supplier's performance should be reviewed annually and audited every third year unless events warrant more frequent assessment. Such evaluation should include monitoring of the supplier's work processes to ensure conformance to those requirements that cannot be readily determined by inspection or test of the product. In some cases, due to the importance of the items being procured or for known quality problems with the supplier, a full-time resident inspector may be assigned to monitor the supplier's performance.
Monitoring may include the following:

- Surveillance of in-process work activities and review of work package documentation
- Inspection of facilities and processes
- Review of plans and progress reports
- 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

f. Discuss how QA criteria are evaluated in a readiness review.

The following is taken from DOE G 414.1-2B.

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 quality policy promulgated and quality improvement is 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?

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

The following is taken from DOE G 414.1-1B.

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 G 414.1, and P 450.5, Line ES&H Oversight.

[Note: DOE G 414.1 does not exist and DOE P 450.5 has been cancelled.]

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.

[Note: DOE G 414.1-2 has been superseded by DOE G 414.1-2B.]

The following is taken from 10 CFR 830.122.

Criterion 3—Management/Quality Improvement

- Establish and implement processes to detect and prevent quality problems.
- Identify, control, and correct items, services, and processes that do not meet established requirements.
- Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.
- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

Criterion 8—Performance/Inspection and Acceptance Testing

- Inspect and test specified items, services, and processes using established acceptance and performance criteria.

Criterion 10—Assessment/Independent Assessment

- Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

The following is taken from DOE G 414.1-2B.

To accomplish DOE missions and objectives, DOE and its contractors are responsible for the management and oversight functions of a wide range of work activities, including basic and applied research; product development; design, construction, operation, modification, decommissioning, and environmental remediation of DOE facilities and sites. This work should be accomplished safely while minimizing potential hazards to the public, site or facility workers, and the environment consistent with the QA requirements of DOE O 414.1D and 10 CFR 830, subpart A. The quality criteria of DOE O 414.1D and 10 CFR 830, subpart A, provide the requirements for a QAP that ensures work is consistent with DOE requirements and expectations.

All software use and development should meet the applicable QA requirements using a graded approach as described in DOE G 414.1-2B.

Table 5, *Integration of QA criteria into DOE O 226.1B*, which follows, conveys the oversight responsibilities displayed in DOE O 226.1B,

Table 5. Integration of QA criteria into DOE O 226.1B

QA Criteria DOE O 226.1 REQUIREMENTS	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
4 REQUIREMENTS										
a. All applicable DOE organizations must:										
1) Establish and implement an effective oversight program consistent with DOE O 226.1B and the requirements of this order	X		X	X	X				X	X
2) Maintain sufficient technical capability and knowledge of site and contractor activities to make informed decisions about hazards, risks and resource allocation; provide direction to contractors; and evaluate contractor performance	X	X								
b. Oversight processes implemented by applicable DOE line management organizations must:										
1) Evaluate contractor and DOE programs and management systems, including site assurance systems, for effectiveness of performance (including compliance with requirements). Such evaluations must be based on the results of operational awareness activities; assessments of facilities, operations, and programs; and assessments of the contractor's assurance system. The level and/or mix (i.e., rigor or frequency in a particular area) of oversight may be tailored based on considerations of hazards, the maturity and operational performance of the contractor's programs and management systems.					X				X	X
2) Include written plans and schedules for planned assessments, focus areas for operational oversight, and reviews of the contractor's self-assessment of processes and systems. Address the role of the Central Technical Authorities and their support staff for core nuclear safety functions.				X	X				X	X
3) Include DOE Headquarters line organizations' conduct of oversight processes that are focused primarily on their DOE Field Elements, including reviewing contractor activities to the extent necessary to evaluate the implementation and effectiveness of the Field Element's oversight of its contractors.				X	X				X	X

Table 5. Integration of QA criteria into DOE O 226.1B (Cont.)

QA Criteria DOE O 226.1 REQUIREMENTS	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
4) Include an issues management process that is capable of categorizing findings based on risk and priority, ensuring relevant line management findings are effectively communicated to the contractors, and ensuring that problems are evaluated and corrected on a timely basis. The issues management process must ensure for issues categorized as high significance findings:			X	X						
a) A thorough analysis of the underlying causal factors is completed			X	X						
b) Corrective actions that will address the cause(s) of the findings and prevent recurrence are identified and implemented;	X		X							
c) After completion of a corrective action or a set of corrective actions, the conduct of an effectiveness review using trained and qualified personnel that can verify the corrective action/corrective action plan has been effectively implemented to prevent recurrences;			X							X
d) Documentation of the analysis process and results described in (a) and maintenance tracking to completion of plans and schedules for the corrective actions and effectiveness reviews described in (b) and (c) above, in a readily accessible system; and			X	X						
e) When findings and/or corrective actions apply to more than one Secretarial Office, a lead office is appointed by mutual agreement between the affected Secretarial Officers.	X		X							
5) Be tailored according to the effectiveness of contractor assurance systems, the hazards at the site/activity, and the degree of risk, giving additional emphasis to potentially high consequence activities.					X					
c. DOE line management must establish and communicate performance expectations to contractors through formal contract mechanisms. Such expectations (e.g., safety performance measures and commitments) must be established on an annual basis, or as otherwise required or determined appropriate by the Field Element.	X						X			
d. DOE line management must have effective processes for communicating oversight results and other issues in a timely manner up the line management chain, and to the contractor as appropriate, sufficient to allow senior managers to make informed decisions.	X		X	X					X	X

Table 5. Integration of QA criteria into DOE O 226.1B (Cont.)

QA Criteria / DOE O 226.1 REQUIREMENTS	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
e. For activities and programs at Government-owned and Government-operated facilities and sites that are not under the cognizance of a DOE Field Element, DOE Headquarters program offices must establish and implement comparably effective oversight processes consistent with requirements for the contractor assurance system (see Attachment 1 of this Guide) and DOE line management oversight processes.									X	X
Note: X indicates cross-reference delineating when the QA criteria are applied to the requirements DOE O 226.1B.										

Source: DOE G 414.1-2B

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 KSA. The Qualifying Official will evaluate its completion.

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

The following is taken from DOE O 226.1B.

Oversight processes implemented by applicable DOE line management organizations must do the following:

- Include an issues management process that is capable of categorizing findings based on risk and priority, ensuring relevant line management findings are effectively communicated to the contractors, and ensuring that problems are evaluated and corrected on a timely basis. The issues management process must ensure for issues categorized as high significance findings:
  - A thorough analysis of the underlying causal factors is completed.
  - Corrective actions that will address the cause(s) of the findings and prevent recurrence are identified and implemented.
  - After completion of a corrective action or a set of corrective actions, the conduct of an effectiveness review using trained and qualified personnel that can verify the corrective action/CAP has been effectively implemented to prevent recurrences.
  - Documentation of the analysis process and results described in the thorough analysis and maintenance tracking to completion of plans and schedules for the corrective actions and effectiveness reviews described in the previous bullets, in a readily accessible system.

- When findings and/or corrective actions apply to more than one secretarial office, a lead office is appointed by mutual agreement between the affected causals.

- Be tailored according to the effectiveness of contractor assurance systems, the hazards at the site/activity, and the degree of risk, giving additional emphasis to potential high consequence activities.
- DOE line management must establish and communicate performance expectations to contractors through formal contract mechanisms. Such expectations must be established on an annual basis, or as otherwise required or determined appropriate by the field element.
- DOE line management must have effective processes for communicating oversight results and other issues in a timely manner up the line management chain, and to the contractor as appropriate, sufficient to allow senior managers to make informed decisions.
- For activities and programs at government-owned and government-operated facilities and sites that are not under the cognizance of a DOE field element, DOE HQ program offices must establish and implement comparably effective oversight processes consistent with requirements for the contractor assurance system and DOE line management oversight processes.

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