U. S. Department of Energy
Office of Legacy Management

Quality Assurance Program Plan

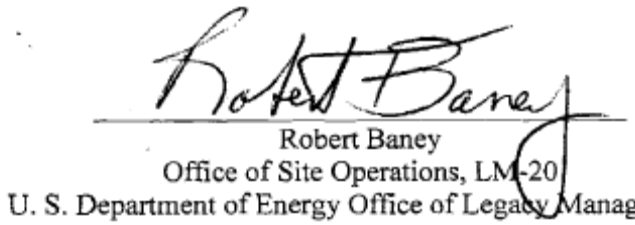
July 2006

DOE-LM Policy Statement

The U.S. Department of Energy (DOE) Office of Legacy Management (LM) performs long-term surveillance and maintenance of LM sites, ground water cleanup, records management, post closure workforce restructuring and benefits, property management and community assistance, site transition from other agencies, and ensures sustainable protection of human health and environment. LM provides innovative, cost-effective services for our customers and has a commitment to complete our work safely, within schedule and budget.

Our goal is quality in all endeavors, which requires the accomplishment of all LM activities in a superior manner. These activities must be accomplished safely and protective of the environment.

The achievement of quality in LM activities and products requires implementation of a formal Quality Assurance (QA) Program. This program establishes principles, requirements, practices, and methods for integrating quality into the daily operations of our programs and projects. The QA Program functions as a management tool to ensure that quality objectives are achieved throughout LM's technical, administrative, and operational functions. Achieving quality is the responsibility of managers as well as those who perform the work. Each employee is expected to do the job in accordance with procedures and other requirements. The name LM must represent quality to us, our customers, our service providers, and our stakeholders.



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Appendix B. Quality Management System Review and Approval Template

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1.0 Introduction

The Quality Assurance (QA) Program is a management system involving all organizational components and is not the sole domain of any single group. The order and rule reflects the concept that all work is a process that can be planned, performed, assessed, and improved. The basic requirements are broken down into three categories: management, performance, and assessment.

1.1 Quality Policy

It is the policy of the U.S. Department of Energy (DOE) to establish quality requirements to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risk posed by the facility or activity and its work. This QA Program Plan (QAPP) for DOE's Office of Legacy Management (LM) is written (1) to satisfy the specific requirements of DOE Order 414.1C, *Quality Assurance*, and (2) to provide a management structure for the identification, application, and communication of quality assurance expectations within DOE-LM.

1.2 Quality Objective

The objective of the QAPP is to establish an effective management system using the performance requirements coupled with appropriate technical standards to ensure that

- Senior management provides planning, organization, direction, control, and support to achieve LM objectives.
- Line organizations achieve quality.
- Line organizations minimize environmental, safety, and health risks and impacts while maximizing reliability and performance.
- Line organizations have basic management systems in place that are consistent with the principles and functions of DOE P 450.4, *Integrated Safety Management System Policy*.
- Each LM organization reviews, evaluates, and strives to improve their overall performance and that of their contractors using a rigorous assessment process based upon an approved QA Program (Title 48 *Code of Federal Regulations* [CFR] Part 970.1100).

1.3 LM Mission

LM's mission is to manage DOE's post closure responsibilities of remediated sites and ensure the future protection of human health and the environment. LM has control and custody for legacy land, structures, and facilities and is responsible for maintaining them at levels suitable for their long-term use.

1.4 LM Functions

Primary functions of LM:

- Protect human health and the environment through effective and efficient long-term surveillance and maintenance.
- Preserve and protect legacy records and information.
- Support an effective and efficient workforce structured to accomplish DOE missions ; implement DOE policy concerning continuity of worker pension and medical benefits.
- Manage legacy land and assets, emphasizing safety, reuse, and disposition.
- Mitigate community impacts resulting from the cleanup of legacy waste and changing DOE missions.
- Coordinate all policy issues with appropriate DOE organizations.

1.5 Implementation of the LM QA Program with a Graded Approach

The DOE QA Program at LM is designed to connect DOE's overall QA requirements with the specific QA needs of LM. This QAPP uses a graded approach that focuses on safety, management and control, and customer satisfaction in accordance with the 10 criteria provided in DOE Order 414.1C. The graded approach provides a flexible, efficient, and effective means of controlling items and activities to ensure that the required quality is achieved and is commensurate with the importance and risk.

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

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

- Importance to safety, safeguards, and security.
- Magnitude of any hazard or risk involved.
- Life-cycle stage of a facility or activity.
- Impact on the programmatic mission of a facility.
- Characteristics of a facility or activity.
- Nuclear safety classification or hazard category of the item or activity.
- Adequacy of existing safety documentation.
- Importance of radiological and nonradiological hazards.

- Complexity of products or services involved.
- Performance history of a facility or activity.
- Any other relevant factors.

Risk is a fundamental consideration in determining to what extent controls should be applied. The varying degrees of controls applied should depend on function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations. Risk is a quantitative or qualitative expression of possible impacts or loss (e.g., project, financial, safety) that considers both the probability of an event causing harm or loss and the consequences of the event. Determination (or estimation) of the probability or likelihood of the occurrence should be a part of the risk expression. For example, procurement of nuclear safety class items would require more rigorous supplier controls to meet procurement requirements than those needed for facility area lighting fixtures. Estimates and qualitative expressions are useful for management issues where quantitative data are unavailable. Process systems, repetitive activities, and hardware are typically more suitable for quantitative expressions of risk.

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

1.6 Integrating the Safety Management and Quality Management Systems

The quality management system complements and integrates with the Safety Management System (SMS) described in DOE P 450.4, *Safety Management System Policy* and DOE Acquisition Regulations in 48 CFR 970.5204-2 (i.e., the Department of Energy Acquisition Regulations [DEAR] Integrated Safety Management System [ISMS] clause). The quality management system provides processes and tools for ensuring that ISMS objectives are achieved. There is no intended hierarchical relationship between the quality management system and the SMS. In fact, creating an artificial hierarchy may reduce the effectiveness of one or both of these management systems. For instance, establishing a quality management system subordinate to the SMS could limit the applicability of the QA criteria to “safety” activities, thus ignoring the quality of critical mission products and services.

DOE P 450.4 expresses a fundamental expectation that all work will be performed safely and will meet established requirements for quality. In this regard, the quality management system ensures compliance with approved standards so that the expectation for safe work within controls is met. Shared attributes of quality and safety management systems include

- Expectations for implementation [DEAR 970.5204-2 (c)].
- Documentation of the management system (ISMS Principle 7).

- Clear roles and responsibilities (ISMS Principle 2).
- Balanced priorities (resources) (ISMS Principle 4).
- Feedback and improvement (ISMS Core Function 5).
- Line management responsibility (ISMS Principle 1).
- Competence and qualifications (ISMS Principle 3).
- Standards and controls for work (ISMS Principle 5 and Core Function 4).
- Graded and tailored controls (ISMS Principle 6).

DOE G 450.4-1B, *Integrated Safety Management System Guide*, contains information on safety management principles, supporting attributes, references on the subject, and integration methods.

1.7 Roles, Responsibilities, and Authorities

This QAPP applies to work performed by all LM personnel. LM management has primary responsibility for implementing quality provisions and requirements for the programs, projects, and other activities. Management is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the quality management system. However, every individual in the organization is responsible for achieving quality in his or her activities. Senior management should require and cultivate the achievement and improvement of quality at all levels of the organization and ensure that the QAPP is understood and implemented.

The QA rule and order and the SMS policy emphasize that management should promote effective achievement of performance objectives through implementation of the SMS policy guiding principles.

1.8 Quality Assurance Requirements and Applicability

LM has established a QA Program as an integral part of its management function and will apply it to all activities that may affect operational safety, conformance of processes and products to specifications, and overall program success. This QAPP identifies and describes QA principles and practices that have been established for LM activities, the applicability of those requirements to LM and contractor employees, the requirements and procedures for applying the requirements on a selective basis to program activities, and guidelines for implementation.

The underlying requirements are consistent with Integrated Safety Management (ISM) Policy, P 450.4, and support ISM implementation:

- Define policies and objectives—ensure they are understood and accepted.
- Specify roles and responsibilities—ensure they are understood and accepted.
- Specify and communicate expectations—identify and allocate resources to achieve them.

- Strive to improve—employees seek new and innovative ways to improve quality and efficiency.
- Ensure that employees are competent at the work they perform.
- Ensure that the right people have the right information.
- Seek and use relevant experience.
- Plan and control the work.
- Assess work to ensure that it meets expectations.
- Identify and remedy errors and deficiencies.
- Periodically review management processes to improve effectiveness and efficiency.

The basic requirements of the QA Program are the following 10 criteria in DOE Order 414.1C that address the major areas of Management, Performance, and Assessment.

- **Management**
  — Criterion 1, Program
  — Criterion 2, Personnel Training and Qualification
  — Criterion 3, Quality Improvement
  — Criterion 4, Documents and Records
- **Performance**
  — Criterion 5, Work Processes
  — Criterion 6, Design
  — Criterion 7, Procurement
  — Criterion 8, Inspection and Acceptance Testing

- **Assessment**
  — Criterion 9, Management Assessment
  — Criterion 10, Independent Assessment

2.0 Management

2.1 Criterion 1, Program

- A written Quality Assurance Program must be developed, implemented, and maintained.
- The Quality Assurance Program must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
- The Quality Assurance Program must describe management processes, including planning, scheduling, and resource considerations.

DOE O 414.1C, Section 4.b(1)

Applicability

All three elements of Criterion 1 are applicable to LM.

Requirements and Responsibilities

- Management retains the primary responsibility and accountability for the scope and implementation of the QAPP. However, every individual in the organization is responsible for achieving quality in his or her activities. Senior management must require and cultivate achievement and improvement of quality at all levels of LM organization and ensure that the QAPP is understood and implemented.
- Management is responsible for identifying necessary resources and filling vacancies with qualified personnel.
- Management is required to provide organizational structure and assign duties to employees.
- Management will ensure proper coverage of activities by employees.
- Management will ensure that management systems are used to integrate safety management and work practices systematically at all levels so that missions are accomplished while protecting the public, the worker, and the environment.

LM Implementation

- LM implements and maintains the QA Program by establishing documents and processes that effectively manage quality and safety controls for program activities, such as
  - —Developing strategic plans, program plans, sampling and analysis plans, and statements of work.
  - —Providing personnel training, worker qualification and staffing assessments.
  - —Using assessments and Lessons-Learned forums to achieve quality improvement.
  - —Establishing a document control and records management system.
  - —Establishing work process management.
  - —Establishing design development and implementation processes.

—Establishing procurement processes.

—Performing on-site inspections and contaminant testing.

—Providing independent assessments.

The work at LM is managed through a hierarchy of governing DOE documents: Policies, Standards of Performance, Management Systems, and subject areas. Standards of performance enforce the high-level practices by which LM carries out its mission and policies. The management process is designed to meet customers' expectations and identify scope, ownership, requirements and drivers, customers, outputs, system operations, and responsibilities. Using the DOE processes and requirements, each office establishes processes for planning, performing, and assessing activities.

The major support contractor has established and incorporated DOE-LM guidelines and sound business practices to ensure quality in all aspects of work performed.

The Human Resources organization maintains the process that forms an understanding between each employee and their supervisor regarding performance expectations.LM Organizational Chart and Areas of Staff Responsibility. (Appendix A)

- LM Management Control Programs.
- LM Contracting Officer Representative (COR)/Task Order Monitor (TOM) appointment memorandums.
- DOE Policy 450.4, *Safety Management System Policy*.
- LM P 450.1, *Environmental Safety and Health Policy*.

2.2 Criterion 2, Personnel Training and Qualification

> - Personnel must be trained and qualified to ensure they are capable of performing their assigned work.
> - Personnel must be provided continuing training to ensure that job proficiency is maintained.
>
> DOE O 414.1C, Section 4.b(2)

Applicability

Both elements of Criterion 2 are applicable to LM.

Requirements and Responsibilities

- Management is required to ensure that employees are trained appropriately and are capable of performing assigned tasks.
- Management is responsible for providing the mechanisms to allow employees to request and attend appropriate training courses to further their knowledge and capabilities.
- Management should establish policies and procedures that describe personnel selection, training, and qualification requirements for each function.
- Management will manage travel and training budgets to allow for appropriate training attendance.
- Management will designate positions requiring technical qualification certification.
- Qualification and training processes ensure that personnel achieve and maintain the required capabilities to perform their work.
- Managers at each level of the organization should adequately describe the training needs of employees in their department.
- Employees are responsible for availing themselves of opportunities to receive continuing training to maintain and improve job performance.

LM Implementation

- Establish a Training Coordinator for the LM organization to oversee the organizational requirements that are delineated in the employees' training plan. The Training Coordinator is responsible for periodically reviewing and updating personnel job training assessment and updating the CHRIS system. The Training Coordinator also provides a documented training and qualification program, which includes standards, procedures, and guidelines.
- The Training Coordinator develops and uses procedures to track and documenting personnel training and education; to ensure that personnel receive QAPP orientation; and to ensure that personnel attend and complete all necessary training (e.g., General Employee Training, Hazardous Worker, Radiation, Emergency Response)

- Each year management commits resources to facilitate training and qualification processes for personnel in the organization and to ensure that personnel hired or transferred into positions meet the appropriate requirements. Managers at each level of the organization identify and implement the training needs and qualifications for each position.
- Policies and procedures that describe personnel selection, training, and qualification requirements are established for each function based on the requirements of staff, and with regulatory training and qualification needs.
- Every employee must prepare an annual Individual Development Plan that describes the training and education needs for their areas of responsibility. Personnel are provided continuing training to ensure that job proficiency is maintained.
- The extent of orientation and training is commensurate with the scope, complexity, and nature of activity, as well as education level, experience, and proficiency of the employee.
- Managers and employees will ensure that certifications are completed, tracked, and maintained for designated positions (e.g., COR, Project Management, Real Property, Records, Actuary, Information Technology, Professional Development, Environmental Regulations, Long-Term Surveillance and Maintenance).
- Management has established and implements required training for each employee (e.g., ethics, Security and Safeguards, Environmental Safety & Health, and other regulatory requirements training).

2.3 Criterion 3, Quality Improvement

- Processes to detect and prevent quality problems must be established and implemented.
- Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and the work affected.
- Correction must include identifying the causes of problems and working to prevent recurrence.
- Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

DOE O 414.1C, Section 4.b(3)

Applicability

All four elements of Criterion 3 are applicable to LM.

Requirements and Responsibilities

- Staff involvement and ownership of the quality improvement process is based on the premise that all work can be planned, performed, measured, and improved. Managers and supervisors have a responsibility to regularly assess the performance of those portions of the QA program for which they have direct cognizance and responsibility. They also have responsibility to support employees in the implementation of the quality improvement process without any hint of reluctance or retribution. The staff is required to assess and correct issues and comments received from internal and external customers associated with LM products.
- LM subscribes to the principal of continuous improvement. All personnel are encouraged, expected, and required to identify and report opportunities for improvement as well as any deficiencies or conditions that do not conform to the requirements of the QAPP.
- Management should foster a "no-fault" attitude to encourage the identification of problems and create an atmosphere of openness to suggestions for improvements.
- Employees are required to continually seek to improve the work they perform.
- Management will conduct semiannual performance evaluations with employees to communicate progress toward goals.
- The staff will use the cost-plus award fee process to monitor and evaluate contractor performance with respect to attaining objectives.

LM Implementation

- All aspects of work activities and the management system are subject to continuous improvement. LM staff shall develop and use procedures to describe and control processes for reporting and evaluating nonconforming conditions, deficiencies, noncompliance, and conditions that adversely affect quality, the environment, and human health. Responsibilities also include other applicable issues, such as determining the levels of control and types of corrections, health and safety issues, work-related environmental impacts, and available risk analysis data.

- LM staff will actively participate in DOE-wide Lesson Learned forums and use feedback to improve deficiencies, services, and the processes that produce them. Management will track the actions to closure and ensure that the actions are effective in providing the anticipated improvements. Methods for determining the significance of a quality problem and the process for handling problems are documented in the quality management system.
- Quality problems are resolved individually and are also analyzed collectively to identify systematic quality problems and opportunities for process improvement.
- LM staff will perform periodic assessments to verify the implementation of the QAPP.
- Effective feedback from multiple sources and lessons learned is the foundation for a process that is designed to identify, prevent, , and correct problems. Management shall track the actions to ensure they are providing the anticipated improvements.
- If the quality problem is likely to affect safety or the mission significantly, the affected items or processes shall be controlled to prevent further use.
- LM management will hold a monthly Senior Management Staff meeting
- Maintain up-to-date customer correspondence and LM response in LM master files.
- Update annual employee Performance Agreements between employees and supervisors and conduct semiannual evaluations on progress with employees.
- Complete semiannual contractor cost-plus award fee Performance Evaluation Plans and Performance Evaluation Reports.
- Periodically review contractor's QA program and verify by conducting spot inspections.
- Conduct Lessons Learned activities in accordance with DOE Manual 411.1-1B, *Safety Management Functions, Responsibilities and Authorities Manual*.
- Develop other reports such as Monthly Task orders Status reports, long-term surveillance and maintenance plans, Integrated Safety Management (ISM), LM P 450.1, *Environmental Safety and Health Policy*.

2.4 Criterion 4, Documents and Records

- Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
- Records must be specified, prepared, reviewed, approved, and maintained.

DOE O 414.1C, Section 4.b(4)

Applicability

Both elements of Criterion 4 are applicable to DOE–LM.

Requirements and Responsibilities

- Documents and records are required for managing, performing, and assessing work. Documents and records include applicable requirements to indicate that work has been properly specified and accomplished. Management must identify any documents and records that must be developed and controlled. Management must commit the resources necessary to accomplish the document and record requirements.
- Documents are required by LM organizations, projects, or programs to control policy, administrative, and technical information. A document control system must be established to supply the documents that are necessary for personnel to perform their assigned responsibilities safely. Document control systems ensure that the mechanism developed to implement the safety management functions of DOE P 450.4 are properly prepared and controlled and are available for managers and staff.
- A record contains information that is retained for its expected future value. Records must be sufficient to support technical and regulatory decisions. Records may be in a variety of forms (e.g., electronic, written or printed, microfilm, photographs, radiographs, or optical disks).
- Records are compiled into a records management system that ensures appropriate records are maintained. The system must include provisions for record retention, protection, preservation, change, traceability, accountability, and retrievability. While in storage, records must be protected from damage, loss, and deterioration. The hardware and software required to ensure retrievability and usability of archived records must be maintained.

Implementation

- LM has established requirements and guidance for management of internal controlled documents and records . These requirements and guidance establish the methods for identifying documents important to the process or work activity. Employees responsible for record management ensure that record information is controlled, maintained, and disposed of in compliance with legal requirements, DOE requirements, and other client requirements.
- The hardware and software tools used to create and store records are maintained to ensure that the record can be retrieved. In 36 CFR 1200–1299, the National Archives and Records Administration, provides a recommended approach for maintenance of records, including electronic records.

- staff are responsible for ensuring that appropriate staff and managers review and coordinate correspondence and products.
- Employees will develop procedures or use established procedures to describe the processes for preparing, reviewing, approving, issuing, and revising all documents; prescribe work process; specify requirements; implement and maintain information management processes; describe the processes for specifying and scheduling, required records; prepare, review, approve, and submit records, including data, to the records storage facility; ensure that records are protected to prevent loss of information as well as to address safeguards and security requirements; and ensure that records are indexed, retained, kept retrievable, and—for those requiring special processing—controlled(to include revised version).
- Records Management staff shall establish and maintain a records management system in accordance with DOE Information Management Program requirements and shall retain all action items.
- LM P 200.1-1 File Plan.
- LM P 200.1-3 Process Litigation Request.
- LM P 200.1-5 Records Disaster Prevention, Mitigation, and Recovery.
- LM P 200.2 Electronic Records.
- LM P 200.3 Classified, Sensitive, and Proprietary Documents Handling.
- LM P 200.4 Records Management.

3.0 Performance

3.1 Criterion 5, Work Processes

- Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.
- Items must be identified and controlled to ensure their proper use.
- Items must be maintained to prevent their damage, loss, or deterioration.
- Equipment used for process monitoring or data collection must be calibrated and maintained.

DOE O 414.1C Section 4.b(5)

Applicability

All four elements of Criterion 5 are applicable to DOE-LM.

Requirements and Responsibilities

- Work is defined as the process of performing a defined task or activity. Work processes consist of a series of actions by qualified workers using specified work processes and equipment under administrative, technical, and environmental controls to achieve end result.
- Management must ensure that the following are clearly identified and conveyed to workers before work begins:
  - —Customer and data requirements for the work and final product.
  - —Acceptance criteria applicable to work and final product.
  - —Hazards associated with the work.
  - —Technical standards applicable to work and final product.
  - —Safety, administrative, technical, and environmental controls to be employed during the work.
- Procedures, work instructions, or other means used to define work processes must be documented. The scope and detail of documentation must be commensurate with the complexity and the importance of the work.
- Establish and implement methods to ensure that prior to start of work, planning is completed to determine task requirements, design requirements, specifications, appropriate codes and standards, and assess and verify processes that are required to perform the work.
- All persons, including Task Order Monitors (TOMs), are responsible for overall management, including safe and environmentally protective execution of work performed under their task orders.
- TOMs are required to develop task orders each fiscal year based on work scope, schedule, and budget.

- Management and staff are responsible for the proper and sound management of government funds.
- When modifying task orders, management will ensure that the requirements of proper change control are documented and adhered to.
- CORs and TOMs are required to monitor technical, schedule, and cost performance deliverables and other items as associated with task orders.
- TOMs and the Contracting Officer (CO) are responsible for developing and administering cooperative agreements.
- All personnel will adhere to property management controls and guidelines.
- The responsible staff will ensure that the support contractor has procedures in place for calibrating and maintaining equipment.

LM Implementation

- LM 413.1-1 Management Control Process.
- LM 481-1 Work for Others and DOE Reimbursable Work Process.
- LM 412.1 Work Authorization Procedures Associated With the Technical Assistance Contract.
- LM 450.1, *Environmental Safety and Health Policy*.
- Procurement process.
- Financial Management Procedures.
- Annual memorandum covering fiscal year task order development.
- Memorandum: "DOE–LM Work Authorization Procedures.
- Responsibilities of a COR.
- Management Reserve and Carryover analyses.

Obligation of funds to contractors and outside parties.

TOM Invoice Review Authorization/Approval Form.

- Title 10 *Code of Federal Regulations* Part 600, "Financial Assistance Rules," including numbers 100, 200, 500, and 125(e) Revision.
- Review and verify adherence of LM contractors' procedures for property management and equipment calibration.

3.2 Criterion 6, Design

- Items and processes must be designed using sound engineering/scientific principles and appropriate standards.
- Design work, including changes, must incorporate applicable requirements and design bases.
- Design interfaces must be identified and controlled.
- The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work.
- Verification and validation work must be completed before approval and implementation of the design.

DOE O 414.1C Section 4.b(6)

Applicability

All five elements of Criterion 6 are applicable to DOE–LM.

Requirements and Responsibilities

- A formal design process must be established that provides control of design inputs, outputs, verification, configuration and design changes, technical and administrative interfaces appropriate to the importance of the design, including computer hardware and software.
- Design work should be based on sound engineering judgment, scientific principles, and applicable codes and standards. Design inputs may include such information as design base, health and safety considerations, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements.
- Aspects critical to the performance, safety, or reliability of the design items must be identified during the design phase.
- Technical and administrative design interfaces should be identified and methods established for their control.
- The final design documentation should be in sufficient detail to permit design verification.
- Design verification is a formal, documented process for ensuring that the resulting items will comply with the requirements. Design verification methods include technical reviews, peer reviews, alternate calculations, and qualification testing.
- Qualified personnel independent of the design process verify the acceptability and adequacy of design work and documents.
- Ensure that where a significant design change is necessary because of an incorrect design, the design process is reviewed, verified, and modified as required.
- The COR and TOM shall ensure that sound engineering/scientific principles are used and are in accordance with applicable requirements.
- The COR and TOM shall ensure the verification of design products.

LM Implementation

- The design process will define the appropriate management controls for developing, reviewing, approving, and verifying implementation of design requirements. While LM likely have few significant design efforts to meet program goals and LM must assure all designs are appropriately and accurately undertaken to reduce costly rework.
- TOMs/COR shall specify design performance requirements to be used in the design control process (e.g., control of design,, inputs and outputs) that controls specifications, drawings, design criteria, and component performance, including hardware and software.
- The responsible staff shall review LM contractors' process and procedures for the design work, including technical requirements and change control.
- Staff involved in the design process will adhere to the policies described in DOE P 413.1, *Program and Project Management for the Planning, Programming, Budgeting, and Acquisition of Capital Assets*, and DOE O 413.3, *Program and Project Management for the Acquisition of Capital Assets*.
- If required for a complex design, the management shall seek the assistance of independent contractors to conduct periodic reviews of LM contractors' designs.

3.3 Criterion 7, Procurement

- Procured items and services must meet established requirements and perform as specified.
- Prospective suppliers must be evaluated and selected on the basis of specified criteria.
- Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

DOE O 414.1C, Section 4.b(7)

Applicability

All three elements of Criterion 7 are applicable to DOE–LM.

Requirements and Responsibilities

- Management will ensure that all procurement activities are in accordance with applicable Federal orders and regulations, including best business practices.
- The procurement process must ensure that items provided by vendors meet the requirements and expectations of the end user.
- This criterion states the extent and nature of the controls applied to ensure the procurement of systems, structures, components, and services that are commensurate with their uniqueness, complexity, and importance to public and operational safety. Purchased items and services shall meet established requirements and performance expectations.
- The development of Statements of Work or specifications of the equipment should be clear and complete and state the test requirements and acceptance criteria for procured items and services.
- Potential suppliers must be evaluated early in the design and procurement process to determine their capabilities.
- The selected vendor's performance must be evaluated periodically to confirm its continuing capabilities.
- Vendor-generated documents must be accepted through the procurement system and controlled and processed according to DOE procedures.
- Management will ensure that appropriate quality requirements are applied through procurement documents.

LM Implementation

- The procurement documents are prepared, reviewed, and controlled in accordance with DOE orders, Department of Energy Acquisition Regulations (the DEAR in 48 CFR Parts 900 through 999), and Federal Acquisition Regulations (FAR) in 48 CFR Parts 1 to 99.

- The COR will include DOE Order 414.1C, Attachment 2, "Contractor Requirements Documents" for contractors. Applicable QA requirements will be specified in subcontract documents.
- A detailed Statement of Work is developed identifying the technical requirements, and acceptance criteria are specified, as applicable.
- Ensure that the suppliers, product developers, and service providers are evaluated, qualified, and selected in accordance with the methods and/or specified to meet Federal and DOE regulations.
- The responsible staff will conduct periodic reviews of LM contractors' adherence to procurement principles.
- Inspections and tests are accomplished to verify that physical and functional aspects of the items, services, software, and processes meet requirements and are fit for acceptance and use.

3.4 Criterion 8, Inspection and Acceptance Testing (Management Assessment)

- Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria.
- Equipment used for inspections and tests must be calibrated and maintained.

DOE O 414.1C, Section 4.b(8)

Applicability
Both elements of Criterion 8 are applicable to DOE–LM.

Requirements and Responsibilities

- Inspections and tests are accomplished to verify that physical characteristics and functions of the systems, structures, and components are acceptable to the end users.
- Establish processes for the inspection and acceptance testing of an item, service, or process against established criteria. The need for inspection and acceptance testing is determined during project or activity planning, based on a graded approach.
- When required, acceptance and performance criteria are developed and documented for key, complex, or critical inspection/test activities.
- Measuring and test equipment used for inspections, tests, and monitoring or data collection must be calibrated and maintained using a documented process.
- The CO and applicable staff members are responsible for reviewing the item/service delivered to ensure DOE has received that which was ordered.

LM Implementation

- Acceptance inspections are performed by individuals other than those who performed the work.
- CORs/COs will ensure that LM contractors have a procedure in place for inspection of items, products, and services procured by them.
- TOMs/COs will ensure that items and services purchased directly by DOE are as requested before approving the invoice for payment.
- TOMs/COs will inspect products purchased directly by DOE to ensure that those products are in proper working order.

4.0 Assessment

4.1 Criterion 9, Management Assessment

> Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.
>
> DOE O 414.1C Section 4.b(9)

Applicability

Both elements of Criterion 9 are applicable to DOE–LM.

Requirements and Responsibility

- Managers are responsible for conducting management assessments. Managers at every level should periodically assess their organizations and functions to determine how leadership is being provided to enable the organization to continuously meet the customer's requirements and expectations. Managers are also responsible for identifying strengths or improvement opportunities and methods to correct a problem.
- The management assessment must include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals of the organization.
- LM managers must retain responsibility for management assessments. Direct participation by managers is essential to the success of the process as it views the organization as a total system. The manager's personal involvement will yield the most meaningful information for that manager to use in taking actions to improve organizational performance.
- LM management is responsible for seeking continuous improvement of the organization.

LM Implementation

- Management is focused for identification and resolution of both systematic management issues and specific problems.
- Strengths and weaknesses affecting the achievement of organizational objectives are identified so that meaningful action is taken to improve quality. Processes being assessed include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.
- Direct observation of work is an effective method of management assessment and includes management by walk-through, open door policy, and customer feedback.
- Follow guidelines provided in LM Management Control Programs.
- Conduct semiannual employee performance evaluation reviews.

- Review and assess the contractor's monthly and other reports.
- Follow the provisions in DOE Guide 414.1–2, *Quality Assurance Management System Guide*.
- Development of "Performance Measures" and evaluations are performed near the end of each FY. DOE-LM will develop a list of management functions to conduct their assessment considering the factors identified in the graded approach.

4.2 Criterion 10, Independent Assessment

- Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
- The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities.
- Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

DOE O 414.1C Section 4.b(10)

Applicability

All three elements of Criterion 10 are applicable to DOE–LM.

Requirements and Responsibilities

- The purpose of the independent assessment process is to obtain impartial evaluations (by qualified and/or certified personnel). The assessment determine the systems' and processes' effectiveness and promotes improved quality and safety processes. The assessment also evaluates performance with regard to customers' requirements and expectations.
- Management is responsible for planning, scheduling, and conducting independent assessments of work processes.
- Management is responsible for ensuring that the individuals performing the independent assessments are qualified, knowledgeable in the areas being assessed, and have the freedom to carry out their responsibilities.
- The independent assessment process must use a performance-based approach to focus on results. Performance-based assessments are conducted on activities that (1) relate directly to final objectives, (2) emphasize safety and reliability, and (3) measure item or service performance.
- An independent assessment provides advice to senior management on the quality of items, services, and processes produced by the organization.

LM Implementation

- Develop and use independent assessment procedures and methods to (1) describe the process for planning, implementing, and managing the independent assessment program; (2) ensure that persons performing independent assessments have sufficient authority and independence from management and the assessed area and are free (to the extent practicable) of cost and schedule constraints; and (3) ensure that periodic independent assessments and surveillance are conducted to

  —Verify the implementation of this QAPP.

  — Identify noncompliance with the LM program documents.

  —Measure item and service quality.

—Measure the adequacy of work performance.

—Promote quality and safety improvement.

—Ensure that personnel conducting independent assessments are technically qualified and/or certified.

- Adhere to DOE Guide 414.1–2, *Quality Assurance Management System Guide*.
- Ensure that contractors have a QA program that adheres to DOE Order 414.1C principles.
- Seven steps of independent assessment planning approach described in Appendix D of DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide* .
- Use DOE-Headquarters and others to conduct independent assessment of LM work processes.
- DOE-LM will develop a list of known independent reviewers to conduct independent assessment for the coming year at the end of each FY.

5.0 Application Using a Graded Approach

The scope, depth, and rigor of the management system's application of requirements to a specific activity should be determined by the use of a grading process. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their level of risk, cost, schedule, and success of the program. The grading process is not used to obtain exemptions from the requirements of DOE Order 414.1C or 10 CFR 830.120.

6.0 Definitions

Assessment: The act of reviewing, evaluating, inspecting, testing, checking, performing surveillance, auditing, or otherwise determining and documenting whether items, processes, systems, or services meet specified requirements and are performing effectively.

Customer: Includes all entities that supply to or receive products and services from the organization, including DOE, regulators, stakeholders, public, contractors, suppliers, and employees.

Graded Approach: The process by which the level of detail in analyses, documentation, and actions necessary to comply with requirements is commensurate with

- The relative importance to safety, safeguards, and security.
- The magnitude of any hazard involved.
- The life-cycle stage of a facility.
- The programmatic mission of a facility.
- The particular characteristics of a facility; and any other relevant factors.

Item: An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance: All those actions that provide confidence that quality is achieved.

Quality Assurance Program: The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Safety: An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.

Service: The performance of work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Work: The process of performing a defined task or activity; for example, research and development, operations, environmental remediation, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

7.0 References

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

7.1 Related Policies, Rules, and Orders

10 CFR 830.U.S. Department of Energy, "Nuclear Safety Management.," *Code of Federal Regulations,* January 1, 2005.

10 CFR 830.120–122 (Subpart A). U.S. Department of Energy,"Quality Assurance Requirements," *Code of Federal Regulations,* January 1, 2005.

36 CFR 1220.10–18. National Archives and Records Administration, "General Provisions," *Code of Federal Regulations,* July 1, 2004..

48 CFR 1–99. Federal Acquisition Regulation, *Code of Federal Regulations,* October 1, 2004.

48 CFR 970., U.S. Department of Energy, "DOE Management and Operating Contracts," *Code of Federal Regulations,* October 1, 2004.

DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, June 17, 2005.

DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual,* December 31, 2003.

DOE O 200.1, *Information Management Program,* September 30, 1996.

DOE O 226.1, *Implementation of Department of Energy Oversight Policy*, September 15, 2005.
DOE O 360.1B, *Federal Employee Training*, October 11, 2001.

DOE O 413.3 Chg 1, *Project Management for the Acquisition of Capital Assets,* October 13, 2000.

DOE O 414.1C, *Quality Assurance*, June 17, 2005.

DOE O 420.1A, *Facility Safety*, May 20, 2002.

- LM P 200.1-1 File Plan.
- LM P 200.1-3 Process Litigation Request.

DOE-LM P 200.1-5 *Records Disaster Prevention, Mitigation, and Recovery,* February 9, 2006

DOE-LM P 200.2 *Electronic Records,* May 5, 2005

DOE-LM P 200.3 *Classified, Sensitive, and Proprietary Documents Handling,* December 1, 005

DOE-LM P 200.4 *Records Management,* February 9, 2006

DOE-LM P 450.1, *Environmental Safety and Health Policy,* April 15, 2005.

DOE P 413.1, *Program and Project Management for the Planning, Programming, Budgeting, and Acquisition of Capital Assets*, June 10, 2000.

DOE P 426.1, *Federal Technical Capability Policy for Defense Nuclear Facilities*, December 10, 1998.

DOE P 450.4, *Safety Management System Policy,* October 15, 1996.

DOE O 5480.20A Chg 1, *Personnel Selection, Qualification, and Training Requirements for DOE Nuclear Facilities,* July 12, 2001.

Office of Management and Budget Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* February 10, 1998.

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

DOE–LM Business Practices Handbook (to be developed by DOE–LM)

STO 1. *Quality Assurance Manual*, continuously updated, prepared by S. M. Stoller Corporation for the U.S. Department of Energy, Grand Junction, Colorado.

7.2 Related Quality Management System Guides and Standards

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

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

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

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

American Society of Mechanical Engineers NQA-1-2002, *Quality Assurance Requirements for Nuclear Facility Applications,* Part 1-4.

ANSI/ISO/ASQ QE19011S-2004, Guidelines for Quality and/or Environmental Management Systems Auditing—U.S. version with supplemental guidance added.

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

DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide,* May 31, 2001.

DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B,* Quality Assurance, November 3, 2004.

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,* June 17, 2005.

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

DOE/NNSA, *Weapon Quality Policy (QC-1)*, Rev. 10, February 10, 2004.

DOE G 450.3-3, *Tailoring for Integrated Safety Management Applications,* February 1, 1997.

DOE G 450.4-1B, *Integrated Safety Management System Guide (Volume I) for Use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); the Functions, Responsibilities, and Authorities Manual; and the DOE Acquisition Regulation,* March 1, 2001.

DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard,* April 2002.

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

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

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

7.3 Related References

American Society for Nondestructive Testing Recommended Practice SNT-TC-1A-2001, 1994.
DOE STD 3009-94, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses,* July.

DOE O 433.1, *Maintenance Management Program for DOE Nuclear Facilities,* June 1, 2001.

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

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

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

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

U.S. Nuclear Regulatory Commission (NRC), 1978. *Quality Assurance Program Requirements (Operation)*, NRC Regulatory Guide 1.33, Rev. 2, February.

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

U.S. Nuclear Regulatory Commission (NRC), 1988. , *Performance-Based Inspections,* NUREG/CR-5151, June.

U.S. Nuclear Regulatory Commission (NRC), 2003., *Qualification and Training of Personnel for Nuclear Power Plants*, NRC Regulatory Guide 1.28, Rev. 3, May.

Appendix A

Office of Legacy Management Organizational Structure, Mission, and Functional Responsibilities

Office of Legacy Management – (LM)

Mission:

The mission of the Office of Legacy Management (LM) is to manage the Department's post-closure responsibilities and ensure the future protection of human health and the environment. LM has control and custody for legacy land, structures, and facilities and is responsible for maintaining them at levels suitable for their long-term use.

Functions:

- Protects human health and the environment through effective and efficient long-term surveillance and maintenance;
- Preserves and protects legacy records and information;
- Supports an effective and efficient work force structured to accomplish departmental missions;
- Implements departmental policy concerning continuity of worker pension and medical benefits;
- Manages legacy land and assets, emphasizing safety, reuse, and disposition;
- Mitigates community impacts resulting from the cleanup of legacy waste and changing departmental missions;
- Actively acts as liaison and coordinates all policy issues with appropriate departmental organizations.

Office of the Director – (LM-1)

Functions:

- Makes recommendations to the Secretary concerning legislative and executive national policy actions affecting LM issues.

- Develops strategies, plans, policies, and program guidance to assure coordination of LM functions within the department.

- Provides overall management and direction to the LM offices.

- Ensures that the LM organization promotes diversity, civil rights, and minority affairs.

- Ensures all needed safety and security programs are in place and fully accountable in accordance with departmental policies.

- Develops Congressional testimony, drafts legislation, proposes report language, reviews legislation, attends Congressional meetings, and oversees Congressional correspondence. Ensures the preparation of Congressionally-mandated reports as well as responses to inquiries.

- Promotes open and communicative relationships with Congressional offices and committee staff, other persons in the Department and representatives of other Federal agencies. Analyzes legislation that has a direct or indirect potential to affect the LM mission.

- Represents the Department and coordinates with outside agencies, national labor unions, and stakeholders on contractor work force issues regarding work force restructuring/transition, labor standards, and labor relations.

- Provides oversight, assistance, and policy for labor relations, labor standards, and coordination with national labor unions in consultation with appropriate Departmental elements.

- Assists sites in planning to reduce the size of their contractor work force and provide separation benefits to contractor employees affected by work force adjustments.

- Coordinates with other Program Secretarial Officers on procurements as they relate to contractor benefits programs; work force restructuring, labor-management relations, and appropriate contractor performance measures.

- Enhances the credibility and public trust of the Department by making public participation a fundamental component of all program operations, planning activities, and decision-making. Coordinates and integrates activities with external organizations that have a relationship with LM.

- Develops public relationships and other outreach strategies and works to establish and maintain relationships with all stakeholders. Consults with national groups on the implementation of environmental remedies and long-term surveillance and maintenance.

- Conducts liaison with national intergovernmental groups and other federal agencies.

- LM serves as the lead within the Department for implementation of the Executive Order on Environmental Justice.

Office of Business Operations – (LM-10)

Functions:

- Coordinates information collection, storage, dissemination, and destruction and manages policies, guidelines, and standards regarding information management.

- Plans, designs, and maintains an information technology infrastructure to effectively support automated needs (i.e. platforms, networks, servers, printers, etc.).

  - Secures Federal data and systems through the creation and definition of security policies, procedures and controls covering such services as identification, authentication, and non-repudiation.

  - Facilitates with other offices and Departmental elements to ensure a smooth and effective process for the design and implementation of changes to methodologies, systems, or procedures.

  - Develops, plans, and oversees the administrative records management policies and procedures which guide and govern the physical and electronic records management operations of the organization. Includes managing records over the standard record life-cycle and developing records retention schedules in conjunction with NARA requirements.

- Develops, plans, and oversees operational records retention, records maintenance and use, and records disposition processes and activities that LM performs to ensure proper documentation of its environmental protection, environmental remediation, and hazardous waste disposition- related policies and activities.

  - Supports DOE stakeholders processing claims associated with Energy Employees Occupational Illness Compensation Program Act, Freedom of Information Act, Privacy Act and other information requests.

- Supports all processes and activities associated with the in-house design, development, and maintenance of software applications.

  - Identifies, collects and shares across the LM organization new corporate knowledge and innovation as best practices and/or technologies/tools to be utilized by other organizational elements.

  - Plans, develops, and executes the processes and activities to ensure appropriate investments are selected for capital expenditures.

- Plans, develops, and executes the Enterprise Architecture Program that describes the current state, defines the target state and the transition strategy for an organization's people, processes, and technology.

- Plans, develops, and implements ongoing efficiencies of business processes and identification of opportunities for reengineering or restructuring.

- Plans, develops, and implements strategic planning efforts which include analyzing current organization status, annual and long-term goals, and the best approach for achieving those goals.

- Plans, develops, and implements systems and processes for budget execution, including day-to-day requisitions and obligations for agency expenditures, invoices, billing dispute resolution, reconciliation, service level agreements, and distributions of shared expenses.

- Plans, develops, and implements systems and processes for budget formulation, including identification of priorities for future spending and an itemized forecast of future funding and expenditures during a targeted period of time through the collection and use of performance information to assess the effectiveness of programs to develop budget priorities.

- Accounts for assets, liabilities, fund balances, revenues and expenses associated with the maintenance of DOE and federal funds and expenditure of federal appropriations (Salaries and Expenses, Operation and Maintenance, Procurement, Working Capital, Trust Funds, etc.) in accordance with applicable federal standards.

- Represents the Department and coordinates with outside agencies, national labor unions and stakeholders regarding contractor employee post-closure benefits.

- Develops, promulgates and shares lessons learned with other Program Secretarial Offices conducting post-closure pension and benefits management.

- Consults, as appropriate, with field offices, unions, and site workers in addressing transition and closure issues in coordination with LM Offices.

- Implements a Departmental policy for continuity of post-closure and retiree benefits for eligible site closure contractor employees. Provides oversight to ensure budgets for post-closure benefits program are in compliance with management controls.

- Conducts programmatic implementation of the Department's Work Force Information System.

- Coordinates on procurements concerning contractor benefits programs after site closures and on appropriate contractor performance measures.

- Informs DOE senior management of significant post closure benefits issues and developments. Coordinates with MA, GC and other Departmental elements as appropriate, as well as with industry associations, to oversee an active outreach to all stakeholders, including plan-eligible participants.

- Provides human resources support to all LM offices. Coordinates human resource policies and procedures with the Servicing Personnel Office.

- Administers travel and time and attendance reporting for all LM offices.

- Provides administrative and office management support to the Office of the Director, LM-1.

Office of Site Operations – (LM-20)

Functions:

- Develops Safety Management Policy and implements integrated safety management principles into all LM functions.

- Develops policy and guidance for monitoring, maintaining, and accepting Legacy Management sites.

- Communicates departmental policies regarding long-term surveillance and maintenance to national stakeholders, including working with Environmental Management through its stakeholder groups, and incorporates their input into long-term surveillance and maintenance policies and decision-making.

- Develops, promulgates, and shares lessons learned with other Program Secretarial Offices.

- Monitors and maintains environmental remedies at LM sites.

- Installs long-term surveillance and maintenance systems at selected sites prior to transfer of the sites to LM.

- Assists other offices within LM with activities such as worker assistance, real property transfers, budget formulation, and stakeholder interactions at defined sites.

- Communicates with appropriate departmental offices, regulators, state agencies, stakeholders, and the public regarding long-term surveillance and maintenance conditions.

- Conducts analyses of long-term surveillance and maintenance science and technology needs and develops and maintains knowledge of state-of-the-art long-term surveillance and maintenance technologies, systems, and science and technology projects.

- Benchmarks performance of systems under a variety of conditions including media, contaminants, and performance requirements.

- Integrates improved technology in ongoing long-term surveillance and maintenance projects.

- Provides post-remediation expertise and assistance to closure sites transitioning to LM.

- Works with closure sites to develop long-term surveillance and Maintenance plans (LTSP).

- Develops and implements LM environmental compliance policy, meeting NEPA and DOE laws, regulations, and orders.

- Provides DOE program and technical support for the Uranium Leasing and Cost Recovery and Liability Programs.

- Supports other Program Secretarial Offices in reviewing transition plans and closure plans to facilitate transfers and/or sales of real property assets to LM.

- Interfaces with other agencies, the private sector, and departmental organizations conducting science and technology activities.

- Serves as site managers and site transition coordinators, coordinating the actions required at an existing site or being transferred to LM.

- Manages and preserves the historical, cultural, and natural resources of sites.

- Plans, develops, and implements systems and processes for maintenance and disposition of real and personal property under the control of LM, including beneficial reuse plans and transfer to community or other organizations.

Appendix B
Quality Management System Review and Approval Template

This review template is intended for use by DOE for evaluating a contractor's QA program submittal in accordance with 10 CFR 830. It may also be used by DOE or contractors to review other QAPPs.

B.1 Reviewer Qualification

Federal personnel assigned to lead review teams and recommend approval of contractor quality management systems should have completed, at a minimum, DOE Std 1150-2002, *Quality Assurance Functional Area Qualification Standard*, in accordance with DOE M 426.1-1A,*Federal Technical Capabilities Manual*, . Team members may also be qualified, but at a minimum should have demonstrated proficiency in quality assurance and should be technically qualified and/or knowledgeable in the areas they are assigned to review.

B.2 Quality Management System Review

The DOE reviewer/approval authority should perform the following as part of the review:

- List the requirements, in addition to the QA rule 10 CFR 830 and DOE O 414.1C, applicable to the quality management system, such as safety structures, systems, and components identified and discussed in the safety basis documents, including
  - —Appropriate standards selected (e.g., NQA-1, ISO 9001).
  - —Integration with other management system and quality requirements (e.g., integrated safety management [ISM], QC-1).
- Use DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, and ASME NQA-1-2000 in the review to ensure that the review is sufficiently rigorous for nuclear and radiological facilities. (The guide and NQA-1 may also be used in a graded approach for other high-risk and hazardous activities.)
- Apply the review to all project quality-related activities (not just safety-related).
  - —Determine the responsibilities for review and approval of initial submittals and revisions.
  - —As part of the review, evaluate the implementation of the program where possible.
  - —Understand the contract quality requirements and expectations.

B.3 General Requirements for the Review

- Prepare a review plan in advance. Base the review plan on DOE G 414.1-2A and NQA-1-2002 (or other appropriate standards for nonnuclear work) and the contract.
- Identify the quality criteria that apply to the work; Prepare checklists for the review.

- Use the questions identified below as a starting point and expand them using the contract, DOE G 414.1-2A, and NQA-1-2002.
- Complete the review and document the results.
- Notify the contractor of the review results, provide any directed changes to the contractor's QAPP, and informs the contractor of the approval status (approved, conditionally approved, disapproved) in the time allotted by 10 CFR 830.
- Notify the contractor of any work restrictions relating to conditional approvals or disapprovals.

B.4 Checklist (see Attachment 1 of DOE G 414.1-2A)

B.4.1 Program

- Does the quality management system (QMS) describe the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work?
  - —Has the organization designated the senior management position responsible for development and maintenance of the QMS?
  - —Does the organization demonstrate senior management leadership for quality and the QMS?
- Are senior management expectations for implementation adequately defined and delineated?
- Have the requirements for ISM been adequately addressed and integrated into the QMS?
- Are there organizations excluded from the scope of the QA program? If so, is there sufficient justification for the exclusion?
  - —Are the internal and external interfaces documented?
- Have adequate resources been identified for quality program activities, such as planning, auditing, supplier qualification, technical document review, inspection, and calibration?
- Does the QMS describe management processes, including planning, scheduling, and providing resources for the work?
- Does the QMS define a process for grading the application of requirements? Does this process adequately address hazards and mission?
- Has the QMS been prepared using NQA-1-2002 and other consensus standards appropriate for the mission?
- Are the processes for determining the quality requirements applicable to subcontractors/suppliers and for passing those requirements down through contracts clearly defined?
- Has contractor senior management endorsed the QMS?

B.4.2 Personnel Training and Qualification

- Is the methodology described for establishing requirements to train and qualify personnel so that they are capable of performing their assigned work?
- Is there evidence that the organization has an established and documented training plan?
  —Have adequate resources been identified to support the selection, training, and qualification of personnel conducting work?
- Does the training and qualification program describe the positions and functions to which it applies?
- Are the requirements defined for the qualification and/or certification of personnel in the various functional areas (e.g., auditors, subject matter experts, nondestructive examination personnel, welders)?
- Is the methodology described for providing continuing training to personnel to maintain their job proficiency?

B.4.3 Quality Improvement

- Has the organization established, implemented, and documented processes to detect and prevent quality problems?
- Do work processes and procedures call for identification and reporting of quality problems?
- Does senior management policy encourage problem detection and prevention?
- Are there processes for communicating lessons learned and performance information?
- Is there a method for categorizing the significance of quality problems?
- Is the approach to identify, control, and correct items, services, and processes that do not meet established requirements (nonconforming) adequately described?
- Does this approach include the requisite discipline involvement to adequately evaluate and resolve the nonconforming item, service, or process?
- Does this approach address the identification and control of nonconforming items such that it prevents inadvertent use?
- Does the QMS address documentation and correction of quality problems associated with services and processes?
- Does the QMS provide for the identification of the causes of problems and require identification of actions to prevent recurrence as a part of correcting the problem?
- Does the QMS describe methods for addressing cause, extent, and remedial and preventive actions for quality problems?
- Is a process identified to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement?

- Is there a quality performance analysis system (e.g., six sigma, metrics and indicators, trending)?
- Does the performance analysis system provide a mechanism for feedback to affected and related entities in the organization?

B.4.4 Documents and Records

- How does the organization prepare, review, approve, issue, use, and revise documents to prescribe such things as processes, requirements, and design? Is there a document control system that provides these functions?
- Verify that key functions relating to the quality criteria (e.g., design, procurement, work control, inspection, testing) are described in an approved document, such as a procedures manual.
- How does the organization specify, prepare, review, approve, and maintain records?
  —Is there a documented records management system that provides these functions?
- How are the requirements of the National Archives and Records Administration addressed?
- What is the quality records standard applied to the contract and is it fully implemented?

B.4.5 Work Processes

- Does the QMS provide methods for ensuring that work performed is consistent with technical standards, administrative controls, and other hazard controls?
- Are the core functions and guiding principles of the DOE Integrated Safety Management System addressed?
- Do the approved instructions, procedures, or other appropriate means for the work processes meet regulatory or contract requirements?
- Does the QMS provide methods to identify and control items to ensure their proper use?
- Is the method to maintain items to prevent their damage, loss, or deterioration adequately described? Does this method address the requirements of DOE O 433.1, *Maintenance Management Program for DOE Nuclear Facilities*?
- Does the QMS describe an adequate calibration and maintenance system for equipment used for process monitoring or data collection?
- Is the system for use and control of software described in accordance with DOE G 414.1-4?

B.4.6 Design

- Do design items and processes use sound engineering/scientific principles and appropriate standards?
- Is the use of software in the design and safety analysis process controlled in accordance with DOE G 414.1-4?

- What method is used to incorporate applicable requirements and design bases in design work?
- Are design changes controlled at the same level as the design?
  —How are design interfaces identified and controlled, within the design authority and externally with customers and suppliers, including subcontractors?
- Does the quality management system describe a process for design verification and/or validation for design products? Does the process require the use of individuals or groups other than those who performed the work?
- Is the work verified/validated before approval and implementation of the design?
- Is there a system for engineering involvement in the identification, analysis, and control of suspect/counterfeit items that could affect safety?

B.4.7 Procurement

- How are the requirements for the procurement of items and services established? Do the requirements include performance specifications and expectations?
- Are procurement document changes managed and controlled at the same level as the original?
- Is there a system to evaluate and select prospective suppliers based on specified criteria?
- Is there a system for identification of potential of suspect/counterfeit items and the prevention of their procurement?
- Is supplier documentation managed and controlled?
  —How are processes to ensure that approved suppliers continue to provide acceptable items and services established and implemented?

B.4.8 Inspections and Acceptance Testing

- How are inspections and tests specified for items, services, and processes? How are acceptance and performance criteria established and used?
- Are inspection and acceptance tests planned and controlled?
- Is there a system for documenting the results of inspections and tests?
- Is inspection and test equipment calibrated and maintained?

B.4.9 Management Assessment

- Does the QMS describe how managers at all levels assess their management processes?
- Does the QMS provide for the identification and correction of problems that hinder the organization from achieving its objectives?

- Do managers take responsibility for, and participate in, the assessments?
  —Has third-party certification been considered? Used?
- Is DOE G 414.1-1A used to develop the process?

B.4.10 Independent Assessment

- Has the independent assessment process been adequately defined and documented?
- Are independent assessments (e.g., audits) planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement?
- Does the group performing independent assessments have sufficient authority and freedom from line management (i.e., not directly responsible for the work being assessed)?
- Are the persons conducting independent assessments technically qualified and/or knowledgeable in the areas to be assessed?
- Is there a process to obtain technical experts for assessments when they are not available in the organization?
- Is there a system for reporting assessment results to responsible management and for assuring that action is taken to correct identified issues?
- Is senior management informed of the assessment results and engaged in ensuring responsible management response to identified issues?
- Are DOE G 414.1-1A and appropriate national standards used to develop the process?

B.5 References

10 CFR 830.U.S. Department of Energy, "Nuclear Safety Management.," *Code of Federal Regulations,* January 1, 2005.

ASME NQA-1-2002. *Quality Assurance Requirements for Nuclear Facility Applications,* American Society of Mechanical Engineers.

DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide,* May 31, 2001.

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*, June 17, 2005

DOE M 426.1-1A, *Federal Technical Capabilities Manual,* May 18, 2004.

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DOE O 433.1, *Maintenance Management Program for DOE Nuclear Facilities,* June 1, 2001.

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