QUALITY ASSURANCE PROGRAM FOR U.S. DEPARTMENT OF ENERGY PROJECTS

DOE/ABQ-Prog-001,R.3

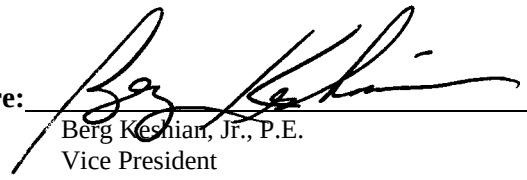
July 16, 2007

Weston Solutions, Inc.
3840 Commons NE
Albuquerque, New Mexico 87109

CERTIFICATION

I certify that this Quality Assurance Program (QAP) for U.S. Department of Energy (DOE) Projects and implementing procedures addresses the requirements of:

- DOE Order 414.1C, *Quality Assurance*
- Title 10 Code of Federal Regulations (CFR) Part 830, Subpart A, *Quality Assurance Requirements*
- American Society of Mechanical Engineers (ASME) NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*

Signature: 

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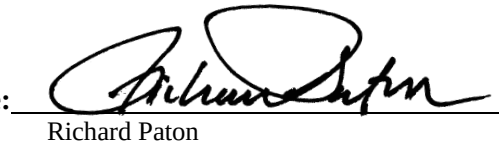
Signature: 

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Acronyms

AHA	activity hazards analysis
ASME	American Society of Mechanical Engineers
BBS	behavior based safety
CFR	Code of Federal Regulations
CRD	Contractor Requirements Document
CSM	client services manager
DOE	U.S. Department of Energy
EDQMP	WESTON's *Engineering Design Quality Assurance Management Plan*
EPA	U.S. Environmental Protection Agency
EHS	environmental, health, and safety
FPD	Federal Programs Division
HASP	health and safety plan
ISMS	integrated safety management system
M&TE	measuring and test equipment
NIST	National Institute for Standards and Technology
NNSA	National Nuclear Security Administration
NQA-1	*Quality Assurance Program Requirements for Nuclear Facilities*
OJT	on-the-job training
OP	operating procedure/practice
OSHA	Occupational Safety and Health Administration
OU	organization unit
PE	Professional Engineer
PLC	Project LifeCycle
PM	project manager
PPT	procurement planning tool
QA	quality assurance
QAP	Quality Assurance Program

QAPD	Quality Assurance Program Document
QAPP	quality assurance project plan
QMM	WESTON's *Quality Management Manual*
QMS	quality management system
QPR	Quality Problem Report
RFP	Request for Proposal
S/CI	suspect/counterfeit item
SOW	statement/scope of work
SQA	software quality assurance
SSO	site safety officer
WI	work instruction
WSHP	10 CFR 851 Worker Safety and Health Program

INTRODUCTION

Weston Solutions, Inc. (WESTON®) is committed to provide services and deliverables that are technically and scientifically defensible and professionally ethical. WESTON's corporate-wide Quality Management System (QMS) is documented in the WESTON *Quality Management Manual* (QMM) and *Corporate Quality Assurance Process Description* (Corporate QAPD). WESTON management and personnel establish and maintain quality assurance (QA) as an integral component of all projects. For projects under contract to the U.S. Department of Energy (DOE) and DOE contractors, WESTON personnel implement the Quality Assurance Program (QAP) described in this document, the QMM, the Corporate QAPD, and supporting documents to address the requirements of:

- DOE Order 414.1C, *Quality Assurance*, and the Contractor Requirements Document (CRD) (Attachment 2 to DOE O 414.1C)
- Title 10 Code of Federal Regulations (CFR) Part 830, Subpart A, *Quality Assurance Requirements*
- American Society of Mechanical Engineers (ASME) NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*

For DOE projects that require a project- or site-specific QA project plan (QAPP), this QAP may be used as a template with client-identified requirements incorporated. Some projects are required by contract, statement/scope of work (SOW), or other client requirement to implement a client's QA program. In these cases, WESTON personnel will implement the client's required program in lieu of this QAP. The WESTON project manager (PM) ensures that WESTON staff implements the client's QA requirements.

WESTON integrates the requirements of DOE O 414.1C with other DOE directives and external requirements including, as applicable:

- 10 CFR Part 851, *Worker Safety and Health Program*, 02-09-06
- DOE P 450.4, *Safety Management System Policy*, dated 10-15-96
- DOE P 450.5, *Line Environment, Safety and Health Oversight*, dated 06-26-97
- National Nuclear Security Administration (NNSA) *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities)
- DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*
- DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Document*, (for the Waste Isolation Pilot Plant and related activities) (QAPD)

WESTON complies with the requirements of the CRD and flows down the applicable QA and safety requirements to subcontractors. When conducting activities or providing items or services that affect, or may affect the safety of DOE nuclear facilities (including NNSA), WESTON will conduct work in accordance with the QA requirements of 10 CFR 830, Subpart A. When responsible for safety software used in nuclear facilities, WESTON will comply with the Safety Software Quality Requirements. As applicable, WESTON will integrate (in the project-specific QAPP) other standards established by standards organizations, the Nuclear Regulatory Commission, and other Federal agencies where practicable and consistent with contractual or regulatory requirements. For example, unique/specific work activities under environmental remediation projects may require that sampling and analysis address U.S. Environmental Protection Agency (EPA) QA requirements (including the *Uniform Federal Policy for*

Implementing Environmental Quality Systems, and projects involving transuranic waste certification require implementation of QAPD requirements and additional requirements of NQA-1.

As required in the DOE O 414.1C CRD, when performing work under DOE contract WESTON will:

- Submit this QAP and/or the project-specific QAPP to DOE for approval before beginning work.
- Implement this QAP and/or QAPP as approved and modified by DOE.
- Regard this QAP as approved by DOE 90 days after DOE receipt, unless approved or rejected by DOE at an earlier date
- Include any modification made or directed by DOE.
- Revise this QAP and/or QAPP, as needed, to address revised CRD requirements.
- Annually, submit the revised QAP to DOE for review and approval. In the submittal identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of the CRD. WESTON may make changes to the approved QAP at any time. Editorial changes made do not require explanation.

The provisions of WESTON's QMS and for DOE projects, this QAP, ensure that the quality of our products and services meet or exceed client's expectations. Through implementation of this QAP (specific to DOE projects), and related procedures, WESTON personnel ensure that:

1. Quality is assured and maintained through a single, integrated, effective QA program.
2. There is management support for planning, organization, resources, direction, and control.
3. Performance and quality improvement are verified through rigorous assessment and corrective action.
4. Workers achieve and maintain quality.
5. Environmental, safety, and health risks and impacts associated with work processes are minimized while reliability and performance of work products are maximized.

This QAP was developed using guidance in the following documents:

- 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*
- NQA-1
- 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*

In general, this QAP follows the sequence of DOE O 414.1C, CRD QA criteria. Each criterion is followed by a description of WESTON's implementation methods. Many requirements are implemented as directed by this QAP or project-specific QAPP while some requirements are implemented in accordance with approved work instructions (WIs) which provide more detail. The applicable WIs are referenced throughout this QAP. Attachment 1 addresses the control of suspect/counterfeit items (S/CI); Attachment 2 describes WESTON's software quality assurance (SQA) process requirements; Attachment 3 lists references; Attachment 4 provides definitions; Attachment 5 provides a matrix that depicts the relationship between this QAP and various QA requirement documents; and Attachment 6 provides a matrix that relates ISMS core functions and guiding principles to elements of this QAP and WESTON's *10 CFR 851 Worker Safety and Health Program* (WSHP). There is no third-party certification affecting the QAP.

1. 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 work.

1.1 QUALITY ASSURANCE PROGRAM

WESTON's commitment to quality is reinforced in the quality policy stated in the Corporate Quality Assurance Process Description (QAPD):

> *It is the policy of WESTON to provide services that consistently meet agreed-upon requirements of its internal and external clients. As a minimum WESTON will provide only services and deliverables that are technically, scientifically, and professionally ethical and defensible. It is further the policy of WESTON to maintain a sustained, continuous improvement attitude such that its work processes are constantly examined and improved for the benefit of WESTON and its clients.*

Corporate quality managers are responsible for defining and implementing an effective QMS and structure for WESTON. The QMS is communicated through the Corporate QAPD, QMM, policies, plans, procedures, and operating practices (OPs) which are available on-line on the WESTON Portal. WESTON senior managers fully support this QMS. The QMS allows flexibility for divisions, programs, profit centers, operations, and organizational units (OUs) to establish location-, client-, or project-specific plans and procedures to supplement the QMS and OPs. This QAP, established for DOE projects, is supplemented by QAPPs, plans, procedures, and WIs to implement applicable QA requirements. WESTON's Nuclear Programs, Client Business Team Manager, Nuclear Programs Operations Manager, and Nuclear Programs QA Officer ensure that this QAP is developed, distributed, updated, and implemented for WESTON DOE projects.

WESTON projects are reviewed through the Project LifeCycle (PLC) process, to ensure that critical project information such as quality, risk, health and safety, schedule, and financial status are periodically addressed by management, project and QA staff, and other appropriate organization representatives.

Integrated Safety Management System

WESTON's *10 CFR 851 Worker Safety and Health Program* (WSHP) demonstrates compliance with DOE and Occupational Safety and Health Administration (OSHA) regulations to establish and implement worker rights and responsibilities for DOE projects. The WSHP is supported by the Environmental, Health, and Safety (EHS) Program which is communicated to personnel through the *Corporate Environmental Health and Safety Program with Integrated Compliance Plan* (Corporate EHS Program); Appendix A to the EHS program, "Integrating Safety Management into Contract Operations" (ISM); and the *Safety Officer Manual*. These documents, hazards analyses templates, procedures, tools, forms, checklists, monitoring information, and guidance are available to all personnel as hard-copy documents or on the WESTON on-line portal site. WESTON's EHS program is standard work practice for every job, with personnel operating in a manner compliant with legislative and regulatory requirements (e.g., OSHA, EPA, DOE, and Department of Defense), required standards, and established procedures.

WESTON's senior management is committed to incorporating QA and EHS into management and work practices at all levels, addressing work activities, hazards, and hazard controls to ensure safety for the workers, the public, and the environment. It is WESTON policy to consider QA and EHS from project planning stages through work execution and completion. WESTON utilizes integrated EHS management

systems to implement our goal to work safely 100 percent of the time. WESTON's Integrated Safety Management System (ISMS) implements job safety analyses and hazards analyses in parallel with project planning for QA, staffing, funding requirements, and project needs and goals. The PM and Nuclear Programs Operations Manager ensure that resources are available to safely perform quality work.

WESTON managers and staff must understand and comply with applicable QA and EHS requirements. Each manager responsible for work must evaluate the EHS hazards and QA controls commensurate with the work being conducted and ensure that appropriate work processes are established and implemented using the graded approach. Each PM must establish clear lines of communication with the client and ensure that, as applicable, project- or site-specific QAPPs, health and safety plans (HASPs), procedures or work instructions, and other required documentation are approved before work begins. Some WESTON contracts require implementation of the client's QA, WSHP, ISMS, and/or EHS program. As applicable, WESTON will implement the client's established programs and will comply with other requirements, measures, and processes that flow down to achieve quality and safety.

1.2 ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

The Corporate QAPD defines QA responsibilities for corporate- and division-level positions. All levels of the organization are responsible for achieving and maintaining quality and conducting work safely. A QA officer is assigned to each division, responsible for implementing the QMS and providing leadership to Project QA Representatives and to maintain open lines of communication with other members of the quality network. Figure 1-1 provides the WESTON quality organization chart. Each PM must designate a Project QA Representative who is qualified to assess project-specific work activities commensurate with the SOW. The PM and Project QA Representative will ensure that this QAP and project-related documents, plans, procedures, and work instructions are available and implemented. Figure 1-2 provides the project/QA organization chart for WESTON's Nuclear Programs.

1.2.1 Corporate QA Manager

The Corporate QA Manager is the management representative independent of operations who reports through the Vice President for Corporate Quality Leadership to the Chief Information and Financial Officer. The Corporate QA Manager is responsible for the implementation and continual improvement of the QMS and approves OPs related to the QMS, identifies repetitive systemic nonconformities, reports to upper management on the performance of the QMS, and serves as a clearinghouse for QMS-related issues. The Corporate QA Manager has the authority to audit, inspect, and test office and field operations; initiate solutions to nonconformities; identify and record root causes of quality problems; recommend solutions based on root cause analysis; and stop work in order to correct quality deficiencies.

1.2.2 Federal Programs Division QA Officer

The Federal Programs Division (FPD) QA Officer is responsible for ensuring implementation of the Corporate QMS in the division, and provides leadership to Project QA Representatives. As part of quality-related responsibilities, the FPD QA Officer:

- Reviews and/or approves program- or project-specific QAPPs and procedures.
- Conducts or directs division audits and project audits, assessments, reviews, or surveillances.
- Participates in regularly scheduled conference calls/meetings with the WESTON QA network.
- Ensures that each PM assigns qualified Project QA Representatives on projects as appropriate and coordinates with project PMs and QA Representatives to ensure QMS implementation.
- Reports quality issues and systemic nonconformities to the Corporate QA Manager.

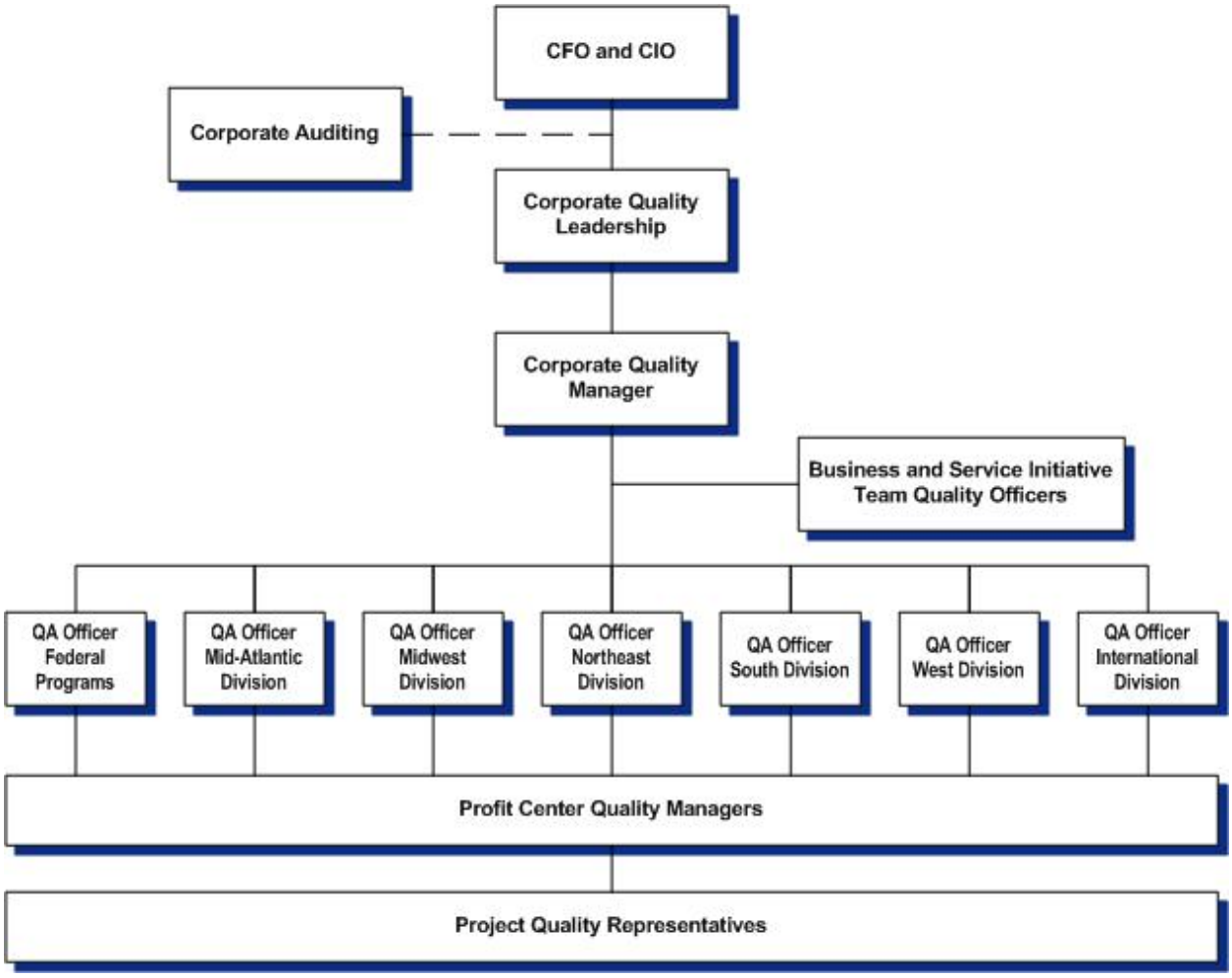

Figure 1-1 WESTON's Quality Organization

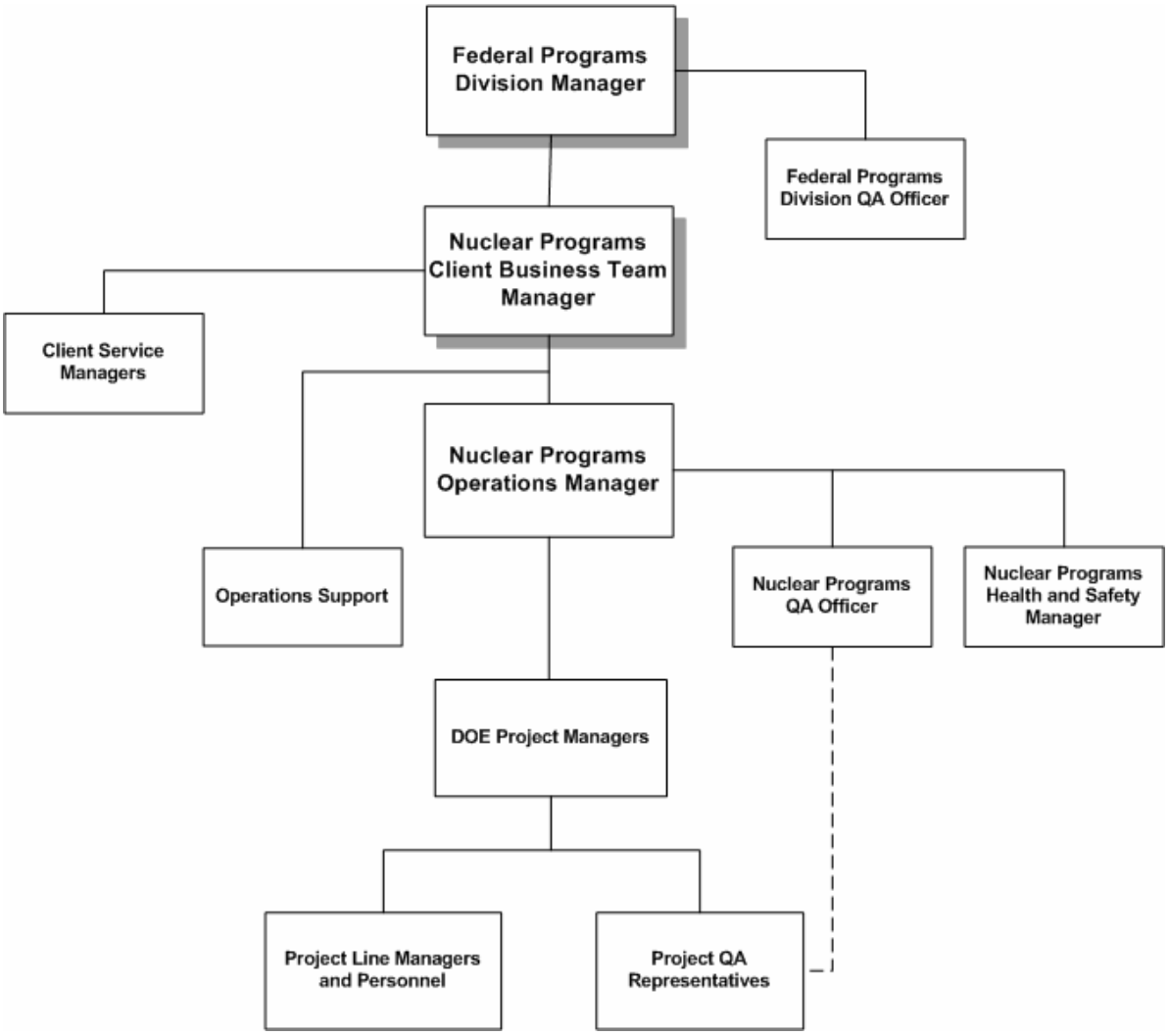

Figure 1-2 WESTON's Nuclear Programs-Project/QA Organization

1.2.3 Nuclear Programs QA Officer

The Nuclear Programs QA Officer is responsible for providing guidance to WESTON personnel who work on DOE projects. As part of quality-related responsibilities, the Nuclear Programs QA Officer:

- Prepares this QAP, reviews at least annually, and revises as needed.
- Works with PMs and FPD QA Officer to ensure that qualified Project QA Representatives are assigned on DOE projects as appropriate.
- As needed, develops or assists in developing QAPPs for DOE projects, using this QAP as a template (unless client specifies format and/or content).
- Develops quality-related plans, procedures, or work instructions for DOE projects.
- Works with the Nuclear Programs Operations Manager, PM, and Project QA Representatives to ensure distribution of controlled documents.
- Encourages and evaluates quality improvement suggestions.
- Works with PM and Project QA Representative to ensure that project records are maintained in accordance with *Records Management* (DOE/ABQ-WI-001).
- Coordinates project training requirements with the PM, Site Manager, Project QA Representative, and/or Nuclear Programs Health and Safety Manager.
- Participates in PLC review meetings and assist PMs in completing PLC requirements.
- Conducts or directs audits, assessments, reviews, or surveillances of DOE projects.

1.2.4 Project QA Representatives

The Project QA Representatives are responsible for ensuring that QA requirements are fulfilled on the project level and coordinate with the Nuclear Programs QA Officer on quality-related matters. As part of quality-related responsibilities, the Project QA Representatives:

- Assist in the development, review, and implementation of project-specific QAPPs, other quality-related plans, procedures, and work instructions.
- Verify that participating suppliers/subcontractors have QA procedures that meet client requirements and WESTON's QMS.
- Participate in or coordinate project audits, assessments, reviews, or surveillances.
- Oversee vendors/subcontractors for quality issues.
- Verify that procured products and services meet specifications.
- As applicable, ensure that S/CI prevention requirements, corrective action requirements, and safety SQA requirements are implemented.
- Work with the PM to ensure that project personnel are knowledgeable of the elements of this QAP, the project-specific QAPP, WIs, and technical requirements.
- Work with the PM to meet requirements for project personnel qualification and training.
- Provide guidance, review, and other QA support to the PM, line managers, and project personnel for QAPP implementation, corrective actions, assessments, and quality improvement.
- Ensure that the current QAPP and other project documents are available to all project personnel.

- Provide guidance on the level and extent of QA appropriate to a given activity.
- Coordinate with managers and project personnel on S/CI processes and controls (Attachment 1).
- Coordinate with the PM or client's S/CI coordinator, when S/CIs are detected.
- Provide guidance on corrective action planning and tracking.
- Provide guidance related to quality awareness and implementation of quality procedures.

For projects with higher risk or complexity, the PM, client services manager (CSM), and/or Nuclear Programs Operations Manager designate a qualified Project QA Representative. For projects of lower risk or complexity, the PM may assume the role of Project QA Representative, if allowed by the contract or client requirements.

1.2.5 Federal Programs Division Manager

The FPD Manager is responsible for creating a work environment in which personnel work safely to ensure that services and deliverables produced by WESTON fulfill contract specifications and meet the quality expected by clients. The FPD Manager is responsible for providing adequate resources and assigning sufficient authority and independence to project and line management to enable them to manage work that is performed safely and productively, and to effectively plan, implement, assess, and improve WESTON's QMS and EHS program.

1.2.6 Nuclear Programs Client Business Team Manager

As part of quality-related responsibilities, the Nuclear Programs Client Business Team Manager:

- Develops a shared vision and strategy and leads the implementation of that strategy.
- Leads strategic implementation and decision-making to achieve strategic milestones.
- Drives client engagement.
- Acts as client advocate to ensure resolution of key client problems and conflicts.
- Builds team engagement.
- Ensures availability of key resources needed for strategically critical efforts.

1.2.7 Nuclear Programs Operations Manager

The Nuclear Programs Operations Manager is responsible for WESTON's DOE projects and works with PMs in opening jobs; planning, scheduling, and monitoring work; providing resources to ensure that work is conducted safely. As part of quality-related responsibilities, the Nuclear Programs Operations Manager:

- Reviews deliverables.
- Maintains contact with the client.
- Coordinates the work effort.
- Administers the contract.
- Maintains integrity of business systems.
- Ensures that WESTON's DOE project staff maintain quality.
- Maintains ongoing communication with the Nuclear Programs QA Officer and Health and Safety Manager.
- Approves project quality pledges.
- Schedules and conducts PLC reviews for selected DOE projects.

As requested, the Nuclear Programs Operations Manager will ensure that this QAP, WSHP, and/or project-specific QAPP are submitted to DOE before beginning work under a DOE contract.

1.2.8 Project Manager

Each PM maintains overall responsibility for project implementation, quality, safety, and regulatory compliance. The PM is responsible for determining the needs, requirements, and expectations of the client for the items or services to be provided. As part of quality-related responsibilities the PM:

- Provides leadership and ensures that applicable scientific, technical, operational, and supporting work activities are defined and planned.
- Ensures that safety and QA requirements are implemented and are communicated to project personnel throughout the project duration.
- Ensures that resources are available to work safely and meet quality commitments and needs.
- Provides leadership in strategic planning.
- Approves planning documents.
- Defines SOW, project goals, objectives, policies, schedules, and milestones for the project.
- Communicates regularly with the client to ensure project and regulatory requirements are met.
- Communicates regularly with the Nuclear Programs Operations Manager regarding project activities/issues.
- Ensures that this QAP or the project-specific QAPP, WSHP, HASP, and activity hazards analyses (AHAs) are distributed (or made available) to project personnel.
- Develops and/or distributes other project documents, procedures, and requirements and ensures that project personnel are aware of client-specific requirements.
- Ensures that employees are qualified and trained specific to their jobs and are capable of performing assigned tasks safely.
- Determines and documents specific training needs and training schedule.
- Identifies lines of communication.
- Plans and schedules project activities.
- Provides visible support for quality in project activities, fosters an atmosphere conducive to continuous quality improvement and safety, and encourages worker feedback.
- Provides guidance to line managers and supervisory personnel.
- Participates in PLC reviews and identifies project needs.
- Documents the project quality pledge and communicates to project personnel.
- Informs managers and project personnel of S/CI processes and controls (Attachment 1).
- Coordinates with the DOE client's S/CI coordinator, when S/CIs are detected.
- As applicable, ensures that corrective action requirements are implemented.
- Provides direction, oversight, and the necessary resources and environment to ensure implementation of project requirements.
- As applicable, ensures that nuclear facility safety SQA requirements are implemented.
- Interfaces with subcontractors to ensure that they meet project and contract requirements.
- Conducts management assessments and accommodates external assessments of the QA program.

(**Note** – The PM may delegate some of these responsibilities to the site manager.)

1.2.9 Nuclear Programs Health and Safety Manager

The Nuclear Programs Health and Safety Manager will ensure that the Corporate EHS Program, 10 CFR 851 WSHP, and client health and safety requirements are implemented on WESTON DOE projects. As part of ISMS- and quality-related responsibilities the Nuclear Programs Health and Safety Manager:

- Ensures safety training requirements are met and related documentation is maintained.
- Monitors and track safety training, qualification, and certification for project personnel.
- Evaluates work for safety and health risks and document evaluation as a project record.
- Works with each PM to assign a qualified site safety officer (SSO) to field projects.
- Performs EHS responsibilities as defined in the WSHP.
- Conducts or participates in safety briefings for field work.
- Works with the Project QA Representative to ensure distribution of controlled safety documents (e.g., WSHP and other safety policies, guidelines, and information) to project personnel.
- Assists in preparation, review, approval and distribution of project- or site-specific HASPs, including AHAs.
- Provides technical support and related training for EHS, hazardous materials shipping, and security issues.
- Coordinates occupational medical examinations and ensures related records are maintained in accordance with the WSHP.
- Conducts periodic work area safety inspections and site safety audits and maintains inspection documentation as project records.
- Ensures security and maintenance of personnel health and safety files.

Health and safety personnel responsibilities are further described in WESTON's EHS program.

1.2.10 Line Managers

Line managers who direct project work (includes, but is not limited to, site managers, team leads, project coordinators) are responsible for QA, quality improvement, and safety within their cognizant areas. As part of quality-related responsibilities line managers:

- Define activity-specific work, goals, objectives, schedules, and milestones.
- Assign tasks.
- Ensure that project personnel are qualified and trained to conduct work safely.
- Promote timely identification and correction of conditions adverse to quality.
- Implement and monitor work to ensure that required actions are performed safely to achieve quality objectives.
- Ensure that equipment is calibrated and/or maintained.
- Ensure that item, equipment, and site inspections are performed.
- Document work activities to provide adequate confidence that requirements have been met.

- Promote quality principles and attitudes through implementation of the QAPP and this QAP.
- Promote ISMS principles and attitudes through implementation of this QAP, the WSHP, the QAPP, and the project- or site-specific HASP.
- Ensure that work is performed within established controls (e.g., procedures, instructions, work plans, work permits, AHAs).
- Conduct management assessments and ensure self-evaluation of work activities within their areas of responsibility to ensure that QAP requirements are being effectively implemented.
- Identify opportunities for quality improvement.

1.2.11 Project Personnel

Personnel performing project activities (including subcontractors) are responsible for working safely and achieving and improving quality in the performance of their work. As part of quality-related responsibilities project personnel:

- Obtain and maintain appropriate qualification, training, and proficiency.
- Comply with applicable requirements and standards.
- Implement the requirements of the QAPP (or this QAP), the HASP, and WSHP and any other project requirements/
- Perform work safely in accordance with established procedures, work instructions, permits, work plans, AHAs, HASP, and client requirements.
- Verify that procedures used are current.
- Document work activities, as applicable.
- Comply with records management procedures.
- Promptly report quality and safety concerns or problems.
- Identify opportunities for quality improvement.
- Perform work to prevent or preclude quality problems.

1.3 STOP WORK AUTHORITY AND RESPONSIBILITY

Under WESTON's behavior based safety (BBS) program, following the Bradley Model, everyone works together to achieve our safety goals. Following the BBS program and WSHP, all project personnel are responsible for stopping any and all work that poses an imminent risk of death, serious physical harm, or other serious hazard to workers. Project personnel are also responsible for identifying practices or conditions that are or may be adverse to quality and for recommending cessation of work to a line manager or supervisor. Supervisors and managers are responsible for assessing unsafe conditions or conditions potentially adverse to quality and for taking appropriate action, including stopping work. These responsibilities override planning and scheduling considerations.

1.4 GRADED APPROACH

WESTON management uses a graded approach to determine the scope, depth, and rigor of the QMS to be applied to items and activities. 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 under consideration. Grading is not used as a substitute for or a means of altering contract standards or

requirements nor to "grade to zero" or eliminate measures to assure quality. The CSM and PM select the controls to be applied to items and activities commensurate with the importance to safety, cost, schedule, and success of the program. The grading process for WESTON DOE projects includes an evaluation by the CSM and PM of risk and complexity of facility- and project-specific factors such as:

- Relative importance to safety, safeguards, and security
- Magnitude of any hazard or risk involved
- Life-cycle stage of a facility or activity
- Impact/consequences on programmatic mission of a facility
- Particular characteristics of a facility or activity
- Relative importance to radiological and non-radiological hazards
- Adequacy of existing safety documentation
- Nuclear safety classification or hazard category of the item or activity
- Complexity of products or services involved
- Performance history of a facility or activity
- Other relevant factors.

A graded approach allows line managers to vary the degree or rigor of controls, verification, and documentation commensurate with the potential risks involved in the work effort. As part of the graded approach, the PM identifies the hazards, consequences, and probability of failure of elements that affect the environment, health and safety, quality, programmatic mission, cost, and schedule. The PM determines the QA controls to be applied based on related requirements and communicates the controls through work plans, procedures, instructions, policy statements, or other written method.

The PM ensures that the controls and implementing procedures that reflect the degree of rigor required are documented and communicated to project personnel. When implementing the unreviewed safety question process or technical safety requirements, WESTON will not use a graded approach.

1.5 DELEGATION OF WORK

The PM may delegate work to other qualified personnel, but retains ultimate responsibility for quality completion.

2. PERSONNEL TRAINING AND QUALIFICATION

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

2.1 TRAINING AND QUALIFICATION

Managers assess the project training and qualification requirements before the work starts to ensure that appropriate personnel are assigned to the project. The PM or site manager ensures that project personnel are trained and qualified, commensurate with their responsibilities and applicable regulations, and as required by the client. Project personnel, the PM, site manager, Nuclear Programs Health and Safety Manager, and SSO work together to ensure that health and safety training and certification requirements are met before starting work on a DOE project and during the project duration. Additional details regarding health and safety training are provided in the WSHP.

Personnel training and qualification records are maintained and include records of professional certifications and lists or certificates of training. Training may consist of formal classroom sessions, on-the-job training (OJT), computer-based or on-line training, workshops, required reading, and other training methods or combination of methods appropriate to the situation and the individual.

Project-specific training requirements are determined as applicable to the scope of the activities as specified in project documents such as the QAPP, HASP, work plans, or project management plan. The PM and site manager ensure that any additional general, institutional, project- or site-specific, QA, and EHS training is provided to project personnel and that requirements flow down to subcontractor(s), as applicable. Training and qualification records are managed as described in *Project Training Record* (DOE/ABQ-WI-002).

If required for DOE projects, inspection and test personnel, nondestructive examination personnel, SQA personnel, and lead audit personnel may need to meet applicable NQA-1 qualification requirements.

2.2 ONGOING PROFICIENCY

Managers are responsible for the continuing training of their staff. Regularly scheduled briefings are conducted to communicate safety topics and work being performed. Training needs are evaluated at least annually during the performance evaluation process or as required to meet project requirements. The PM or site manager monitors project activities throughout the project duration to ensure personnel proficiency. If proficiency requirements are not met and if safety or quality could be compromised, the PM or site manager must determine whether to suspend the applicable task and must take corrective action in accordance with *Quality Improvement* (DOE/ABQ-WI-003).

3. 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 include prevention of recurrence as part of corrective action planning. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

3.1 QUALITY IMPROVEMENT

The objective of quality improvement is to identify quality problems, prevent or minimize problems, and improve the quality of products and services delivered to clients. Quality improvement is also the result of suggestions for improvement from WESTON personnel, clients, vendors, and peers and is implemented as described in *Quality Improvement* (DOE/ABQ-WI-003). To the extent possible, project personnel are involved in the planning of project activities. Direct input from individuals with practical knowledge of work performance is critical. Additionally, up-front and continual worker involvement increases their level of understanding and effectiveness of troubleshooting activities prior to work execution of work – this increases safety, quality and productivity.

Process implementation and item characteristics are periodically reviewed through monitoring daily work performance, periodic review of procedures and processes, periodic inspections, and assessments, to identify areas needing improvement. The PM, Project QA Representative, and DOE QA Officer evaluate quality improvement suggestions, considering safety priorities, and monitor implemented improvements to verify effectiveness.

3.2 PREVENTING QUALITY PROBLEMS

WESTON personnel strive to detect and prevent quality problems during work activities. Examples of practices observed to minimize or prevent quality problems include:

- Continuous interaction with the client
- Ensuring that personnel are qualified and trained to perform assigned work activities
- Including procurement personnel in purchases and subcontracts
- Performing work in accordance with approved procedures or work instructions

Additional methods of prevention are described in *Quality Improvement.* The PM or site manager and Project QA Representative are actively involved in project activities and ensure that project personnel implement quality practices commensurate with the scope of the work.

3.3 IDENTIFYING QUALITY PROBLEMS

Although efforts are ongoing to ensure quality, problems may surface. While conducting project activities, quality problems may be identified by managers, project personnel, or the client. As described in *Quality Improvement,* WESTON personnel are required to report quality problems and encouraged to suggest and improve work processes. Primary consideration is given to quality problems that have the greatest potential for posing adverse risks to the environment and human health, impacting the safety and reliability of operations and products, and affecting the ability to meet client requirements. Project personnel receive training and periodic briefings on identifying and reporting quality problems.

3.4 REPORTING QUALITY PROBLEMS

When project personnel identify quality problems, safety concerns, or work processes that deviate from regulations and requirements, they must report them to line managers, the PM, and other site personnel in accordance with project-specific or client-prescribed procedures or *Quality Improvement*. If required by the DOE client, WESTON reports quality problems in accordance with the client's established process. The site manager, PM, or Project QA Representative ensures that the problem and resolution are implemented and documented as required by the client's process, maintaining a copy of documentation for the WESTON project record.

Quality problems are managed using a graded approach. Isolated minor problems identified during field and other work activities that can be corrected at the time of discovery (e.g. missing signatures or dates, incorrect log entries) require remedial action only and do not require a formal Quality Problem Report (QPR). The isolated problem is reported to the site manager or PM and Project QA Representative, immediately resolved, and documented as appropriate to the problem. For problems that are not isolated or cannot be immediately corrected, the PM identifies the cause and manages the quality problem in accordance with *Quality Improvement*.

For a nonconforming item, project personnel promptly identify, mark or tag, and if possible, segregate it to prevent inadvertent use. The site manager or PM notifies the Project QA Representative and ensures that a QPR (or equivalent) is completed. For nonconforming services or processes, the PM, site manager and/or Project QA Representative determine whether work must be stopped in accordance with Section 1.3 of this QAP and consult the Nuclear Programs QA Officer, as needed.

3.5 QUALITY PROBLEM RESOLUTION

Project personnel resolve identified quality problems using a graded approach as described in *Quality Improvement.* Quality problem resolution involves evaluating the significance and extent of the problem, identifying the cause of the problem, and may include repairing, reworking, inspecting, testing, replacing, and/or rejecting services, data, or item(s). The PM or site manager must determine or review and approve corrective actions and ensure that prevention of recurrence is included. Following problem resolution, the PM (or designee) and/or Project QA Representative determine the effectiveness in preventing recurrence of the problem. The Project QA Representative tracks quality problems and corrective actions from identification through resolution. For more complex problems the PM and/or Nuclear Programs QA officer may determine the need for root cause analysis (commensurate with the significance of the problem) in accordance with *Quality Improvement*, or client-specific root cause analysis methods.

3.6 LESSONS LEARNED AND TRENDS ANALYSIS

The Nuclear Programs QA officer promotes identification and documentation of lessons learned, monitors implemented improvements to verify their effectiveness, and distributes the results of the lessons learned through the Corporate QA Manager. The Nuclear Programs QA officer includes an evaluation of the lessons learned, quality improvement suggestions, and results of management and independent assessments in a trend analysis report submitted to the Nuclear Programs Operations Manager and Nuclear Programs Client Business Team Manager as described in *Quality Improvement*.

4. 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.

4.1 DOCUMENTS

The PM determines the documents that need to be developed or updated to meet client requirements. Project personnel will prepare, review, revise, approve, and use controlled documents as required in this QAP, the QAPP, and implementing work instructions and procedures. Controlled documents to be implemented during a project may be developed by WESTON or by the client, depending on the SOW. Controlled documents may include, but are not limited to, operating procedures, work instructions, HASPs, work plans, integrated work documents, implementation plans, waste management procedures or plans, sampling plans, design drawings or specifications, equipment maintenance procedures, QAPPs and procedures, and other documents that prescribe processes, specify requirements, or establish design.

4.1.1 Document Preparation

Qualified personnel prepare, revise, and review documents and client deliverables in accordance with *Document Preparation, Review, and Control* (DOE/ABQ-WI-004) or provide guidance and pertinent information to other project personnel who are assigned to prepare the document. Document requirements, including approval authority, will be identified in the QAPP or other project-specific document. The PM is ultimately responsible for ensuring the quality of documents and deliverables and will ensure incorporation of internal and client review comments.

4.1.2 Document Review

WESTON personnel qualified to perform the work, other than the document author(s), will review the document for adequacy, completeness, and correctness and provide comments to the document author(s). The document author resolves and incorporates internal comments received. For deliverable documents, the internal review and comment incorporation will be performed before the deliverable is submitted to the client. The PM submits deliverable documents to the client. Document revisions (i.e., electronic and hard copies) are maintained in accordance with *Document Preparation, Review, and Control* and *Records Management*. The PM and document author ensure that client review comments are incorporated and maintained in the project file.

4.1.3 Document Revision

Documents are revised when necessary to reflect changes in processes or new requirements and periodically as determined by the PM, Nuclear Programs Operations Manager, Nuclear Programs Client Business Team Manager, or Nuclear Programs QA officer. Revised documents are reviewed and approved by individuals in the same positions as those who reviewed and approved the original revision of the document.

4.1.4 Document Control

The PM ensures that project-specific plans, operating procedures, and/or work instructions are controlled in accordance with *Document Preparation, Review, and Control* and that project personnel are working safely and correctly to current procedures. The PM also identifies deliverable documents that are to be controlled to ensure project quality and deliverable version control.

4.2 RECORDS

WESTON personnel generate, review, approve, classify, store, maintain, and retrieve records in accordance with *Records Management* (DOE/ABQ-WI-001) and client requirements. The PM specifies records to be maintained for the project, establishes the record guidelines, communicates the guidelines to project personnel, and ensures that record review and approval meet the project requirements. The PM or site manager and Project QA Representative ensure that in-process project records are maintained in accordance with *Records Management*. In-process records may be maintained at the project site; however, these storage locations must meet *Records Management* storage requirements.

4.2.1 Records Submittal and Storage

Project personnel provide legible and organized records to the records center with the required record submittal form that includes project information sufficient to trace each record. WESTON offices maintain and control records, including electronic and hard copy records, and apply controls through all phases of record life through disposition. Record information is maintained in a database. Records storage facilities are access-controlled and secure; and records are protected from fire and damage due to weather, relative humidity, and dust. Records are accessible for ease of retrieval. Records are maintained for a period specified in the contract, or as required in WESTON's Records Retention Schedule (Attachment 1 to Weston's Corporate *Records Management Procedure,* OP 04-17-001). Electronic files are stored in WESTON's local and wide area network environment and are maintained, backed up, and archived by the Information Services Department.

4.2.2 Changes to Records

Changes to in-process records are made in accordance with *Records Management*. Changes to records entered and stored in the records center must be documented and approved by the PM.

5. WORK PROCESSES

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

5.1 PLANNING AND PERFORMING WORK

The PM or site manager ensures that project personnel plan and perform work in accordance with approved and current instructions, procedures, and/or plans that define work processes and process controls, and, as applicable, project- or site-specific HASPs that identify hazards and controls. The PM or site manager ensures that project personnel are trained and qualified to perform the work and that resources and staff are available to perform work productively and safely.

Project personnel are informed of project requirements at a project kickoff meeting and at regularly scheduled meetings/briefings. The PM or site manager ensures that project personnel are aware of and understand the contractual requirements, client objectives, project scope, regulatory requirements, safety issues, EHS requirements, potential hazards and hazard controls, work plan, schedule, expected quality, and product or deliverables. Client expectations and quality metrics are documented on the Project Quality Pledge and communicated to project personnel.

A Project Plan form is available for guidance in planning the project kickoff meeting and documenting project data for distribution to project personnel and for project files. At the project kickoff meeting and regularly scheduled project meetings/briefings, the PM ensures that the following are identified (or updated) and clearly conveyed to project personnel:

- Customer and data requirements for the work and final product
- Acceptance criteria applicable to the work and final product
- Hazards associated with the work and controls to mitigate the hazards
- Technical standards applicable to the work and final product
- Site or equipment/material inspection requirements
- Procedures for reviewing and/or verifying work
- Worker rights and responsibilities
- PM, site manager, and worker responsibilities related to QA and safety
- Safety, administrative, technical, and environmental controls to be used.

The PM and site manager ensure that the appropriate equipment and instructions, training, resources, administrative controls, and controlled conditions are provided to accomplish the work. Throughout the duration of the project, the PM or site manager informs project personnel of results; status reviews; problems; and/or adjustments to scope, plan, or schedule.

Project personnel are responsible for the quality of their work and must work efficiently and safely in accordance with current, approved procedures, work instructions, and HASPs. Project personnel should be involved in work process development and process evaluation, and are encouraged to provide feedback and suggestions for improving work processes. Work that involves radioactivity is performed in accordance with established WESTON OPs.

5.2 ITEM IDENTIFICATION AND USE CONTROL

WESTON personnel identify, maintain, and control items as described in *Item and Equipment Control* (DOE/ABQ-WI-005) to:

- Ensure that correct items are used properly
- Prevent the use of incorrect or defective items
- Prevent damage, loss, or deterioration
- Identify and control S/CI
- Provide for control and maintenance of items.

WESTON equipment, furniture, and computers are tagged and tracked. Project personnel verify that the correct item is used based on administrative controls, procedural requirements, and item identification. Project personnel verify that the appropriate conditions (e.g., protective environments, moisture levels, and specific temperatures) are present for handling, storage, or shipping of specific items or equipment. Technical standards, manufacturer instructions, or project-specific WIs that specify special handling, shipping, preservation, and storage controls are followed for precision instrumentation, items with limited operating life or shelf life, and items that require environmental controls (e.g., temperature, humidity).

5.3 SAMPLE CONTROL

Project personnel ensure that they identify samples with unique identification that traces them to their source(s) and relates to other pertinent information. Such samples must be identified and controlled (e.g., chain of custody, preservation, temperature) in a manner consistent with their intended use as specified in project-specific procedures, sampling plans, work plans, or QAPP.

5.4 EQUIPMENT CALIBRATION AND MAINTENANCE

The PM and site manager ensure that equipment used for process monitoring or data collection is of the proper type, range, and/or accuracy. Monitoring and data collection equipment must be maintained and adjusted as needed and, if necessary, calibrated at prescribed intervals as described in *Item and Equipment Control*. Calibrated equipment is tagged by the calibration vendor or WESTON personnel. Calibration must be traceable to nationally recognized standards such as the National Institute for Standards and Technology (NIST). If no nationally recognized standards exist for the equipment, the basis for calibration is documented.

Calibration and maintenance are documented and records are maintained in the project file in accordance with *Records Management* (DOE/ABQ-WI-001) or client-specific procedures. Equipment that has not been calibrated or is out-of-calibration is removed from service, tagged, and, if possible, segregated. The PM, site manager, and/or Project QA Representative evaluate any suspect data and corresponding significance, and, if determined appropriate, perform corrective action.

5.5 CONTROL OF SPECIAL ITEMS

If a PM (or staff member) determines that items require special control, he/she communicates the necessary controls to staff members and subcontractors. Controls might include storage in a locked/secure facility; inspection and/or check-out requirements; property removal documents; or inventory tracking.

Radioactive (exempt quantity) sources are managed in accordance with the applicable regulations and conditions of the license issued by the New Mexico Environment Department. Source management includes inventory control and tracking through WESTON's EquipTrack system.

5.6 SOFTWARE CONTROL

Software must be controlled to ensure that computer applications perform as intended. The PM or site manager and Project QA Representative ensure that software is access- and version-controlled in accordance with applicable procedures, QAPP, and/or client-specific procedures.

6. 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 / validate the adequacy of design products using individuals or groups other than those who performed the work. Verify / validate work before approval and implementation of a design.

6.1 DESIGN OF ITEMS AND PROCESSES

Design requirements apply to specifications, drawings, design bases and criteria, and component and systems performance of engineered systems, processes, hardware, and software. Design projects include data collection and analysis activities that support design development and verification, the planning of scientific investigations, analysis, and report preparation. Design documentation generated by WESTON personnel includes pertinent records such as:

- Assumptions
- Design inputs, calculations, and analyses
- Engineering reports
- Approved and controlled computer codes
- Standards
- Regulatory requirements
- Computer calculations
- Design output/Drawings
- Design reviews
- Design changes
- Design verification activities.

The PM ensures that an Engineer of Record who is a registered professional engineer [PE] (also referred to as Engineer of Responsible Charge) maintains direct control and personal supervision of engineering work for the project. The Engineer of Record/Responsible Charge is responsible for direct control of the project design and personnel supervision of the engineering work and ensures that design activities are planned, reviewed, and performed by qualified personnel using sound engineering/scientific principles. The Engineer of Record/Responsible Charge ensures that state-specific engineering requirements/regulations are met for the applicable project state.

The Engineer of Record/Responsible Charge may assign discipline-specific PEs to the project. Each PE assigned to the project is responsible for quality of design drawings; for including sufficient detail to allow any technically qualified person to review, understand, and verify the adequacy; and for signing/sealing documents to signify adherence to engineering standards. The Engineer of Record/Responsible Charge ensures that designs meet requirements and are protective of the public, workers, and the environment.

For engineering design, WESTON personnel comply with general industry standards and specifications, client requirements, and the WESTON Standard Practices Manual, *Engineering Design Quality Assurance Management Plan* (SP No. 15-06-003) (EDQMP), as applicable. For each engineering design project, the PM, Engineer of Record/Responsible Charge, Nuclear Programs QA Officer, and/or Project QA Representative develop a QAPP as described in the EDQMP. The QAPP will identify specific requirements to be implemented (e.g., NQA-1) and describe methods of implementation or will reference implementing procedures/instructions. If required by the client, WESTON will comply with the client's

established design requirements, manuals, and/or processes. WESTON design documentation must be controlled and maintained as described in *Records Management* (DOE/ABQ-WI-001).

6.2 DESIGN INPUTS

Design inputs may include design bases, health and safety considerations (including hazards and controls), expected life cycle, performance parameters, required codes and standards, and reliability requirements. The Engineer of Record/Responsible Charge specifies project design requirements, standards, methods, and/or materials in the QAPP and other applicable documents and communicates these to project engineering/design staff through distribution of documents, during project meetings/briefings, and other communication methods. The Engineer of Record/Responsible Charge also ensures that:

- qualified engineering/design staff develop design documents required in the SOW, ensuring compliance with applicable general industry standards and specifications and DOE client requirements and/or methods.

- design inputs are identified and documented to the level of detail necessary to permit the design activities to be implemented correctly and to provide a consistent basis for making design decisions, verifying the design, and evaluating design changes.

- controls are established and implemented for selecting and reviewing design methods, materials, parts, equipment, and processes essential to the function of items used on the project.

6.3 DESIGN PROCESS

During the design process, project engineering/design staff identifies elements critical to the performance, safety, or reliability of designed items. The engineering/design staff ensures that the design process translates design inputs into design output documents that are technically correct and compliant with the end user's requirements. The Engineer of Record/Responsible Charge defines technical and administrative design interfaces and establishes methods for their control. The engineering/design staff documents design activities to the level of detail needed to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.

Design methods, materials, parts, equipment, and processes that are essential to the function of items, are reviewed for suitability of application. Design documentation should specify required inspections and tests and related acceptance criteria for the item designed and, if applicable, assemblies and/or components that are part of the design.

During the design process, the engineering/design staff ensures that design status is clearly marked on design documentation (e.g., Draft, Not for Construction, X% Review). Design reviewers will sign and date calculation notes, review/redlined copies of designs, check prints, review checklists, and other review documentation. The PM coordinates with the Engineer of Record/Responsible Charge to ensure that design review records and transmittals are maintained in accordance with *Records Management*. Electronic files will be controlled to ensure that design reviews are performed on current designs. Software that is used to originate or analyze designs or that is developed for a client must be controlled as described in Attachment 2 of this QAP. Software used to analyze or verify designs that might have safety, operational, or programmatic consequences should be appropriately documented and validated.

6.4 DESIGN OUTPUT

The completed design should be documented in design output such as drawings, specifications, test/inspection plans, maintenance requirements, reports, or other design documents specified in the SOW. The Engineer of Record/Responsible Charge ensures compliance with requirements for design review and verification, document control, configuration management, and records management. Project engineering/design staff ensures that designs are analyzed and reviewed to ensure that design output meets design input requirements.

The engineering/design staff ensures that client-required information is included in title blocks of drawings (e.g., client name, project title, location, drawing/revision number, name, signature, date). The PM or Engineer of Record/Responsible Charge ensures that deliverable approval documentation is completed and signed in accordance with *Document Preparation, Review, and Control* (DOE/ABQ-WI-004) before submitting a design to the client. WESTON design records are maintained as permanent records in accordance with WESTON's Records Retention Schedule (Attachment 1 to *Records Management Procedure* [OP 04-17-001]).

6.5 DESIGN VERIFICATION

The Engineer of Record/Responsible Charge ensures that designs are verified through design/technical review, alternate calculation and analyses, qualification testing, or design review by qualified personnel. Characteristics which provide reasonable assurance that the item will perform its intended function are verified.

EDQMP design review checklists may be modified for each project and included in the QAPP. Technically competent reviewers who verify the design must not be directly involved in the original design activities. The extent of the design verification should be based on a graded approach, commensurate with the complexity, risk, uniqueness, degree of standardization, and similarity with previously validated designs.

Design verifications are documented and maintained in the project file in accordance with *Records Management*. Interim verifications may be performed during different stages of the design process. The Engineer of Record/Responsible Charge ensures that design work and design changes have been verified and documented before using the design in project activities.

6.6 DESIGN CHANGES

The Engineer of Record/Responsible Charge ensures that all changes to approved designs meet the appropriate requirements, are still valid, and are justified and documented. This includes design changes made in the field. Design changes must have the same level of review and be approved or verified and validated by the same groups or organizations that approved the original design or have the same level of approval. Design change reviewers must have demonstrated competence in the specific design area and have an adequate understanding of the requirements and intent of the original design. Design change documentation must be controlled in the same manner as the original design. If design changes affect safety, related implementing procedures, or training programs, the PM ensures that the appropriate line managers, health and safety officer, and Project QA Representative are informed and necessary changes are implemented.

6.7 DESIGN INTERFACES

The Engineer of Record/Responsible Charge identifies design interfaces in the QAPP or other design planning document, and ensures that design information is distributed across design interfaces. Design

interfaces may include WESTON engineering/design staff, client contacts, and external organizations responsible for the review, approval, release, distribution, and revision of design documents. The PM coordinates with the Engineer of Record/Responsible Charge to ensure that interface records are controlled and maintained as records in the project file. When verbal transmittal of design information is necessary, it must be confirmed promptly with printed documentation.

7. 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.

7.1 PROCURED ITEMS AND SERVICES

The PM ensures that qualified personnel review and approve procurement documents prior to the purchase of items or contract award for services. Personnel who review and approve procurements should be aware of the *Buy American Act* provisions and clauses required in the Federal Acquisition Regulations (48 CFR 25.1101 and 48 CFR 52.225). The PM also ensures that procurement of items and services complies with the requirements established in the *Procurement Procedures Manual* (OP 04-05-001) and related documents and that procurement documents include the following, as applicable:

- Acceptance criteria
- Specifications, standards, and other documents referenced in the design documents
- Submittal documentation
- Product related documentation
- Applicable technical and QA requirements for the item being procured
- Problem reporting
- Administrative documentation
- Personnel qualification
- Materials qualifications
- Performance expectations for services
- Safety requirements
- Clause prohibiting delivery of S/CI
- Tests, inspections, and reviews.

The procurement process incorporates the necessary checks and balances among the requester, approver, and procurement representative to ensure the following:

- Procurement transactions are accurate, complete, and clearly describe the item or service.
- Associated technical, quality, and safety requirements are included.
- The quality system elements for which the supplier is responsible are included.
- Verification procedures to ensure compliance with the requester's requirements.
- Client satisfaction is achieved.

The PM ensures that receipt inspection and/or testing are conducted in compliance with Section 8 of this QAP and *Item and Equipment Control* (DOE/ABQ-WI-005) to ensure that items perform as specified. The PM also ensures that services are accepted by technical verification of the data produced, surveillance of the activity, or review of objective evidence for conformance to procurement document requirements. The PM ensures that procurement records are maintained in accordance with *Records Management* (DOE/ABQ-WI-001).

The PM manages any procurement nonconformance's as described in Section 3 of this QAP. The PM determines and approves the appropriate disposition, taking into consideration the technical or material requirements specified on procurement documents.

7.2 EVALUATION AND SELECTION OF SUPPLIERS

When components or services are subcontracted, WESTON retains responsibility for the successful completion of the overall project. All potential subcontractors must demonstrate the ability to successfully perform the proposed SOW, must possess the financial capability and capacity to perform, and must exhibit a proven track record for safety in the field. WESTON evaluates the capabilities and capacity of subcontractors to provide required services and deliverables that comply with specified criteria and project quality requirements. This evaluation is conducted prior to award of the contract and as needed through the duration of the project.

The PM selects suppliers following the guidelines of the *Procurement Procedures Manual* (OP 04-05-001), Procurement Planning Tool (PPT), and WESTON's SubTrack on-line system, and must include the WESTON contracts/financial organization in performing cost analyses and the contracts/legal department in the contract review process. The PPT identifies high risk work elements of a project that are intended to be subcontracted and requires risk mitigation plans to be developed. This tool also provides guidance on developing Requests for Proposal (RFPs) to ensure that consistent, comprehensive proposal responses are received from subcontractors. SubTrack is a database of subcontractors and suppliers from whom WESTON has obtained due diligence information and conducted an evaluation and established a qualification rating based on that information. This tool also has a performance evaluation module to capture and share feedback on subcontractors' specific project performance with WESTON.

Procurement personnel ensure that suppliers have been evaluated to verify their capability to meet safety, performance, and schedule requirements. The evaluation provides adequate confidence that the item or service will meet requirements and may be conducted through one or a combination of the following:

- Quality program assessment(s) at the supplier's facility
- A review of the supplier's history for providing identical or similar items or services
- A review of shared supplier quality information
- An evaluation of certifications or registrations awarded by nationally accredited third parties
- An evaluation of documented qualitative and quantitative information provided by the supplier.

WESTON contract and procurement personnel ensure that applicable requirements flow down in subcontracts and purchase orders. Where applicable and following the graded approach, procurement documents may require suppliers to provide a copy of their QA program and/or certificates of conformance. Procurement personnel ensure that suppliers and purchase of commercial-grade materials are evaluated to prevent the procurement of S/CI. (Attachment 1 describes WESTON's S/CI prevention process.)

7.3 SUPPLIER MONITORING

At intervals consistent with the complexity and required quality of the services or deliverables, the PM or Project QA Representative assesses how effectively subcontractors control quality so that any areas requiring corrective actions can be identified and improved. This assessment ensures that the supplier continues to provide acceptable items and services. The mechanism for providing such feedback is the subcontractor evaluation process as described in Procedure 3.27 of the *Procurement Procedures Manual*. Monitoring may include surveillances, facility/process inspections, and/or review of plans, progress reports, and nonconformance's.

8. 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.

8.1 INSPECTION AND TESTING

WESTON personnel conduct inspection and acceptance testing as described in *Item and Equipment Control* (DOE/ABQ-WI-005) to verify that systems, materials, items, designs, and components are acceptable. The PM determines when inspection or testing is required and ensures that inspections are conducted under controlled conditions by qualified personnel or under qualified supervision.

8.1.1 Inspection

Procured items, equipment, and standards are inspected as described in the *Procurement Procedures Manual* (OP 04-05-001), *Item and Equipment Control*, and project-specific requirements. Items, equipment, and standards may be inspected by technically qualified personnel before use in project activities and/or throughout the project as recommended by the manufacturer or as determined by the PM. Inspection requirements and acceptance criteria are based upon applicable technical and safety standards. Project personnel check items prior to use to ensure that items are suitable for their intended application. A combination of direct inspection and process monitoring are performed throughout the project duration to ensure that the specified requirements for control, safety, and quality are being achieved. Personnel independent of the work being performed inspect work processes in accordance with *Assessments* (DOE/ABQ-WI-006) (See Section 10). The PM and/or Project QA Representative conduct periodic inspections to verify that project personnel have complied with instructions, procedures, plans, and drawings. Inspections that focus on health and safety are performed as described in the WSHP.

8.1.2 Testing

Examinations, measurements, and tests of items, materials, or products are performed for each project as determined by the PM. Qualified personnel conduct testing in accordance with *Item and Equipment Control*, project-specific requirements, published standards or methods, or supplier manuals. Testing requirements and acceptance criteria must be documented and based upon applicable design or technical requirements. As applicable, test results are verified, and the verification is documented.

8.1.3 Inspection and Test Records

Inspection and test records document that specified item/equipment requirements meet applicable performance or acceptance criteria. Inspection and test record content is determined by the PM or line manager. Inspection and testing results and status must be clearly defined in records associated with the items or processes to prevent inadvertent use by project personnel. Inspection and test results must be readily available to project personnel to ensure that only those systems, materials, items, and components with acceptable inspection and test results are used. Records are available at the work site during the project duration and maintained in accordance with *Records Management* (DOE/ABQ-WI-001).

8.2 EQUIPMENT CALIBRATION AND MAINTENANCE

Inspectors ensure that measuring and test equipment (M&TE) used for inspections and tests is calibrated, maintained, and controlled as described in Section 5.4 of this QAP. Project personnel check M&TE before use to ensure that it is of the proper type, range, accuracy, and that it is uniquely identified and traceable to its calibration data.

9. MANAGEMENT ASSESSMENT

Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

Management assessments are periodically conducted by CSMs, PMs, Nuclear Programs Operations Manager, and/or the Nuclear Programs Client Business Team Manager to determine performance in achieving customer requirements and expectations and mission objectives. Management assessments should identify and recognize strengths or noteworthy practices, identify improvement opportunities, and identify and resolve problems that may prevent customer requirements and expectations from being met.

Managers conduct management assessments by various techniques, such as direct observation, worker and client interviews, and performance and document reviews in accordance with *Assessments* (DOE/ABQ-WI-006), the QMM, or *Assessments: Audits, Surveillances and Peer Reviews* (OP-10-01-005). Managers gather data necessary to make effective determinations, formally report their conclusions, and take appropriate action to address identified concerns and problems. Managers do not delegate management assessments to audit groups or other personnel. Management assessment results should be used as input to WESTON's improvement process. Results from internal and external independent assessments should be used as input to the management assessment. Managers should consult the DOE guidance document *Management Assessment and Independent Assessment Guide* (DOE G 414.1-1A) when planning and performing management assessments of DOE projects.

Managers ensure follow-up on any corrective actions determined to be necessary. Quality problems identified will be managed in accordance with Section 3 of this QAP.

10. 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 independent assessment teams. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Independent assessments are performed to evaluate the performance of work processes with regard to requirements, expectations of customers, and efforts required to achieve the mission and goals of the client and WESTON. The Project QA Representative, Nuclear Programs QA Officer, or FPD QA Officer coordinates or conducts independent assessments of each project. The rigor and frequency should be based on the status, complexity, risk, and importance of the activities or processes. Assessments may be used to evaluate WESTON projects, subcontractors, or suppliers. WESTON personnel who conduct independent assessments must be technically qualified, have the necessary knowledge to accurately observe and evaluate activities being assessed, and must have no responsibility for the work or organization they are assessing. The assessment team must have sufficient authority and freedom from line management. Independent assessments may be conducted by outside organizations as requested by the client, or at the request of WESTON management.

Assessments provide a means to measure the quality of items and services, measure the adequacy of the work performed, and promote quality improvement. Methods used to conduct independent assessments may include monitoring operations, inspections, peer and technical reviews, client interviews, or a combination thereof in accordance with *Assessments* (DOE/ABQ-WI-006). Assessors should consult the DOE guidance document *Management Assessment and Independent Assessment Guide* (DOE G 414.1-1A) when planning and performing independent assessments of DOE projects.

Assessment results are documented and should include mentions of acceptable work performance; exemplary practices; opportunities for improvement; and quality problems identified. Assessors provide assessment results to the organization that was assessed and WESTON management. Managers use results of independent assessments to evaluate the performance and to identify quality improvement opportunities. Lessons learned during assessments should be communicated to the affected organization(s) and shared on the WESTON Portal site.

Quality problems identified will be managed in accordance with Section 3 of this QAP. Where corrective actions are required, the PM and Project QA Representative must verify the completion and adequacy of the corrective actions. The Project QA Representative coordinates tracking of corrective actions with the Nuclear Programs QA Officer until a resolution has been completed and verified.

Attachment 1 – Suspect/Counterfeit Item Prevention Process

Substandard materials known as suspect/counterfeit items (S/CI) may pose immediate and potential threats to the safety of DOE and contractor workers, the public, and the environment. Some manufacturers and suppliers use inferior materials and processes to make substandard items that deviate significantly from established standards and specifications. WESTON personnel prevent the use of S/CIs in project activities as required by the DOE client's S/CI prevention process and as summarized in this attachment.

The PM will ensure that project personnel are knowledgeable of S/CI requirements and, if applicable, receive training to meet the client's requirements. WESTON personnel may follow the DOE guidance document, 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*. Appendix 4 of this guidance provides examples of common S/CIs and their indicators. Additional resources, tools, safety alerts, and reports to help identify S/CIs are available on the DOE web site http://www.eh.doe.gov/sci/. The PM will coordinate with the client's S/CI coordinator to ensure proper reporting and managing of S/CI. The Nuclear Programs Operations Manager is the WESTON management point of contact for receiving S/CI information notices from the DOE Office of Environment, Safety, and Health.

A1.1 Suspect/Counterfeit Item Definition/Description

An item is suspect when visual inspection or testing indicates that it may not conform to established government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

1. defects resulting from inadequate design or production quality control;
2. damage during shipping, handling, or storage;
3. improper installation; deterioration during service;
4. degradation during removal;
5. failure resulting from aging or misapplication; or
6. other controllable causes.

S/CIs can include a broad range of items, such as:

- threaded fasteners
- electrical components: circuit breakers, current and potential transformers, fuses, resistors, switchgear, overload and protective relays, motor control centers, heaters, motor generator sets, DC power supplies, AC inverters, transmitters;
- piping components: fittings, flanges, valves and valve replacement products, couplings, plugs, spacers, nozzles, pipe supports; and
- preformed metal structures, computer components, semiconductors, elastomers (O-rings seals), spare/replacement kits from suppliers other than original equipment manufacturers, weld filler material, diesel generator speed governors and pumps.

S/CIs have been discovered in:

- cranes, elevators, and forklifts: critical load paths of lifting equipment;
- aircraft: engines and attachments, wings, tails, or landing gear;
- vehicles: engines, brakes, or steering mechanisms; and
- facilities: valves, compressors, and vessels used to contain radioactive fluids, high-temperature or high-pressure steam or fluids, or other hazardous material or safety systems supporting safe operation or shutdown of a facility or process.

A1.2 Use of Qualified Suppliers

WESTON personnel involve procurement and contracts personnel when initiating purchases or identifying potential suppliers. WESTON procurement and contracts personnel ensure that purchase orders and contracts identify the applicable technical and QA specifications for the item being procured and contain clauses prohibiting delivery of S/CIs (see QAP, Section 7). WESTON personnel will obtain, from available sources, up-to-date information on S/CI and associated suppliers, and maintain and disseminate the information. As needed, engineering or design personnel will be involved in procurement of items and services.

A1.3 Inspection and Acceptance

WESTON personnel inspect procured items, items currently in the inventory, or items in installed components or assemblies (QAP, Section 8). Inspection and maintenance personnel receive training in identifying and reporting S/CI. Regular equipment maintenance may require item replacement. As needed, engineering or design personnel will be consulted during inspection and testing and when replacing, maintaining, or modifying equipment. If inspection personnel identify S/CI, they notify the PM or Nuclear Programs Operations Manager who, as applicable, ensure that the client's S/CI coordinator is notified. If allowed, use of S/CI may be restricted only to those items that have been found acceptable through engineering analysis and a formal disposition process.

A1.4 Preventive Measures

In addition to the preventive measures summarized above, WESTON personnel will disseminate information regarding reported S/CIs to affected project personnel and, as needed, to the Nuclear Programs Operations Manager for further distribution. S/CI information will be shared during lessons learned and trending activities (QAP, Section 3.6). As needed to meet client- or site-specific requirements, formal S/CI training may be provided to project personnel who conduct inspections, testing, and/or maintenance.

As applicable, the PM ensures that procurement processes include engineering evaluations and disposition of S/CI installed in safety application systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact and include a schedule for replacement (if required).

A1.5 Identifying and Reporting S/CI

WESTON personnel who identify S/CI during inspection and routine maintenance will promptly inform the PM. The PM will initiate the S/CI reporting process in coordination with the Nuclear Programs Operations Manager and the client's S/CI coordinator. The PM will ensure that the S/CI is appropriately

marked, tagged, or segregated until the completion of evaluation or investigation and disposition determination.

The Nuclear Programs Operations Manager will ensure that S/CI reporting is completed in accordance with DOE O 231.1A, Change 1, *Environment, Safety, and Health Reporting*, dated 06/03/04, and DOE O 221.1, *Reporting Fraud, Waste and Abuse*, dated 03/22/01, to the following:

- the responsible DOE/NNSA line management offices
- the Office of Environment, Safety, and Health
- the Office of the Inspector General

Additionally, the PM will coordinate with the Nuclear Programs Operations Manager or client's S/CI coordinator to ensure that the DOE Inspector General is contacted before destroying or disposing of S/CI and related documentation to determine the need to retain them for criminal investigation or litigation.

Attachment 2 – Software Quality Assurance

Computer hardware and software are tested and controlled using a graded approach. The PM or site manager and Nuclear Programs QA Officer or Project QA Representative ensure that applicable software QA requirements are specified in the project QAPP.

A2.1 General Software Quality Requirements

Software QA (SQA) is applied to software used within WESTON and/or developed as a client deliverable. SQA is commensurate with potential consequences to data integrity, safety, environmental impact, and importance to the project mission. The PM ensures that software is designed, developed, tested, installed, verified, and validated in accordance with SQA procedures and/or client-specified procedures. The PM or SME ensures that technical and quality requirements are specified in procurement documentation. Software is maintained under configuration control to track different versions of software and provide access control. SQA records are maintained in accordance with *Records Management* (DOE/ABQ-WI-001). For procured software, the procurement requirements (QAP, Section 7) apply. Software QA procedures may need to meet NQA-1, Subpart 2.7 and/or QAPD requirements, for projects that include Waste Isolation Pilot Plant (WIPP) compliance certification and characterization of transuranic waste.

A2.2 Software Design

WESTON personnel will document software design requirements in procurement documentation or in a design document. The PM (or designee) reviews and approves the design requirements. The software design documentation includes, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures.

The software design is implemented and verified by competent individuals other than those who developed the original design; verification results are documented. Verification methods include any one or a combination of design reviews, alternate calculations, and tests commensurate with the complexity of the software, the degree of standardization, the similarity with previously proved software, and the importance to safety. The verifiers may be from the same group/organization that designed the software.

A2.3 Software Testing

Commercially available computational software, which includes spreadsheet and math programs should be tested and controlled for the type of problem and range of values for which the software will be used. The software application should be tested on the same platform and operating system that will be used for the actual computation. WESTON tests software to demonstrate the acceptability of the software against approved requirements and to verify the software functionality. Tests on developed software will be specified in a Software Testing Plan and should evaluate whether the software:

- adequately and correctly performs all intended functions
- properly handles abnormal conditions and events and credible failures
- does not perform adverse unintended functions
- does not degrade the system

A2.4 Software Configuration Management

Software configuration controls are performed throughout the software life cycle to ensure the following:

- software is uniquely identified and labeled
- changes to software are documented, justified, approved, verified, and/or tested
- software status is maintained current

The PM or Project QA Representative communicates software configuration controls to project personnel.

A2.5 Safety Software Quality Requirements

Safety software quality requirements are necessary to ensure that DOE/National Nuclear Security Administration (NNSA) safety software in nuclear facilities performs its intended specific safety functions in relation to structures, systems, or components (SSCs) and that the classification, design, and analysis associated with nuclear facility operations is correct. These requirements complement those of 10 CFR Part 830 and provide detail for work associated with safety software that is conducted under the nuclear facility QAP compliant with 10 CFR Part 830. For work that WESTON may perform that involves safety software, the PM and Project QA Representative will implement the client's SQA process or develop a project-specific process to ensure that SQA requirements are addressed.

Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements.

1. Facility design authority involvement in identifying software specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement.

2. Identify, document, and maintain safety software inventory.

3. Establish, approve, and document grading levels for safety software.

4. Using the established and approved grading levels, select and implement applicable SQA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2000, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. The PM will consult DOE G 414.1-4, *Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements* for implementation strategies and appropriate standards for these work activities.

    - Software project management and quality planning
    - Software risk management
    - Software configuration management
    - Procurement and supplier management
    - Software requirements identification and management
    - Software design and implementation
    - Software safety
    - Verification and validation
    - Problem reporting and corrective action
    - Personnel training in the design, development, use, and evaluation of safety software

Procedures or WIs may be developed to address project-specific software requirements, at the discretion of the PM and/or Nuclear Programs Operations Manager.

Attachment 3 – References

American Society of Mechanical Engineers (ASME), NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*

DOE O 414.1C, *Quality Assurance*, including the Attachment 2 Contractor Requirements Document

DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide*, 5-31-01

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*

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*, 11-03-04

DOE G 414.1-4, *Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, 6-17-05

DOE, DOE P 450.4, *Safety Management System Policy*, 10-15-96

DOE, DOE P 450.5, *Line Environment, Safety and Health Oversight*, 06-26-97

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

DOE, DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Document*, (for the Waste Isolation Pilot Plant and related activities) (QAPD)

EPA, *Uniform Federal Policy for Implementing Environmental Quality Systems*, March 2005

National Nuclear Security Administration (NNSA) *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities)

Title 10 Code of Federal Regulations (CFR) Part 830, Subpart A, *Quality Assurance Requirements*

Title 10 CFR Part 851, *Worker Safety and Health Program*

Title 48 CFR 25.1101 and 48 CFR 52.225, *Buy American Act and Federal Acquisition Regulation*

WESTON, *10 CFR 851 Worker Safety and Health Program*, (DOE/ABQ-Prog-002), Current Revision

WESTON, *Assessments* (DOE/ABQ-WI-006), Current Revision

WESTON, *Corporate Environmental Health and Safety Program with Integrated Compliance Plan*, Current Revision

WESTON, *Corporate Quality Assurance Process Description*, Current Revision

WESTON, *Document Preparation, Review, and Control* (DOE/ABQ-WI-004), Current Revision

WESTON, *Engineering Design Quality Assurance Management Plan* (SP 15-06-003), Current Revision

WESTON, *Item and Equipment Control* (DOE/ABQ-WI-005), Current Revision

WESTON, *Procurement Procedures Manual* (OP 04-05-001), Current Revision

WESTON, *Project Training Record* (DOE/ABQ-WI-002), Current Revision

WESTON, *Quality Improvement* (DOE/ABQ-WI-003), Current Revision

WESTON, *Quality Management Manual,* Current Revision

WESTON, *Records Management* (DOE/ABQ-WI-001), Current Revision

WESTON, *Records Management Procedure* (OP 04-17-001), Current Revision

WESTON, *Safety Officer Manual,* Current Revision

WESTON, *Technical Publications Manual* (OP 09-09-003)

Attachment 4 – Definitions

For the purposes of this QAP and WESTON DOE Projects, the following definitions apply.

Acceptance Testing: The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment. (ASME NQA-1-2000)

Administrative Controls: The provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. (10 CFR 830)

Assessment: A review, evaluation, inspection, test, check, surveillance, or audit performed to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Configuration Management: The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. (ASME NQA-1-2000)

Corrective Action: Action taken to eliminate the root cause(s) and symptom(s) of an existing deviation or nonconformity to prevent recurrence.

Design/Technical Review: A documented verification process that ensures that the reviewed material (e.g., report, plan, work assessment, data, analysis assessment, evaluation) is technically adequate to satisfy applicable requirements. The design review determines if a proposed design will meet the established design criteria and perform as expected when implemented.

Engineer of Record: The professional engineer that develops the criteria and concept for the project, performs the analysis, and is responsible for the preparation of the plans and specifications.

Finding: A conclusion of importance based upon observation(s).

Graded Approach: The process of ensuring that the level of analyses, documentation, and actions used to comply with requirements are commensurate with (10 CFR 830):

1. The relative importance to safety, safeguards, and security
2. The magnitude of any hazard involved
3. The life-cycle stage of a facility or item
4. The programmatic mission of a facility
5. The particular characteristics of a facility or item
6. The relative importance to radiological and non-radiological hazards, and
7. Any other relevant factors.

Hazard Controls: Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment including (10 CFR 830):

1. Physical design, structural, and engineering features
2. Safety structures, systems; and components
3. Safety management programs
4. Technical safety requirements

5. Other controls necessary to provide adequate protection from hazards.

Inspection: The examination and/or observation of activities and/or items to determine whether they meet acceptance criteria and performance objectives defined in requirements, contracts, procedures, specifications, drawings, or checklists.

ISM Core Functions for Integrated Safety Management: Five core safety management functions that provide the necessary structure for any work activity that could potentially affect the public, the workers, and the environment. The functions are applied as a continuous cycle with the degree of rigor appropriate to address the type of work activity and the hazards involved.

Define the Scope of Work. Missions are translated into work, expectations are set, tasks are identified and prioritized, and resources are allocated.

Analyze the Hazards. Hazards associated with the work are identified, analyzed and categorized.

Develop and Implement Hazard Controls. Applicable standards and requirements are identified and agreed-upon, controls to prevent/mitigate hazards are identified, the safety envelope is established, and controls are implemented.

Perform Work within Controls. Readiness is confirmed and work is performed safely.

Provide Feedback and Continuous Improvement. Feedback information on the adequacy of controls is gathered , opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.

ISM Guiding Principles for Integrated Safety Management: The guiding principles are the fundamental policies that guide DOE and contractor actions, from development of safety directives to performance of work.

Line Management Responsibility for Safety. Line management is directly responsible for the protection of the public, the workers, and the environment. As a complement to line management, the Department's Office of Environment, Safety and Health provides safety policy, enforcement, and independent oversight functions.

Clear Roles and Responsibilities. Clear and unambiguous lines of authority and responsibility for ensuring safety shall be established and maintained at all organizational levels within the Department and its contractors.

Competence Commensurate with Responsibilities. Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.

Balanced Priorities. Resources shall be effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment shall be a priority whenever activities are planned and performed.

Identification of Safety Standards and Requirements. Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.

Hazard Controls Tailored to Work Being Performed. Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards.

Operations Authorization. The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon.

Item: An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems. (10 CFR 830)

Management: Individuals directly responsible for day-to-day operations who are accountable for planning, implementing, and assessing work. Senior management refers to managers responsible for mission accomplishment and overall operations, not day-to-day operations.

Nuclear Facility: A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by 10 CFR 830. (10 CFR 830)

Process: A series of actions that achieves an end result. (10 CFR 830)

Professional Engineer: (1) An engineer who has fulfilled education and experience requirements and passed rigorous exams that, under state licensure laws, permit them to offer engineering services directly to the public. (2) Any person who by reason of his/her knowledge of mathematics, the physical sciences, and the principles of engineering, acquired by professional engineering and holds a current certificate of registration.

Quality: The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. (10 CFR 830)

Quality Assurance: Actions that provide confidence that quality is achieved. (10 CFR 830)

Quality Assurance Program: 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. (10 CFR 830)

Quality Problem: A collective term that may be a deficiency in an activity, product, service, item characteristic, or process parameter; a noncompliance with a legal, contractual or other requirement; or the existence of a substandard condition or a S/CI. (Also referred to as condition adverse to quality.)

Record: Documentation of results of work that provides objective evidence of an item or process. Records may include documentation, photographs, drawings, or notebooks and may be maintained as hard copies or on other recording media.

Responsible Charge: Direct control and supervision of engineering work. Responsible charge of engineering means that degree of control an engineer is required to maintain over engineering decisions made personally or by others over whom the engineer exercises supervisory direction and control authority.

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

Safety Management Program: A program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment. (10 CFR 830)

Safety Software: Includes the following.

1. Safety System Software: Software for a nuclear facility that performs a safety function as part of a structure, system, or component (SSC) and is cited in either a DOE approved documented safety analysis or an approved hazard analysis per DOE P 450.4, *Safety Management System Policy*, dated 10-15-96 and the DEAR clause.
2. Safety and Hazard Analysis Software and Design Software: Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.
3. Safety Management and Administrative Controls Software: Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause.

Service: Work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation or the like. (10 CFR 830)

Software: Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. (NQA-1-2000)

Surveillance: Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Suspect/Counterfeit Items (S/CI): An item is suspect when visual inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

1. Defects resulting from inadequate design or production quality control
2. Damage during shipping, handling, or storage
3. Improper installation
4. Deterioration during service
5. Degradation during removal
6. Failure resulting from aging or misapplication

7. Other controllable causes.

Technical Safety Requirements: The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. (10 CFR 830)

Testing: Determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Verification and Validation: The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements. (IEEE Std-610.12-1990)

Work: A defined task or activity such as research and development, operations, environmental remediation, maintenance and repair, administration, safety software development/validation/testing and use, inspection, safeguards and security, data collection and analysis.

Attachment 5 – Quality Assurance Requirements Matrix

DOE O 414.1C QA Element and Weston's QA Program	NQA-1[a] Basic and Supp. Requirements	10 CFR §830.120 Criteria	EPA QA/R-2	ANSI/ASQC E4
Management				
1. Program	1 and 1S-1 Organization 2 QA Program	1. Program	3.2 Management and Organization 3.3 Quality System Components 3.8 Planning 3.9 Implementation of Work Processes	2.1 Management and Organization 2.2 Quality System and Description 2.7 Planning
2. Personnel Training and Qualification	2S-1 through 2S-4 Qualification of Personnel; Indoctrination and Training	2. Personnel Training and Qualification	3.4 Personnel Qualification and Training	2.2 Personnel Qualification and Training
3. Quality Improvement	15 and 15S-1 Nonconforming Items 16 Corrective Action	3. Quality Improvement	3.11 Quality Improvement	2.10 Quality Improvement
4. Documents and Records	6 and 6S-1 Document Control 17 and 17S-1 QA Records	4. Documents and Records	3.6 Documents and Records 3.9 Implementation of Work Processes	2.5 Documents and Records
Performance				
5. Work Processes	9 and 9S-1 Control of Processes	5. Work Processes	3.8 Planning 3.9 Implementation of Work Processes	2.8 Implementation of Work Processes
6. Design	3 and 3S-1 Design Control	6. Design	3.8 Planning 3.7 Computer Hardware and Software	
7. Procurement	4 and 4S-1 Procurement Document Control 7 and 7S-1 Control of Purchased Items and Services	7. Procurement	3.5 Procurement of Items and Services	2.4 Procurement of Items and Services

DOE O 414.1C QA Element and Weston's QA Program	NQA-1[a] Basic and Supp. Requirements	10 CFR §830.120 Criteria	EPA QA/R-2	ANSI/ASQC E4
8. Inspection and Acceptance Testing	10 and 10S-1 Inspection 11 and 11S-1 Test Control 14 Inspection, Test and Operating Status	8. Inspection and Acceptance Testing	3.5 Procurement of Items and Services	2.4.2 Procurement of Items and Services -- Guidelines
Assessment				
9. Management Assessment	18 and 18S-1 Audits	9. Management Assessment	3.10 Assessment and Response	2.9 Assessment and Response
10. Independent Assessment	18 and 18S-1 Audits	10. Independent Assessment	3.10 Assessment and Response	2.9 Assessment and Response
Additional Requirements				
Safety Software Quality Requirements (Section 8.3 of QAP)	11S-2 Supplementary Requirements for Computer Program Testing	Not specifically required	3.7 Computer Hardware and Software	2.6 Computer Hardware and Software
Suspect/Counterfeit Items Prevention, Attachment 2, 2.a(1) of DOE O 414.1C Attachment 1 of QAP		Not specifically required	Not required	N/A

[a]Although NQA-1 is addressed in this QAP, as applicable to project requirements, the project-specific Quality Assurance Project Plan will describe implementation of the applicable NQA-1 requirements.

Attachment 6 – Integrated Safety Management/Quality Assurance Program Matrix

Integrated Safety Management System Guiding Principle/Core Function	Quality Element	Management Criterion 1 – Program	Management Criterion 2 – Personnel Training and Qualification	Management Criterion 3 – Quality Improvement	Management Criterion 4 – Documents and Records	Performance Criterion 5 – Work Processes	Performance Criterion 6 – Design	Performance Criterion 7 – Procurement	Performance Criterion 8 – Inspection and Acceptance Testing	Assessment Criterion 9 – Management Assessment	Assessment Criterion 10 – Independent Assessment	Supplemental Criteria – Suspect/Counterfeit Items	Supplemental Criteria – Safety Software	10 CFR 851 Worker Safety and Health Program
Guiding Principle *														
Line Management Responsibility for Safety		✓	✓			✓	✓					✓	✓	✓
Clear Roles and Responsibilities		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓
Competence Commensurate with Responsibilities		✓	✓		✓	✓	✓		✓	✓	✓		✓	✓
Balanced Priorities		✓				✓				✓			✓	✓
Identification of Safety Standards and Requirements					✓	✓	✓	✓	✓		✓	✓	✓	✓
Hazard Controls Tailored to Work Being Performed			✓		✓	✓	✓						✓	✓
Operations Authorization		✓				✓	✓				✓			✓
Core Function *														
Define the Scope of Work		✓			✓	✓	✓	✓		✓	✓			✓
Analyze the Hazards		✓			✓	✓	✓						✓	✓
Develop and Implement Hazard Controls						✓	✓						✓	✓
Perform Work within Controls		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Provide Feedback and Continuous Improvement		✓	✓	✓		✓	✓	✓		✓	✓		✓	✓

*Guiding Principles and Core Functions defined in Attachment 4 of QAP.