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History Sheet

Rev	Date	Reason for revision	Revised by
2c	TBD	Updated front matter to move the Project Director's Policy Statement to be a section separate from the Front Matter. Also to incorporate reference to the commercial grade dedication processes assigned to the Materials Management organization and reflect this and other changes to document. Updated Policy Q-01.1 to specify the responsibility of the Manager of Quality and Performance Assurance in reviewing and concurring with project documents and to update to current organization title of "Information Systems & Technology - Chief Information Officer". Updated and restructured Policy Q-03.1 to incorporate reference to the commercial grade dedication processes assigned to the Materials Management organization. Revised Appendix C, Glossary, definition of "adverse condition" and added definition of "finding" as committed to in 24590-WTP-PIER-MGT-08-769 resulting from report EM-PA-08-0015.	D. B. Fugitt
2b	04/15/08	Updated requirements citations pertinent to Commercial Grade Dedication in the Front Matter, Policies Q-03.1, *Design Control*, and Q-07.1, *Control of Purchased Items and Services*, and Glossary. Revised Appendix A, Policy Q-02.6, *Qualification and Certification of Inspection and Test, including NDE Personnel*, Sections A2.6.5.2.1, A2.6.5.3.1, and A2.6.5.4.1, to conform with QARD, Section 2.2.11.B and the intent that by incorporation in the QARD, the guidance referenced becomes a requirement. 24590-WTP-CRPT-QA-08-102. Updated Revision Status Sheet and Contents and listed of the Appendix A policies. Corrected references to DOE Guide 414.1-2A, Appendix A throughout Added reference to the *WTP Graded Approach to Quality* document number in Front Matter. Obtained new signature on Policy Statement in Front Matter. Updated to current title for the Assistant Project Director: Quality and Safety Assurance/Technology and Plant Operations, and Assistant Project Director, Business Services throughout. Conformed use of BSII Manager of Quality Assurance and BSII Manager of Environmental, Safety and Health throughout. Corrected Figure 1 to include DOE Order 226.1A. Corrected numbering sequence in Policy Q-05.1. Corrected miscellaneous typographical errors in Policy Q-16.1 and Appendix A. Added Appendix F to incorporate software quality requirements of Policy Q-03.2 of 24590-WTP-QAM-QA-01-001, Rev 7b, for the duration of Implementation Plan, 24590-WTP-PL-IT-08-0001, which is necessary to implement NQA-1-2000, Subpart 2.7.	D. B. Fugitt

History Sheet

Rev	Date	Reason for revision	Revised by
		Added references to Appendix F in Front Matter, Policy Q-03.2, Appendix A Policy Q-03.2, and Appendix E.	
2a	02/04/2008	Issue for use. This supercedes 24590-WTP-QAM-QA-01-001, *Quality Assurance Manual*, Rev. 7C. Changed the *Quality Assurance Program Description* and Policy Q-01.1, *Organization*, to reflect organizational changes and reporting relationships. Changed Policy Q-07.1, *Control of Purchased Items and Services*, to clarify the commercial grade items/services process. These changes continue to satisfy the WTP contract quality assurance requirements and do not adversely affect safety or represent a reduction from regulatory commitments.	D. B. Fugitt
2	10/11/2007	Complete rewrite of the Quality Assurance Program Description to incorporate DOE/ORP comments. Complete rewrite of Policies Q-02.2, *Management Assessment*, Q-16.1, *Corrective Action,* and Q-18.1, *Independent Assessment (Audit)* to incorporate DOE O 226.1A requirements. Change Policy Q-01.1, *Organization* to meet the new organizational changes. Changed Policy Q-02.1, *Quality Assurance Program,* Policy Q-02.4, *Personnel Training and Qualification*, Policy Q-02.5, *Qualification and Certification of Auditors*, Policy Q-04.1, *Procurement Document Control*, Policy Q-05.1, *Instructions, Procedures, and Drawings,* and Appendix C, *Glossary* to incorporate DOE O 226.1A requirements. Changed Policies Q-07.1, *Control of Purchased Items and Services,* Appendix A, Q-07.1, *Control of Purchased Items and Services* and Appendix C, *Glossary* to incorporate 24590-WTP-SE-ENS-06-0179 changes to the *Safety Requirements Document*. Issue for DOE approval only, upon DOE approval this manual will be revised for implementation. These changes continue to satisfy the WTP contract quality assurance requirements and do not adversely affect safety or represent a reduction from regulatory commitments.	P. Talmage
1	9/7/2007	Revised to incorporate DOE/ORP comments in the Quality Assurance Manual policies with tracked changes. Complete rewrite of the Front Matter and changed the Foreword title to Quality Assurance Program Description. Title and revision change on each page. Issue for DOE approval only, upon approval this manual will be revised for implementation.	P. Talmage
0	2/15/2007	Issue for DOE approval only, upon approval this manual will be revised for implementation.	P. Talmage

Revision Status Sheet

Document Part	Title	Revision	Pages w/Tracked Revisions
Front Matter	Quality Assurance Program Description	2c	i, ii, iv, v, vi, viii, xv, xvi
Policy Statement	Project Director's Policy Statement	2c	Policy-1
Policy Q-01.1	Project Organization	2c	01.1-6, 01.1-7
Policy Q-02.1	Quality Assurance Program	2a	
Policy Q-02.2	Management Assessment	2a	
Policy Q-02.3	Quality Assurance Surveillance	2b	02.3-1
Policy Q-02.4	Personnel Training and Qualification	2a	
Policy Q-02.5	Qualification and Certification of Auditors	2a	
Policy Q-02.6	Qualification and Certification of Inspection and Test, including NDE, Personnel	2a	
Policy Q-03.1	Design Control	2c	03.1-3
Policy Q-03.2	Software Quality	2b	03.2-1,03.2-2
Policy Q-04.1	Procurement Document Control	2a	
Policy Q-05.1	Instructions, Procedures, and Drawings	2b	05.1-2
Policy Q-06.1	Document Control	2a	
Policy Q-07.1	Control of Purchased Items and Services	2b	07.1-1,07.1-2,07.1-6 through 07.1-11
Policy Q-08.1	Identification and Control of Items	2a	
Policy Q-09.1	Control of Special Processes	2a	
Policy Q-10.1	Inspection	2a	
Policy Q-11.1	Test Control	2a	
Policy Q-12.1	Control of Measuring and Test Equipment	2a	
Policy Q-13.1	Handling, Storage, and Shipping	2a	
Policy Q-14.1	Inspection, Test and Operating Status	2a	
Policy Q-15.1	Control of Nonconforming Items	2a	
Policy Q-15.2	Control of Suspect/Counterfeit Items	2a	
Policy Q-16.1	Corrective Action	2b	16.1-1
Policy Q-17.1	Quality Assurance Records	2a	
Policy Q-18.1	Audit (Independent Assessment)	2a	
Appendix A			
Policy Q-01.1	Immobilized High Level Waste (IHLW) Addenda	2b	A01.1-1, A01.1-2
Policy Q-02.4	Personnel Training and Qualification	2a	
Policy Q-02.5	Qualification and Certification of Auditors	2b	A02.5-2
Policy Q-02.6	Qualification and Certification of Inspection and Test, including NDE, Personnel	2b	A02.6-2 through A02.6-4
Policy Q-02.7	Special Reviews	2a	
Policy Q-03.1	Design Control	2b	A03.1-2 through A03.1-4
Policy Q-03.2	Software Quality	2b	A03.2-3 through A03.2-5
Policy Q-04.1	Procurement Document Control	2a	

Revision Status Sheet

Document Part	Title	Revision	Pages w/Tracked Revisions
Policy Q-05.1	Instructions, Procedures, and Drawings	2a	
Policy Q-06.1	Document Control	2b	A06.1-2, A06.1-3
Policy Q-07.1	Control of Purchased Items and Services	2b	A07.1-2 through A07.1-6
Policy Q-08.1	Identification and Control of Items	2a	
Policy Q-09.1	Control of Special Processes	2a	
Policy Q-10.1	Inspection	2b	A10.1-2
Policy Q-11.1	Test Control	2b	A11.1-2, A11.1-3
Policy Q-12.1	Control of Measuring and Test Equipment	2b	A12.1-2, A12.1-3
Policy Q-15.1	Control of Nonconforming Items	2b	A15.1-2
Policy Q-17.1	Quality Assurance Records	2b	A17.1-2 through A17.1-4
Policy Q-18.1	Audit (Independent Assessment)	2b	A18.1-2, A18.1-3
Supplement II	Sample Control	2b	AS II-1
Supplement V	Control of the Electronic Management of Information	2a	
Appendix B	Acronyms and Abbreviations	2a	
Appendix C	Glossary	2c	C-1, C-3
Appendix D	Quality Assurance Criteria and Integrated Safety Management System Crosswalk (10-CFR-830.121 (c)(2))	2a	
Appendix E	Supplement to Policy Q-03.2, Software Quality	2b	E-1 through E-13
Appendix F	Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2	2b	All

Contents

Appendices

Quality Assurance Program Description

This Quality Assurance Program Description describes the quality assurance program using the structure of the following quality assurance process areas and associated criteria:

- Management Processes
- Performance Processes
- Assessment Processes

Management process requirements are applied throughout the performance processes and assessment processes as appropriate to the type of work being accomplished. Performance process requirements specify the quality assurance controls for conducting the supporting work, design, procurement and inspection and test activities. The performance process requirements are applied to items and services. Assessment process requirements provide the oversight processes utilized in the monitoring of all quality process activities. The assessment process requirements include management assessment, audit, and surveillance. The assessment processes assure that the WTP, subcontractors, and suppliers comply with the quality assurance requirements. (10 CFR 830.121(4)(c)(4); DOE G 414.1-2A, Appendix A, Section 4.1)

The Project Director demonstrates quality leadership through the endorsement and expectation of compliance to the quality assurance program in the Quality Assurance Manual policy statement. The Project Director has designated the Manager of Quality and Performance Assurance as the senior management position responsible for the development and maintenance of the Quality Assurance Manual, which provides the quality commitments stated below and any additional quality standards as necessary to address unique/specific work activities including best management practices. (DOE G 414.1-2A, Appendix A, Section 4.1)

The WTP quality assurance program has been established to plan, implement, and maintain the policies governing the activities performed within the scope of designing, constructing, and commissioning for Bechtel National, Inc. (BNI) at the Hanford Tank Waste Treatment and Immobilization Plant (WTP). (NQA-1-2000, RQMT 2, 100(a))

The requirements of the quality assurance program apply to activities that could affect the quality of structures, systems, and components. Activities affecting quality include training, siting, designing, procuring, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, and decommissioning. This includes items or services that affect, or may affect, nuclear safety of DOE nuclear facilities and other activities based on a graded approach as defined in 24590-WTP-PD-MGT-0001, *WTP Graded Approach to Quality*, and implementing procedures. (NQA-1-2000, Introduction, 200, RQMT 2, 100(a), 10 CFR 830.120, 3, 7)

Quality assurance and quality control are applied throughout all phases and to all activities associated with the WTP as part of a comprehensive system, utilizing a graded approach, to ensure with high confidence that all items delivered and services and tasks performed meet required standards. (DOE/RL-96-0006, Revision 3)

The quality assurance program is:

- Structured to emphasize a safety/quality culture that embraces excellence in all WTP personnel actions and interactions and all WTP activities. (DOE/RL-96-0006, Revision 3)

- Planned, implemented, and maintained in accordance with quality requirements that are derived from 10 CFR 830.122 and DOE O 414.1C criteria and implemented using the NQA-1 standard. (NQA-1-2000, RQMT 2, 100(a))

The quality assurance program is the management system that implements the requirements of the U.S. Department of Energy (DOE) Order 414.1C, *Quality Assurance* and the U.S. Code of Regulations, 10-CFR-830, Subpart A, *Quality Assurance Requirements* for managing, performing, and assessing the adequacy of work. (DE-AC27-01RV14136)

This Quality Assurance Program Description encompasses:

- How the quality assurance criteria of 10 CFR 830.122 are satisfied.
- How the quality assurance criteria are integrated with the Safety Management System.
- How BNI uses voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identifies the standards used.
- How BNI ensures that subcontractors and suppliers satisfy the criteria of 10 CFR 830.122. (10 CFR 830.121, (c))

The Quality Assurance policies meet the contractual requirements specified in the following sources:

1 U.S. Code of Federal Regulations (CFR) 10 CFR 830, Subpart A, *Quality Assurance Requirements*. (10 CFR 830.121, (a))

2 U.S. Department of Energy Order 414.1C, Quality Assurance. (DE-AC27-01RV14136)

3 American National Standard, ASME NQA-1-2000, Part I and Subpart 2.7, *Quality Assurance Program Requirements for Nuclear Facility Applications*. (DOE O 414.1C, Attachment 2, 2(a)(2)(a))

4 Office of Civilian Radioactive Waste Management (OCRWM), DOE/RW-0333P (Rev. 18), *Quality Assurance Requirements and Description* (QARD). (DOE O 414.1C, Attachment 2, 2(a)(4)(d))

Additional standards may be applied where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory). These standards are adopted through regulation, code, contract, quality assurance program, or procedure and when adopted, compliance with the standard is required. (DOE O 414.1C, Attachment 2, 2(a)(3); 10 CFR 830.121, (c)(3))

The Quality Assurance Manual integrates, where practicable and consistent with contract or regulatory requirements, quality management program requirements as defined in DOE O 414.1C with other quality or management system requirements in DOE directives and external requirements, including, as applicable:

(a) DOE P 450.4, *Safety Management System Policy,* dated 10-15-96.

(d) DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*. (DOE O 414.1C, Attachment 2, 2(a)(4); 10 CFR 830.121, (c)(2))
The requirements of DOE O 226.1A are integrated with this manual, the *WTP Assurance Program Description*, and implementing procedures. The requirements of DOE O 470.2B are implemented through the WTP Quality and Performance Assurance External Interface organization and implementing procedures.

When identified, DOE directives or site-specific requirements that conflict, are unclear, or are incomplete shall be brought to the attention of the WTP Contracting organization. (DOE O 226.1A, Attachment 1, 2(i))

The implementation of this Quality Assurance Manual applies to future WTP activities, as of the effective date of this Quality Assurance Manual. The implementation of this new Quality Assurance Manual does not require retrofit of existing items procured or processes and activities conducted under the prior Quality Assurance Manual. (Management Requirement)

Other technical commitments (e.g., ISA-S84 for safety instrumentation software, ISO 10007 and ANSI/EIA-649 for Configuration Management, ASME Section VIII for vessels) are identified in various Authorization Basis documents, incorporated in the Basis of Design or other documents and plans, and implemented through procedures, and/or specifications, as applicable.

The program complies with applicable laws, regulations, permits, licenses, other regulatory authorizations and approvals. Changes to commitments are accomplished in accordance with regulatory requirements. (DE-AC27-01RV14136)

The following non-mandatory guidance was considered during the development of this Quality Assurance Manual:

- DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide*
- DOE G 414.1-2A, *Quality Assurance Management System Guide*
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide*
- DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and DOE O 414.1C, *Quality Assurance*
- DOE G 414.1-5, *Corrective Action Program Guide*
- ASME NQA 1 2000, Part III, Subpart 3.1
- ASME NQA 1 2004, Part IV, Subpart 4.5 (DOE O 414.1C, Attachment 2, 2(c))

Maintenance elements of this manual include:

- BNI submits this Quality Assurance Manual (QAM) to DOE for approval. The manual is considered approved 90 days after submittal, unless it has been formally approved or rejected by DOE at an earlier date. Upon formal DOE direction, this manual may be modified as necessary.
- Changes to the Quality Assurance Manual are incorporated in alpha revisions. The alpha changes are incorporated into a numeric revision which is submitted to DOE annually for approval. The submittal provides justification for the changes to ensure the manual continues to satisfy the quality assurance requirements.

BNI conducts work in accordance with this manual and where appropriate, uses a graded approach to implement the requirements of this manual. (10 CFR 830.121(b), 10 CFR 830.7)

This manual also applies to Immobilized High Level Waste (IHLW) items and activities that are considered Waste Acceptance Impacting and are subject to additional requirements (e.g., QARD, Revision 18, and NQA-1-1983, in part) identified in Appendix A, *Immobilized High Level Waste Addenda* (based on items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*). (NQA-1-2000, RQMT 2, 100(a); DE-AC27-01RV14136)

The QARD requirements, when equivalent to the NQA-1-2000 requirements, are cited in the main body of the manual. When the QARD requirements are more stringent or diverge from the intent of consensus standards they are cited in Appendix A of the Quality Assurance Manual.

Requirements sources are cited within this manual as an aid in confirming compliance. Non-mandatory guidance sources are cited within this manual as an implementation aid. Management requirements are requirements imposed by BNI/WTP.

1.1 Management Process (DOE O 414.1C, Attachment 2, 3(a))

The management process requirements serve to establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The management process requirements are designed to provide a robust quality program that identifies and implements solutions to problems, provides a training program that ensures personnel are trained and qualified, provide programs that promote quality improvement, and provide a document and records program to ensure appropriate control and maintenance of documents and records.

Management process criteria are applied throughout the performance and assessment processes. The management process requirements of Policy Q-05.1, *Instructions, Procedures, and Drawings* are applied to all quality assurance criteria.

1.1.1 Quality Program (DOE O 414.1C, Attachment 2, 3(a); DOE G 414.1-2A, Appendix A, Section 4.1, 4.5)

The Quality Assurance Manual describes the top level organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing work. Implementing procedures provide additional detail. The senior management quality expectations are defined in the Policy Statement and in Policy Q-01.1, *Organization*. The requirements for implementing safety and quality integration are addressed in this description, in Policy Q-02.1, *Quality Assurance Program*, and in the *WTP Project Integrated Safety Management System Description.*

The Quality and Performance Assurance organization is responsible for the WTP Quality Assurance Manual. All WTP organizations are responsible for the implementation and effectiveness of the quality assurance program. No organizations are excluded from compliance with the quality assurance program. Quality assurance program requirements are implemented in accordance with 24590-WTP-PD-MGT-0001, *WTP Graded Approach to Quality*, and implementing procedures. Internal and external interfaces are documented as described in Policy Q-01.1, *Project Organization*. Suppliers and subcontractors may work to their own quality assurance programs, or, in some cases, work to the BNI quality assurance program and implementing procedures.

The Quality and Performance Assurance program functional responsibilities and levels of authority include:

- The Manager of Quality and Performance Assurance is accountable to the WTP Project Director for all issues and actions related to execution of the project quality assurance program as defined in the WTP Quality Assurance Manual. Execution authority for the WTP project quality assurance program flows directly from the WTP Project Director to the Manager of Quality and Performance Assurance. The Manager of Quality and Performance Assurance has direct and unlimited access to the WTP Project Director and to the BSII Manager of Quality Assurance.
- Technical and programmatic authority for both the quality assurance program and the performance assurance program flows from the BSII Manager of Quality Assurance directly to the WTP Manager of Quality and Performance Assurance. To ensure independence, salary and performance administration for the Manager of Quality and Performance Assurance and for personnel assigned to the Quality Assurance element of the Quality and Performance Assurance Organization is controlled by the BSII Manager of Quality Assurance.
- The Manager of Quality and Performance Assurance receives day to day coordination from the Assistant Project Director: Quality and Safety Assurance, Technology and Plant Operations. The Supplier Quality Manager receives day to day coordination from the WTP Acquisition Services Manager. The Field Quality Control Manager receives day to day coordination from the WTP Manager of Construction.

- The Supplier Quality Manager and the Field Quality Control Manager are accountable to the Manager of Quality and Performance Assurance for all issues and actions related to execution of the project quality assurance program as defined in the WTP Quality Assurance Manual. The Field Quality Control Manager and the Supplier Quality Manager have direct and unlimited access to the Manager of Quality and Performance Assurance and to their respective corporate program managers.
- Technical and programmatic authority for Supplier Quality and Field Quality Control flows directly from their respective corporate level organizations. To ensure independence, salary and performance administration for personnel in the Field Quality Control and the Supplier Quality organizations is controlled by their respective BSII corporate level organizations.

Descriptions of the functional responsibilities and levels of authority for the remaining organizations (e.g., engineering, construction, operations, acquisition services, etc.) are described in Policy Q-01.1, *Project Organization,* the *Project Execution Plan,* and other project documents. When more than one organization is involved in the execution of activities, the responsibilities, internal and external interfaces, and authority of each organization are clearly defined and documented in implementing documents, such as procedures and the *Project Execution Plan.*

The Business Services organization provides the human resource processes for the hiring of personnel. The Project Controls organization provides the planning, scheduling and identifying resources for the work as described in the *Earned Value Management System Description.* Resources are identified and provided for quality program activities, such as planning, scheduling, auditing, supplier qualification, technical document review, inspection, calibration, in implementing documents as described in Policy Q-01.1, *Project Organization.*

The management process requirements define the program for grading the application of requirements commensurate with safety, hazards, mission and other factors. Management process requirements ensure the requirement commitments of this manual are met.

Quality controls are applied based on the importance of the item or service, in terms of safety (hazards), mission, risk, and other considerations. The BNI graded approach is described in the *WTP Graded Approach to Quality* and other implementing documents. Implementing documents are designed to apply the graded approach in a consistent manner, ensuring the appropriate grading activities are clearly described.

1.1.2 Personnel Training and Qualification (DOE G 414.1-2A, Appendix A, Section 4.2)

The Assistant Project Director: Quality and Safety Assurance, Technology and Plant Operations is responsible for implementing and managing the WTP training program, including management of the *List of Qualified Individuals*. Management is responsible for identifying the appropriate training requirements to ensure personnel are trained, qualified, and capable of performing their assigned tasks. The WTP training program utilizes a systematic approach for positions that perform activities directly affecting installed structures, systems, and components and may apply a systematic approach to positions that indirectly affect installed structures, systems, and components to identify initial and continuing training needs and the methods for completion (e.g., classroom, required reading, read and discuss, computer-based) as described in the *WTP Graded Approach to Quality* and the *WTP Assurance Program Description*. Each individual has a training profile that documents initial and continuing training requirements and provides a status of completion. The Quality and Performance Assurance organization is responsible for the implementation and management of the training of auditors.

The personnel training and qualification program is described in:

- Policy Q-02.4, *Personnel Training and Qualification*
- Policy Q-02.5, *Qualification and Certification of Auditors*

- Policy Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel*

Personnel training and qualification includes training for project personnel, training for auditors, and training for inspection and test personnel. Managers identify the appropriate training and qualification required for their personnel, to ensure those personnel are capable of performing their work. Profiles and sometimes supplemental training plans are utilized to track the training assignments and ensure continued job proficiency. Training plans may include required resources, positions and functions, and qualification and/or certification requirements.

1.1.3 **Quality Improvement** (DOE G 414.1-2A, Appendix A, Section 4.3, 4.4, 4.5)

Quality problems are identified primarily through assessment, inspection, and internal process controls as described in the *WTP Assurance Program Description*. Quality problems are reported through the nonconformance and/or corrective action programs. Construction and/or Operations, depending on the project phase, is responsible for the nonconformance program which provides the controls for items that do not conform to specified requirements, including suspect/counterfeit items, to prevent their inadvertent installation or use. Nonconforming items are identified primarily through inspection, and are subsequently tagged and/or segregated by appropriate personnel, and evaluated and dispositioned by the responsible organization. Engineering provides disposition of nonconformances involving "Repair" or "Use-As-Is", including dispositions submitted by suppliers.

Quality problems may be in relation to items, services or processes. Solutions to quality problems and other good practices are submitted as Lessons Learned, as described in the *WTP Assurance Program Description.*

The quality improvement processes serve as a strategic approach to performance monitoring, analyzing, identifying, implementing, planning solutions, and trending as described in the *WTP Assurance Program Description*. The quality improvement processes also serve as the vehicle for the identification, analysis, disposition, and prevention, and dissemination of Suspect/Counterfeit Items (S/CIs).

The corrective action management processes provide for determination of scope and extent of adverse conditions in a graded manner that increases rigor in the identification of causes, corrective actions, and recurrence controls. In the case of significant conditions adverse to quality (a subset of conditions adverse to quality), formal root cause determination is made. Corrective action plans to prevent recurrence are based on the root cause of the deficiency and prioritized based on the significance of risk associated with the deficiency. For all adverse conditions, suitable corrective actions and target dates are identified and documented.

The quality improvement program requirements are described in:

- Policy Q-02.2, *Management Assessment*
- Policy Q-02.3, *Quality Assurance Surveillance*
- Policy Q-15.1, *Control of Nonconforming Items*
- Policy Q-15.2, *Control of Suspect/Counterfeit Items*
- Policy Q-16.1, *Corrective Action*
- Policy Q-18.1, *Audit (Independent Assessment)*

1.1.4 **Documents and Records** (DOE O 414.1C, Attachment 2, 3(d); DOE G 414.1-2A, Appendix A, Section 4.4, 4.5)

The documents and records processes are managed by the Assistant Project Director: Business Services. All organizations are responsible for ensuring the requirements regarding documents and records are properly implemented and submitted in accordance with the appropriate document control and records

procedures and as described in the *WTP Graded Approach to Quality*. Distribution is controlled through the Electronic Document Management System (EDMS) to ensure that the latest issued documents are available for use. The requirements for distribution and use are incorporated into implementing documents.

The responsible manager specifies the need for a document, the type of document to be prepared, and assigns a preparer for the document. The preparer identifies the scope, resolves any impact on other documents, and identifies the required distribution, reviews, and reviewers. The preparer distributes the document for review and ensures comments are resolved, as appropriate. Upon resolution the preparer obtains appropriate approvals and submits the document to Project Archives and Document Control (PADC).

The documents and records process requirements are specified in:

- Policy Q-05.1, *Instructions, Procedures, and Drawings*
- Policy Q-06.1, *Document Control*
- Policy Q-17.1, *Quality Assurance Records*

The documents and records policies include the requirements for documents that prescribe processes, specify requirements, or establish design (e.g., instructions, procedures, and drawings, other documents, and quality assurance records). The Quality Assurance Manual requires that procedures provide instructions for the following document control activities:

- Preparation
- Review
- Approval
- Issuance and distribution
- Revision and maintenance
- Use

These requirements ensure that the quality criteria of management, performance, and assessment processes are described in approved procedures. BNI employs additional tools such as document control, configuration management, and records management processes as necessary to ensure the control of documents. Policy Q-05.1, *Instructions, Procedures, and Drawings* provides the document requirements for:

- Prescribing internal and external (including supplier and subcontractor oversight) programs.
- Ensuring work is planned and performed consistent with regulatory, contractual, technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements.

Records provide sufficient evidence to support technical and regulatory decisions and document that the work was performed. Records include, but are not limited to procedures, plans, and manuals; training and qualification results; inspection and acceptance test results; technical/regulatory correspondence; operational records; design basis descriptions; design review results; design documents and revisions; configuration management information; and corrective action reports. Records are specified, prepared, reviewed, and approved in accordance with approved project procedures. Upon authentication, a document that has been specified as a record through implementing procedures, becomes a record and is maintained in accordance with the records process. Records are reviewed to ensure they are legible and traceable to associated items and activities. Quality Assurance records are classified as lifetime or nonpermanent to ensure the proper records are retained with their final disposition specified.

The WTP records management system provides the processes for collection, maintenance, storage, retrieval and disposition of project records. Quality Assurance records are specified in accordance with Policy Q-05.1, *Instructions, Procedures, and Drawings.* Quality Assurance records are prepared, reviewed, approved and maintained in accordance with Policy Q-06.1, *Document Control* and Policy Q-17.1, *Quality Assurance Records*. Quality Assurance records are retained in accordance with 24590-WTP-PL-PADC-03-004, *Hanford Tank Waste Treatment and Immobilization Plant Records Retention and Turnover Plan.* The WTP Records Retention and Turnover Plan is maintained in accordance with DOE O 1324.5B, *Records Management Program* and DOE Records Schedules (version in effect on effective date of Contract).

1.2 Performance Process

Performance process criteria include: supporting work processes, design, procurement, and inspection and acceptance testing. These criteria provide assurance that work is performed consistent with technical standards, administrative controls, and hazard controls adopted by BNI to meet contractual or regulatory commitments, using approved procedures.

BNI assures work is performed consistent with technical standards, administrative controls, and other hazard controls as described in implementing documents which are verified to be technically adequate, and appropriate to the hazards associated with the work.

Integrated project teams are formed to ensure successful interface management within these controls. These teams help to ensure that resources, safety, budget, and schedule are adequate to support the work activities. Additional performance processes in support of the commissioning phase are developed as required, in accordance with the project schedule.

1.2.1 Supporting Work Processes (DOE O 414.1C, Attachment 2, 3(e),(f); DOE G 414.1-2A, Appendix A, Section 4.5)

Supporting work processes are managed and controlled by the construction and operations organization, depending on the project phase. Supporting work process requirements provide the methods used to identify and control items to ensure their proper use. Supporting work process activities are accomplished in accordance with:

- Policy Q-08.1, *Identification and Control of Items*
- Policy Q-09.1, *Control of Special Processes*
- Policy Q-12.1, *Control of Measuring and Test Equipment*
- Policy Q-13.1, *Handling, Storage, and Shipping*

Materials Management is responsible for the identification, control, handling, shipping, and storage of items and materials received at the WTP as described in the *Project Execution Plan.* Materials Management is a multi-functional service, consisting of Material Services, Government Property, and staff from the Engineering, Procurement, Construction, and Operations organizations.

Material Services is responsible for activities and processes associated with procurement, including commercial grade dedication and procurement strategies. Material Services interfaces with the Quality and Performance Assurance organization for review of procurement-related documents and coordination of external commercial grade supplier surveys and audits. Material Services interfaces with Engineering and Acquisition Services for the development of procurement documents, monitoring of suppliers, and review of supplier submittals associated with commercial grade dedication activities. Material Services has the role in translating quality and technical requirements provided by Engineering into products for procurement of commercial grade dedicated items as managed by the Material Services organization.

Identification and control of items ensures that only correct items are installed and used. Items are identified, controlled, and maintained during storage. Identification of items is maintained either on the item or in documentation traceable to the item. When required by applicable codes, standards, or specifications, items are identified from initial receipt or fabrication up to and including installation or use. Procedures are established and used by workers to ensure that, when items having identification or traceability requirements are subdivided or sampled, identification is transferred to each part, container of parts, or sample, at the time of subdividing or sampling. S/CI are identified and controlled in accordance with the quality improvement processes.

Controls for handling, storing, cleaning, packaging, shipping, housekeeping, and preservation of items and consumables, are developed in accordance with design requirements to prevent damage or loss and to minimize deterioration. Controls to identify the inspection test, and operating status of items throughout fabrication, construction, installation, testing, and operations are implemented in procedures. These controls serve to ensure required inspections and tests are performed and that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. The status of inspection and test activities is identified either on the items or in documents traceable to the items. Status is maintained through indicators and the authority for the application and removal of indicators is specified.

Construction and Operations maintain the Measuring and Test Equipment (M&TE) program, including, calibrating M&TE, verifying M&TE accuracy, coordinating with Acquisition Services for the procurement of M&TE, and coordinating off-site calibration services. Receipt inspection is performed for all calibrated M&TE. The Quality and Performance Assurance organization perform audits and surveillances on the M&TE program.

M&TE is calibrated at specified periods, adjusted, and maintained to specified accuracy limits. Calibration is against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration is documented. The calibration method and interval of calibration for measuring and test equipment is defined, based on the type of equipment, stability characteristics, required accuracy, intended use, degree of use, and other conditions affecting capability. Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy. M&TE is labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification provides traceability to calibration and test data. M&TE found to be out-of-calibration or out-of-tolerance is controlled to prevent use, and procedures require review of the usage to determine if the failure affected acceptability of items or processes on which the tool was used.

Policy Q-08.1, *Identification and Control of Items*, provides the requirements for identifying and controlling items (including consumables and partially fabricated assemblies). Policy Q-09.1, *Control of Special Processes*, provides the requirements for control and performance of special processes (e.g., welding, heat treating, and nondestructive examination). Policy Q-13.1, *Handling, Storage, and Shipping*, (in conjunction with the management process requirements in Policy Q-15.2, *Control of Suspect/Counterfeit Items*) provides the requirements for maintaining items during design, procurement, test, inspection, installation, and maintenance to prevent their damage, loss, or deterioration. Policy Q-12.1, *Control of Measuring and Test Equipment* provides the requirements for the calibration and maintenance of equipment used for process monitoring and data collection.

1.2.2 Design (DOE O 414.1C, Attachment 2, 3(f); DOE G 414.1-2A, Appendix A, Section 4.6)

Design processes are managed and controlled by the Engineering organization. Engineering interfaces with the Quality and Performance Assurance organization for review of procurement documents and coordination of external supplier surveys and audits. Engineering interfaces with Acquisition Services for the development of procurement documents, monitoring of suppliers, and review of supplier submittals.

Engineering interfaces with Acquisition Services, Construction, and Operations to ensure coordination of receipt, storage, installation, and maintenance of items and materials. For the design performance process, BNI Engineering has the lead role in converting top level Authorization Basis requirements, (e.g., contract, regulatory codes, standards, orders, etc.), technical standards, administrative controls, and other hazard controls into design products for procurement, construction, and operations. This includes applying sound engineering principles to the development of design inputs that drive subsequent grading of technical, work process, and quality requirements. Design activities are accomplished in accordance with:

- Policy Q-03.1, *Design Control*
- Policy Q-03.2, *Software Quality*
- Appendix E, *Supplement to Policy Q-03.2, Software Quality*

Configuration management, as described in the *Project Execution Plan*, is a management discipline that applies technical and administrative direction over the life cycle of the WTP to identify, document, and control the configuration of structures, systems, and components.

Software requirements are specified in:

- Policy Q-03.1, *Design Control*
- Policy Q-03.2, *Software Quality*
- Appendix E, Supplement to Policy Q-03.2, Software Quality

The overall software configuration management process is managed by the Business Services organization. Engineering is responsible for the configuration management of software installed in the plant. The software process implements the requirements for software development and acquisition, including safety software used in design and analysis. The software processes for development, use, control, and oversight of software include project and quality planning, risk, configuration, procurement, supplier requirements, and design management. Other elements include verification and validation and problem reporting. Corrective action and training are in accordance with the management processes. The outputs of the software lifecycle are identified in implementing procedures and, depending on the software category and type, may include planning, requirements, design, test, installation, and change control documentation and/or records. Responsibilities vary by software type and are described in implementing procedures.

The design process consists of design development, design review, design verification, design change control, and implementation. Design development includes activities of identifying design inputs, conducting analysis and studies, controlling changes, design interface coordination (internal and external), and review of design documents. Products of the design development process include drawings, calculations, specifications, and supplier submittals.

Policy Q-03.1 provides the requirements for the design processes that include the following elements to ensure quality:

- Documentation and approval of design criteria and performance requirements.
- Analysis of hazards associated with work and implementation of controls.
- Design changes are controlled to the same level of rigor as conducted for the original design.
- Design interface information, including internally within BNI and externally with regulatory agencies, suppliers, and subcontractors is recorded in controlled documents, such as interface control documents, drawings, specifications, and procurement documents.
- The methods used for design verification including reviews, alternate calculations, and qualification testing. These reviews are performed in accordance with implementing procedures, as applicable to

the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. Design verification is performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met, such as when insufficient data exist. Design verification is performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization.

- Preventing the introduction of suspect/counterfeit items (S/CI) is accomplished, in part, through engineering involvement in the design, procurement, testing, inspection, maintenance, evaluation, and disposition of S/CI information.
- Engineering evaluates the impact of design changes for material in procurement, construction, and operations. After the design change documents have been approved, engineering coordinates with procurement, construction, and operations to identify the appropriate method to implement the change.
- Engineering is responsible for the implementing documents of the design process.

Appendix F to this Quality Assurance Manual provides requirements related to software quality other than those provided in main policies and Appendices A and E. Appendix F encompasses the requirements previously included in 24590-WTP-QAM-QA-01-001 and applies to work activities identified in 24590-WTP-PL-IT-08-0001, *IS&T Project Plan for Implementation of 24590-WTP-QAM-QA-06-001 rev 2a*, Rev 0. This plan was developed to communicate the project plan for implementation of the software quality requirements of the new 24590-WTP-QAM-QA-06-001, *Quality Assurance Manual*. The scope of this plan includes the Software Plan, Guide, Procedures, and Forms as identified in the Project Schedule (Appendix A to the plan). The plan defines five efforts:

- To perform a safety software pre-survey to determine the types and sources of safety software
- To modify the existing procedures, guides and forms to include the new QAM requirement reference and to switch to the software designations Levels D, E, or F
- To extensively modify and develop plans, procedures, guides, and forms in order to implement safety software designation Levels A, B, and C
- Modify automated systems that support procedure driven process
- Develop Training for WTP Staff who have procedural responsibility

The requirements of 24590-WTP-QAM-QA-01-001, Policies 03.1 and 03.2, and 24590-WTP-QAM-QA-06-001, will coexist for the duration of 24590-WTP-PL-IT-08-0001. The procedures subject to the plan will remain compliant with the software quality requirements of 24590-WTP-QAM-QA-01-001, Policy 3.2, Software Quality, until reissued, in accordance with the plan schedule, as compliant with the applicable policies of 24590-WTP-QAM-QA-06-001.

1.2.3 Procurement (DOE O 414.1C, Attachment 2, 3(g); DOE G 414.1-2A, Appendix A, Section 4.7)

The Acquisition Services organization is responsible for the management and control of procurement activities as described in the *Project Execution Plan*.

Engineering specifies technical requirements in specifications that are included in the procurement package. Engineering identifies the required supplier submittal documentation in the procurement documents. Engineering also evaluates supplier submittals and reviews and statuses, as appropriate, design changes proposed by the supplier. Supplier document submittals are received, managed and

controlled in accordance with the document control process. Technical and quality issues are identified and managed through the quality improvement processes.

Procurement documents contain, as applicable to the item or service being procured; the scope of work, technical requirements (drawings, specifications, codes, & standards), quality requirements, regulations, procedures, instructions, test, inspection, and acceptance criteria. Procurement documents include identification of the quality level of the item. Items and services, including software and/or software services are procured in accordance with implementing documents.

Procurement documentation activities consist of development, review, approval, and change control in accordance with the documents and records processes. The procurement process relies on the determinations and decisions made by the design authority during the engineering design phase.

Supplier Quality uses an *Approved Suppliers List* to document those suppliers that have been qualified to the specific quality requirements in accordance with the *WTP Graded Approach to Quality* and implementing procedures.

The procurement performance process requirements for procurement activities are specified in:

- Policy Q-04.1, *Procurement Document Control*
- Policy Q-07.1, *Control of Purchased Items and Services*

These policies provide the requirements that ensure procured items and services meet established design and performance requirements as specified, and describe the process controls that ensure approved suppliers continue to provide acceptable items and services. Prospective suppliers are evaluated and selected on the basis of specified criteria in design and procurement documents. Policy Q-04.1, *Procurement Document Control* addresses procurement document content, review, approval, and change control. Policy Q-07.1, *Control of Purchased Items and Services* addresses supplier evaluation and selection, proposal and bid evaluation, supplier generated documents, acceptance of items and/or services, certificate of conformance, source verification, receiving inspection, post-installation testing, supplier nonconformance's, and commercial grade items/services.

Requirements for the procurement of items and services are established in engineering specifications, which also identify any performance expectations. Specifications, procurement documents, and standard contract clauses are used to notify suppliers and subcontractors of the applicable requirements (S/CI, 10 CFR 830, NQA-1-2000, QARD, etc.). Policy Q-15.2, *Control of Suspect/Counterfeit Items,* specifies requirements for management of S/CIs. Procurement document changes affecting the technical or quality assurance program requirements are subject to the same degree of control as utilized in the preparation of the original documents. Prior to awarding a contract, BNI evaluates the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier document submittals are received, managed and controlled.

Source verification and receiving inspections of permanent plant material and items are conducted by supplier quality representatives to ensure the supplied material and items meet the requirements, as specified in the Material Acceptance Plans (MAPs). Policy Q-07.1, *Control of Purchased Items and Services,* specifies requirements for these activities. The extent of supplier documents, inspection, data requirements, and quality source verification vary depending on the nature of the items, the quality standards required for the product desired, and any special project requirements.

1.2.4 Inspection and Acceptance Test (DOE O 414.1C, Attachment 2, 3(h); DOE G 414.1-2A, Appendix A, Section 4.8)

Engineering is responsible for identifying test requirements and acceptance criteria for inspection and acceptance testing. Acquisition Services is responsible for assuring that factory inspections and testing

are completed, as required. The Construction and/or Operations organizations are responsible for the implementation and management of the field inspection and test processes. Acceptance criteria are documented in system descriptions and engineering specifications that support the design, including applicable codes and standards as described in the *Safety Requirements Document*.

The inspection and acceptance test performance process requirements include:

- Policy Q-10.1, *Inspection*
- Policy Q-11.1, *Test Control*
- Policy Q-14.1, *Inspection, Test and Operating Status*

Controls are established in approved procedures for inspection planning, execution, reporting, and documentation. Engineering establishes the required inspections and acceptance criteria for items, services, and processes. Implementing documents identify characteristics to be examined, inspection techniques, hold and witness points when required, and assignment of responsibility to perform the inspections. Controls are established in approved procedures for test and inspection planning, execution, reporting, and documentation. S/CI's identified during inspection and/or testing are managed in accordance with the management process requirements in Policy Q-15.2, *Control of Suspect/Counterfeit Items*. Inspection and test personnel incorporate the engineering acceptance criteria into implementing documents. Results of inspections and tests are documented and maintained in accordance with the management process requirements in Policy Q-17.1, *Quality Assurance Records*. Inspection, measuring, and test equipment is controlled, calibrated, and maintained in accordance with the performance process requirements in Policy Q-12.1, *Control of Measuring and Test Equipment*. Special process inspections are conducted in accordance with the performance process requirements in Policy Q-09.1, *Control of Special Processes*.

1.3 Assessment Process

The assessment process requirements include oversight and follow-up of issues and deficiencies. The assessment process requirements specify the oversight controls for the performance and management process activities. The assessment requirements are specified in:

- Policy Q-02.2, *Management Assessment*
- Policy Q-02.3, *Quality Assurance Surveillance*
- Policy Q-18.1, *Audit (Independent Assessment)*

1.3.1 Management Assessment (DOE O 414.1C, Attachment 2, 3(i); DOE G 414.1-2A, Appendix A, Section 4.9)

The management assessment requirements are specified in Policy Q-02.2, *Management Assessment* and the *WTP Assurance Program Description*. Management assessment procedures describe the controls for conducting assessments to identify improvement opportunities and issues that may hinder the organization from achieving its objectives. Managers, at every level, participate in management assessments to periodically assess their organizations and functions to determine how well they use resources and meet their objectives, identify strengths or improvement opportunities, and correct problems. Management assessment of the quality assurance program may be performed for WTP senior management by a third-party not associated with the WTP, but having adequate experience and qualifications to assess for performance to and/or conformance with the WTP quality assurance program. Management assessments are documented in reports and used to identify opportunities for improvement and take action, as appropriate. Quality problems are identified in accordance with the quality improvement processes.

1.3.2 Audit (DOE O 414.1C, Attachment 2, 3(j); DOE G 414.1-2A, Appendix A, Section 4.10)

The audit program is managed and controlled by the Quality and Performance Assurance organization as described in the *WTP Assurance Program Description*. The assessment process of audit includes planning, scheduling, conducting, and reporting in accordance with Policy Q-18.1, *Audit (Independent Assessment)*. Audit follow-up requirements are in accordance with the management process programs for quality improvement. Audits are utilized to measure item and service quality and are planned and conducted to measure the adequacy of work performance and to promote improvement. Audit personnel are given sufficient authority and organizational freedom to make the audit process meaningful and effective. Audits are performed by personnel who do not have direct responsibility for performing the activities being audited. The assessment process requirements are designed to ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

1.3.3 Surveillance

The surveillance program is managed and controlled by the Quality and Performance Assurance organization as described in the *WTP Assurance Program Description*. The assessment process requirements for surveillance describe the controls for conducting periodic evaluation of ongoing work activities to ensure those activities are being performed in accordance with implementing documents and by qualified personnel. Surveillance is an effective tool that complements the audit assessment process. Surveillances are conducted in accordance with Policy Q-02.3, *Quality Assurance Surveillance.*

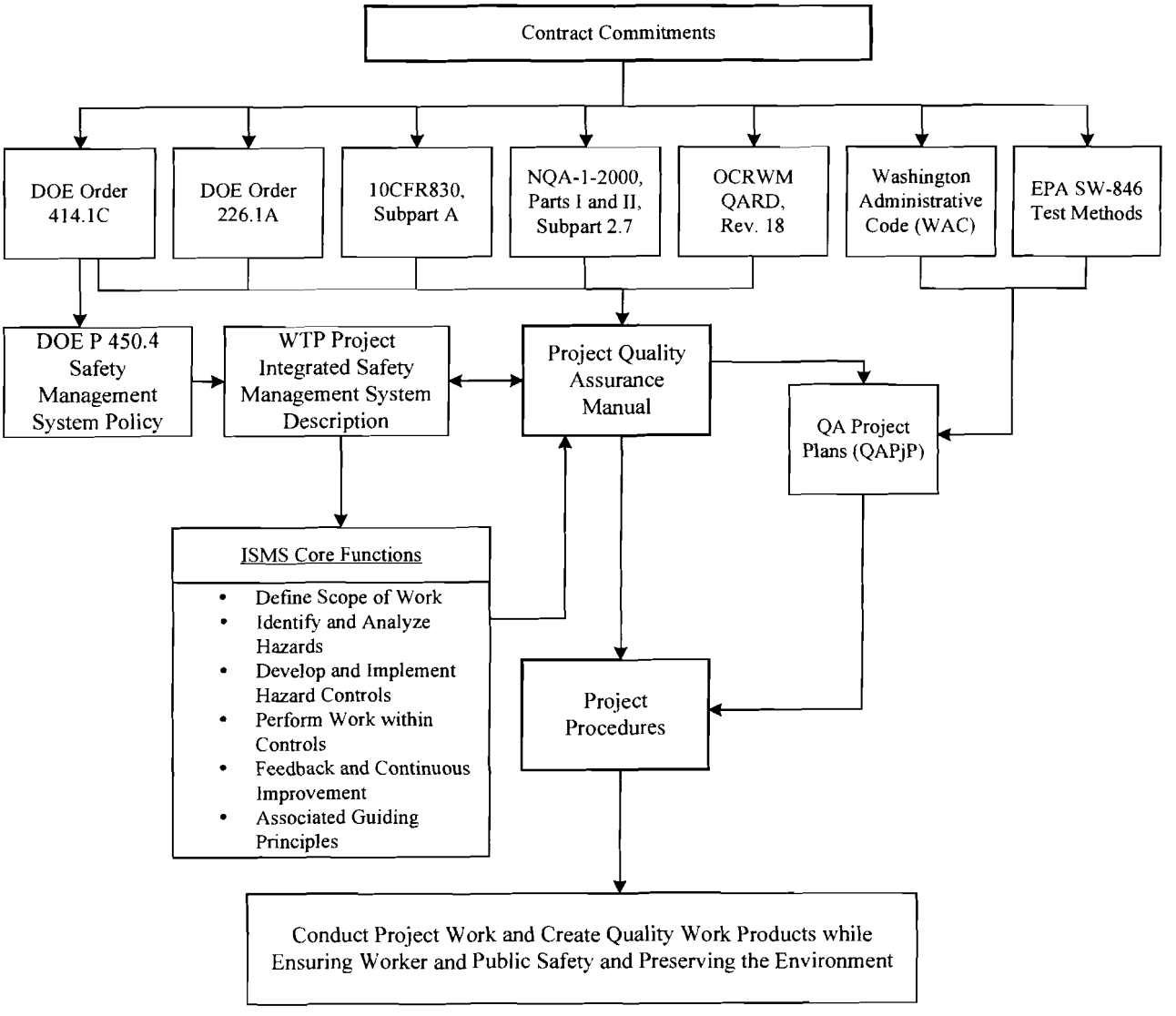


Figure 1, Quality Management Program Requirements Flowdown

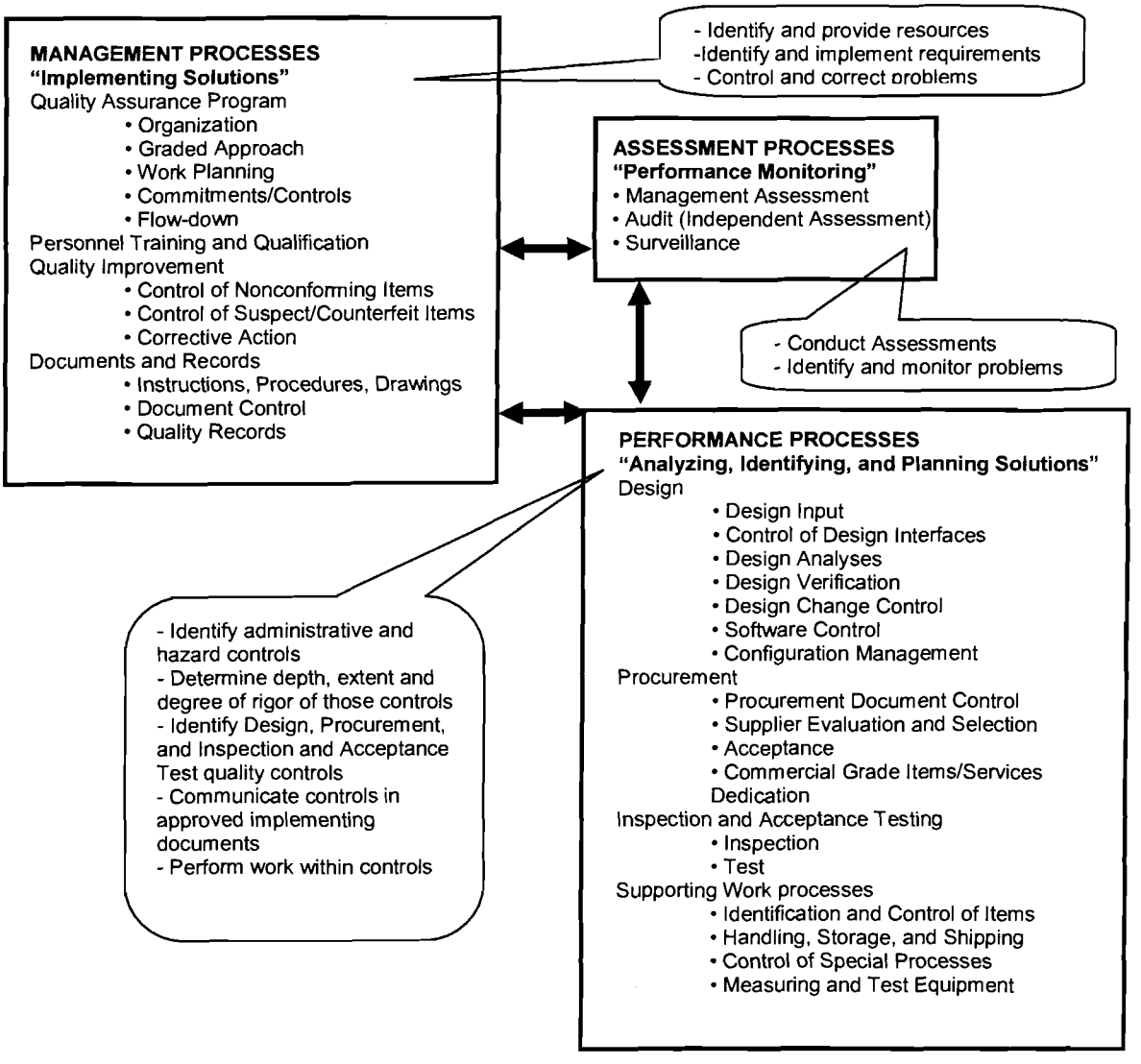


Figure 2, Quality Assurance Program

10 CFR 830.122/DOE O 414.1C	Requirement Source	QAM Policy
Management Process		
Quality Assurance Program	NQA-1-2000, RQMT 1, 2	Policy Q-01.1, *Project Organization*, Policy Q-02.1, *Quality Assurance Program*
Personnel Training and Qualification	NQA-1-2000, RQMT 2	Policy Q-02.4, *Personnel Training and Qualification*, Policy Q-02.5, *Qualification and Certification of Auditors*, Policy Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel*
Quality Improvement	NQA-1-2000, RQMT 15, 16	Policy Q-02.2, *Management Assessment*, Policy Q-02.3, *Quality Assurance Surveillance*, Policy Q-15.1, *Control of Nonconforming Items*, Policy Q-15.2, *Control of Suspect/Counterfeit Items*, Policy Q-16.1, *Corrective Action*, Policy Q-18.1, *Audit (Independent Assessment)*
Documents and Records	NQA-1-2000, RQMT 5, 6, 17	Policy Q-05.1, *Instructions, Procedures, and Drawings*, Policy Q-06.1, *Document Control*, Policy Q-17.1, *Quality Assurance Records*
Performance Process		
Supporting Work Processes	NQA-1-2000, RQMT 8, 9, 12, 13	Policy Q-08.1, *Identification and Control of Items*, Policy Q-09.1, *Control of Special Processes*, Policy Q-12.1, *Control of Measuring and Test Equipment*, Policy Q-13.1, *Handling, Storage, and Shipping*
Design	NQA-1-2000, RQMT 3 & Subpart 2.7	Policy Q-03.1, *Design Control*, Policy Q-03.2, *Software Quality, Appendix E, Supplement to Policy Q 03.2, Software Quality*
Procurement	NQA-1-2000, RQMT 4, 7	Policy Q-04.1, *Procurement Document Control.*, Policy Q-07.1, *Control of Purchased Items and Services*
Inspection and Acceptance Testing	NQA-1-2000, RQMT 10, 11, 14	Policy Q-10.1, *Inspection*, Policy Q-11.1, *Test Control*, Policy Q-14.1, *Inspection, Test and Operating Status*
Assessment Processes		
Management Assessment	NQA-1-2000, RQMT 2	Policy Q-02.2, *Management Assessment*
Independent Assessment	NQA-1-2000, RQMT 18	Policy Q-18.1, *Audit (Independent Assessment)*, Policy Q-02.3, *Quality Assurance Surveillance*

Figure 3, 10 CFR 830/DOE O 414.1C/NQA-1/BNI QAM Crosswalk

Policy Statement

Our mission is to design, build, and commission the Hanford Tank Waste Treatment and Immobilization Plant (WTP) in a quality manner that protects health, safety, and the environment while fostering public confidence.

As the Project Director, I am responsible for the safety of the WTP staff and the quality of our work. I take these responsibilities very seriously. My commitment to the quality of our work is reflected in this Quality Assurance Manual.

This manual meets the requirements of the American National Standard American Society of Mechanical Engineers (ASME) NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, and other contractually imposed requirements including best management practices. Our organization and responsibilities to meet these requirements are defined in this manual.

Everyone is responsible for the quality of his or her work. Compliance with this manual is mandatory and is achieved through implementing procedures. Line management is responsible for achieving, verifying, and maintaining quality. The Quality Assurance and Performance organization is responsible for the independent verification of quality.

Our overriding priorities are safety and quality. We have created, and sustained, an open and trusting environment where each of us:

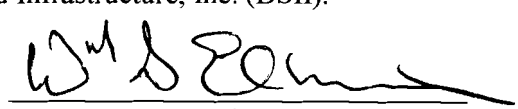
- Takes pride and ownership of safety and quality
- Questions what does not seem right - stops and asks
- Identifies and shares improvement opportunities
- Embraces and accepts procedure compliance as the foundation of our work
- Achieves quality in everything we do

The core functions and guiding principles of the Integrated Safety Management System are integrated into the quality assurance program to ensure that work is performed safely and in compliance with requirements.

Quality is planned into our work by ensuring that requirements are incorporated into implementing documents. In addition, we hold ourselves to high standards, to objectively assess ourselves against these standards, and to take prompt action when we find divergence. By taking advantage of lessons learned we continue to improve our work.

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

I am responsible for the development of this manual, its implementation, and verification of the quality of our work. Work shall not proceed unless the work can be accomplished as described in approved procedures, instructions, and drawings. Ultimate authority on matters pertaining to quality assurance resides with the Project Director. Conflicts involving interpretation of the requirements of the quality assurance program shall be resolved by the Manager of Quality and Performance Assurance or, if deemed necessary, the Manager of Quality Assurance, Bechtel Systems and Infrastructure, Inc. (BSII).



W. S. Elkins, Project Director

Policy Q-01.1 Project Organization

1.1.1 Purpose and Applicability

1.1.1.1 This policy establishes the WTP management program, as follows:

1.1.1.1.1 The organizational structure. (DOE O 414.1C, Attachment 2, (3)(a)(1); 10 CFR 830.122(a)(1))

1.1.1.1.2 The functional responsibilities. (DOE O 414.1C, Attachment 2, (3)(a)(1); 10 CFR 830.122(a)(1))

1.1.1.1.3 Levels of authority. (DOE O 414.1C, Attachment 2, (3)(a)(1); 10 CFR 830.122(a)(1))

1.1.1.1.4 Interfaces for those managing, performing, and assessing WTP work. (DOE O 414.1C, Attachment 2, (3)(a)(1); 10 CFR 830.122(a)(1))

1.1.1.1.5 Processes, including:

1.1.1.1.5.1 Planning. (DOE O 414.1C, Attachment 2, (3)(a)(2); 10 CFR 830.122(a)(2))

1.1.1.1.5.2 Scheduling. (DOE O 414.1C, Attachment 2, (3)(a)(2; 10 CFR 830.122(a)(2))

1.1.1.1.5.3 Providing resources. (DOE O 414.1C, Attachment 2; (3)(a)(2); 10 CFR 830.122(a)(2))

1.1.1.2 This policy applies to WTP employees and organizations that prescribe, perform, or verify activities. (Management Requirement)

1.1.2 Requirements

1.1.2.1 General

1.1.2.1.1 Responsibilities for the establishment and implementation of the quality assurance program are defined in this manual and in the implementing procedures/documents. (NQA-1-2000, RQMT 1, 100)

1.1.2.1.2 The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are documented in this manual and in the implementing procedures/documents. (NQA-1-2000, RQMT 1, 100)

1.1.2.1.3 The organizational structure and responsibility assignments are such that: (NQA-1-2000, RQMT 1, 201)

1.1.2.1.3.1 Senior management has established the overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. (NQA-1-2000, RQMT 1, 201(a))

1.1.2.1.3.2 Quality is achieved and maintained by those assigned responsibility for performing work. (NQA-1-2000, RQMT 1, 201(b); QARD, Rev. 18, 1.2.1)

1.1.2.1.3.3 Quality achievement is verified by those not directly responsible for performing the work. (NQA-1-2000, RQMT 1, 201(c); QARD, Rev. 18, 1.2.1; NQA-1A-1983, Supp RQMT 2S-3, 5.1)

1.1.2.1.3.4 Those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function. (NQA-1-2000, RQMT 1, 201(d))

1.1.2.2 Delegation of Work

1.1.2.2.1 The individual(s) responsible for establishing and executing the quality assurance program as described in this manual may delegate any or all of the work to others but shall retain responsibility for the delegated work. (NQA-1-2000, RQMT 1, 202)

1.1.2.3 Interface Control

1.1.2.3.1 Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. (NQA-1-2000, RQMT 1, 300; QARD, Rev. 18, 2.2.1.B.3)

1.1.2.3.2 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented. (NQA-1-2000, RQMT 1, 300; QARD, Rev. 18, 2.2.1.B.3)

1.1.3 Organization and Responsibilities

1.1.3.1 Project Employees

1.1.3.1.1 Project employees are responsible for:

1.1.3.1.1.1 Complying with the indoctrination, training, and qualification requirements applicable to their job assignment, and maintaining their job proficiency.

1.1.3.1.1.2 Complying with the requirements of this manual as defined in implementing documents (instructions, procedures, and drawings). (NQA-1-2000, RQMT 9, 300)

1.1.3.1.1.3 Safely accomplishing work activities in accordance with the most current instructions, procedures, and drawings.

1.1.3.1.1.4 Achieving acceptable quality during the performance of work activities.

1.1.3.1.1.5 Reporting errors or deficiencies in processes, instructions, procedures, and drawings to their immediate management.

1.1.3.1.1.6 Stopping work activities and informing their supervisor when it appears that adherence to a procedure is not possible or may result in an imminent danger to employee safety and health, the environment, facilities, or property.

1.1.3.1.1.7 Identifying and reporting items that could be categorized as nonconforming.

1.1.3.1.1.8 Promptly identifying, documenting, and reporting potential conditions adverse to safety and quality.

1.1.3.1.1.9 Identifying and reporting items that could be categorized as suspect/counterfeit (S/CI) items.

1.1.3.2 Managers/Supervisors

1.1.3.2.1 Managers and supervisors are responsible for:

1.1.3.2.1.1 Ensuring the safety of employees.

1.1.3.2.1.2 Developing and maintaining a comprehensive set of management controls.

1.1.3.2.1.3 Ensuring that procedures/documents are developed and maintained in accordance with the requirements of this manual.

1.1.3.2.1.4 Ensuring that activities within their area of responsibility are performed in accordance with documented instructions, procedures, and drawings.

1.1.3.2.1.5 Incorporating Integrated Safety Management System (ISMS) provisions into work processes.

1.1.3.2.1.6 Establishing position specific minimum education and experience requirements.

1.1.3.2.1.7 Establishing and maintaining training requirements for project personnel including job specific training.

1.1.3.2.1.8 Committing resources to provide training to personnel performing activities.

1.1.3.2.1.9 Ensuring that personnel within their organization comply with requirements for indoctrination, training, qualification, and that suitable proficiency is achieved and maintained.

1.1.3.2.1.10 Assigning qualified personnel to perform work activities.

1.1.3.2.1.11 Providing necessary resources to the project organizations.

1.1.3.2.1.12 Interfacing and communicating with other managers in accomplishing facility design, construction, and commissioning activities.

1.1.3.2.1.13 Complying with regulatory and contractual requirements.

1.1.3.2.1.14 Supporting the Safety, Quality Assurance, and Employee Concerns Programs, thereby assuring that work performed under their cognizance will conform to and support the requirements of this manual.

1.1.3.2.1.15 Supporting the supplier selection process.

1.1.3.2.1.16 Ensuring that conditions adverse to quality are identified and controlled in accordance with approved procedures and for ensuring that an atmosphere is created in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

1.1.3.2.1.17 Ensuring that nonconforming items that pose a threat to employee safety or health, or represents an imminent threat to the environment, the public, or property are placed in a safe condition and that an evaluation is conducted to determine if stopping work is warranted.

1.1.3.2.1.18 Identifying and implementing appropriate corrective actions when work is not in compliance with the applicable requirements.

1.1.3.2.1.19 Stopping activities within their areas of responsibility that do not comply with the AB and/or regulatory requirements.

1.1.3.2.1.20 Participating in the prevention and control of S/CI.

1.1.3.2.1.21 Participating in the performance of management assessment processes to evaluate the adequacy and effectiveness of their management control systems for improving processes and eliminating barriers to achieving project goals and objectives.

1.1.3.3 Project Director

1.1.3.3.1 The Project Director has the overall responsibility for the development, design, procurement, modification, maintenance, construction, and commissioning of WTP. In addition, the Project Director is responsible for:

1.1.3.3.1.1 Establishing the overall vision for the project and instilling a culture of excellence for safety and quality, including performance expectations.

1.1.3.3.1.2 Establishing and implementing the organizational structure of the project.

1.1.3.3.1.3 Providing a single point of accountability with the DOE Office of River Protection (ORP).

1.1.3.3.1.4 Approving this manual and ensuring that the Manager of Quality and Performance Assurance has the authority and independence to effectively verify the conformance to quality requirements.

1.1.3.3.1.5 Ensuring the stoppage of applicable work activities when conditions warrant.

1.1.3.3.1.6 Ensuring integration of nuclear and industrial safety, quality, and environmental protection requirements into work activities.

1.1.3.3.1.7 Ensuring implementation of the management assessment program.

1.1.3.3.1.8 Reviewing the status and adequacy of the quality assurance program.

1.1.3.3.1.9 Acting on recommendations from corporate safety and quality oversight.

1.1.3.3.1.10 Establishing and implementing processes to ensure that approved suppliers continue to provide acceptable items and services.

1.1.3.3.2 The Project Director is responsible for ensuring independence of the Employee Concerns Program and that employees are provided with an avenue to raise issues or concerns to the attention of management without fear of retaliation.

1.1.3.3.2.1 The Employee Concerns Program Officer reports to the Project Director and is responsible for creating a framework for identifying, reporting, and resolving employee concerns.

1.1.3.3.3 The Project Director is responsible for ensuring independence of the Manager of Quality and Performance Assurance. (DOE O 226.1A, Attachment 1, 2(g))

1.1.3.3.3.1 The Manager of Quality and Performance Assurance reports to BSII Quality Assurance for technical and programmatic direction and to the Assistant Project Director, Quality and Safety Assurance, Technology and Plant Operations, for day-to-day coordination. (DOE O 226.1A, Attachment 1, 2(g))

1.1.3.3.3.2 The Manager of Quality and Performance Assurance is responsible for the development, implementation, assessment, and improvement of this manual.

1.1.3.3.3.3 The Manager of Quality and Performance Assurance shall concur with changes to the positions and interpretations affecting this manual.

1.1.3.3.3.4 The Manager of Quality and Performance Assurance has direct communication access to the Project Director when needed, to ensure independence and to provide an avenue for resolving issues that cannot be adequately addressed through normal reporting channels. (DOE O 226.1A, Attachment 1, 2(g))

1.1.3.3.3.5 Consistent with these reporting relationships, the Manager of Quality and Performance Assurance has the authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation. (DOE O 226.1A, Attachment 1, 2(g))

1.1.3.3.3.6 The Manager of Quality and Performance Assurance is the point of contact responsible for S/CI information notices. (DOE O 414.1C, Attachment 2, 2(a), 4(a)(6))

1.1.3.3.3.7 The Manager of Quality and Performance Assurance is responsible for providing Price-Anderson Amendments Act (PAAA) Program identification, documentation, and supporting function for the WTP.

1.1.3.3.3.8 The Manager of Quality and Performance Assurance is responsible for providing for the review of and concurrence with quality-related procedures and other quality-related documents prepared on the project to ensure compliance with the project quality program. Procedures and other documents requiring Quality and Performance Assurance review and concurrence are documented in project implementing procedures.

1.1.3.3.4 The Project Director is responsible for ensuring independence of the Safety Assurance Manager.

1.1.3.3.4.1 The Safety Assurance Manager reports to BSII Environmental, Safety, and Health for technical and programmatic direction and to the Assistant Project Director, Quality and Safety Assurance, Technology and Plant Operations, for day to day coordination.

1.1.3.3.4.2 The Safety Assurance Manager has direct communication access to the Project Director when needed, to ensure independence and to provide an avenue for resolving issues that cannot be adequately addressed through normal reporting channels.

1.1.3.3.4.3 Consistent with these reporting relationships, the Safety Assurance Manager has the authority and organizational freedom to identify safety problems; to initiate, recommend, or provide solutions; and to verify implementation.

1.1.3.3.5 The Assistant Project Director, Quality and Safety Assurance, Technology and Plant Operations, reports to the Project Director and is responsible for the management and oversight of the plant operations, Quality Assurance, health and safety, and environmental compliance, integrated issues management system, root cause analysis, lessons learned, and the WTP training program.

1.1.3.3.5.1 The Assistant Project Director, Quality and Safety Assurance, Technology and Plant Operations is responsible for the activities of the Chief Process Engineer, including research and technology activities, development and execution of the Research and Technology Plan, and WTP contract deliverables and scheduled Research and Technology activities conducted by subcontractors.

1.1.3.3.6 The Project Manager reports directly to the Project Director and is responsible for engineering, procurement, construction, and modification. The Project Manager is responsible for the activities of the Area Project Managers, Manager of Engineering, Manager of Construction, Acquisition Services Manager, Material Management Manager, and Manager of Project Controls.

1.1.3.3.6.1 The Manager of Engineering is the Design Authority and is responsible for:

1.1.3.3.6.1.1 Establishing and maintaining the design requirements.

1.1.3.3.6.1.2 Ensuring that design output documents accurately reflect the design basis.

1.1.3.3.6.1.3 Maintaining design control.

1.1.3.3.6.1.4 Maintaining the technical adequacy of the design process.

1.1.3.3.7 The Project Operations Manager is responsible for Strategic Projects, Risk Management, Management Support and Plantwide Integration activies.

1.1.3.3.8 The Assistant Project Director, Business Services, reports to the Project Director for work authorization accountability and day-to-day direction and is responsible for providing business services to assure regulatory adequacy of business activities, administering the Prime Contract, managing business and administrative functions. Reporting to the Assistant Project Director, Business Services, are Contracts, Human Resources, Information Systems and Technology-Chief Information Officer, Controller, Washington Group International, Inc. (WGI), Business Services, and Office and Administrative Services.

Policy Q-02.1 Quality Assurance Program

2.1.1 Purpose and Applicability

2.1.1.1 Purpose

2.1.1.1.1 The WTP Quality Assurance program has been established to plan, implement, and maintain the policies governing the activities performed within the scope of designing, constructing, and commissioning WTP. The key elements are described in the individual policies of this manual. (10 CFR 830.121, (b)(4))

2.1.1.1.2 The Quality Assurance program is the management system that implements the requirements of the U.S. Department of Energy Order 414.1C, *Quality Assurance* and the U.S. Code of Regulations, 10-CFR-830, Subpart A, *Quality Assurance Requirements* for managing, performing, and assessing the adequacy of work. (DE-AC27-01RV14136; 10 CFR 830.121, (b)(4))

2.1.1.2 Applicability

2.1.1.2.1 The requirements of this manual apply to activities that could affect the quality of structures, systems, and components. Activities affecting quality include training, siting, designing, procuring, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, and decommissioning. (NQA-1-2000, Introduction, 200; QARD, Rev. 18, 2.2.2.A, 2.2.2.C)

2.1.1.2.2 A grading process, as defined in Section 2.1.2.2, "Graded Approach", of this policy, shall be developed and controlled through procedures concurred with by the Quality Assurance organization. The importance of the item or activity is critical to the amount of controls imposed necessary to assure the requisite or desired quality. Further grading of the requirements in this manual is permitted which provides for applying additional requirements (e.g.; IHLW), or reducing the application of requirements (e.g.; non-safety, Commercial (CM)). The procedures shall be designed to apply the graded approach in a consistent manner, ensuring the processes for grading are clearly described for Quality (Q) and Commercial (CM) items and activities. (DOE G 414.1-2A; 10 CFR 830.3, 7)

2.1.1.2.3 This manual also applies to Immobilized High Level Waste (IHLW) items and activities that are subject to additional requirements (e.g. QARD, Revision 18, and NQA-1-1983, in part) identified in Appendix A, *Immobilized High Level Waste Addenda.* (DE-AC27-01RV14136; QARD, Rev. 18, 2.1)

2.1.2 Requirements

2.1.2.1 General

2.1.2.1.1 The program shall provide for indoctrination, training, and qualification as necessary, of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained. (NQA-1-2000, RQMT 2, 100(b))

2.1.2.1.2 The program shall provide control over activities affecting quality to an extent consistent with their importance. The grading process is applied prior to performing the activities. (NQA-1-2000, RQMT 2, 100(a); DOE G 414.1-2A, 4.1.3)

2.1.2.1.3 The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. (NQA-1-2000, RQMT 2, 100(a))

2.1.2.1.4 The WTP shall establish and implement processes to detect and correct quality problems. (NQA-1-2000, RQMT 2, 100(a))

2.1.2.1.5 The Quality Assurance program has been established in accordance with the schedule for accomplishing the activities. (NQA 1 2000, RQMT 2, 100(a))

2.1.2.1.6 The quality assurance system shall include self-evaluations of compliance with applicable laws, regulations, national standards, DOE directives, DOE-approved plans and program documents (e.g., security plans, authorization basis documents, and quality assurance program), site-specific procedures/manuals, criteria review and approach documents, contractual performance objectives, and other contractually mandated requirements. (DOE O 226.1A, Attachment 1, 2(d))

2.1.2.2 Graded Approach

2.1.2.2.1 Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with: (DOE O 414.1C, 7.E; 10 CFR 830.3, 7)

2.1.2.2.1.1 The relative importance to safety, safeguards, and security. (DOE O 414.1C, 7.E)

2.1.2.2.1.2 The magnitude of any hazard involved. (DOE O 414.1C, 7.E)

2.1.2.2.1.3 The life cycle stage of a facility. (DOE O 414.1C, 7.E)

2.1.2.2.1.4 The programmatic mission of a facility. (DOE O 414.1C, 7.E)

2.1.2.2.1.5 The particular characteristics of a facility or item. (DOE O 414.1C, 7.E)

2.1.2.2.1.6 The relative importance of radiological and nonradiological hazards. (DOE O 414.1C, 7.E)

2.1.2.2.1.7 Any other relevant factor. (DOE O 414.1C, 7.E)

2.1.2.3 Work Planning

2.1.2.3.1 The procedures shall provide for the planning (prior to the start of work) and accomplishment of activities affecting quality under suitably controlled conditions. (NQA-1-2000, RQMT 2, 100(a); QARD, Rev 18, 2.2.4.A, 2.2.4.B)

2.1.2.3.1.1 Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied. (NQA-1-2000, RQMT 2, 100(a); QARD, Rev 18, 2.2.4.B)

2.1.2.3.2 The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. (NQA-1-2000, RQMT 2, 100(a); QARD, Rev 18, 2.2.4.C)

2.1.2.4 Performance Measures

2.1.2.4.1 Management shall establish programs that identify, gather, verify, analyze, trend, disseminate, and make use of performance indicators to measure the performance of facilities, programs, and organizations. (DOE O 226.1A, Attachment 1, 2(b)(6), Appendix A, 7)

2.1.2.4.2 Performance indicator data shall be considered in allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices. (DOE O 226.1A, Attachment 1, 2(b)(6), Appendix A, 7)

2.1.2.5 Control of the Quality Assurance Program

2.1.2.5.1 Revisions to the Quality Assurance Manual do not require approval by the DOE prior to issuance, but shall be submitted to the DOE at least annually in accordance with the requirements of Section 830.121(b)(3) of 10 CFR Part 830, Subpart A, "Quality Assurance Requirements". (DOE O 414.1C, Attachment 2, 2(b)(6); 10 CFR 830.121, (b)(3))

2.1.2.5.2 The submittal of a revision to the manual to DOE shall include a justification for why the changes continue to satisfy the quality assurance requirements. Changes made to correct spelling, punctuation, or other editorial items do not require explanation. (DOE O 414.1C, Attachment 2, 2(b)(6))

2.1.2.5.3 Revisions shall be submitted to the DOE for approval and regarded as approved 90 days after submittal, unless it is approved or rejected by the DOE at an earlier date. (DOE O 414.1C, Attachment 2, 2(b)(5); 10 CFR 830.121, (b)(1), (b)(2))

2.1.2.5.4 Changes to implementing procedures resulting from changes to this manual shall be incorporated within 90 days of the manual DOE change approval date unless an interim action plan is defined and approved by the Manager of Quality and Performance Assurance. (Management Requirement)

2.1.2.6 Regulatory Commitments

2.1.2.6.1 The program shall comply with applicable laws, regulations, permits, licenses, other regulatory authorizations and approvals. (DE-AC27-01RV14136)

2.1.2.6.2 Changes to commitments shall be accomplished in accordance with regulatory requirements. (DE-AC27-01RV14136)

2.1.2.6.3 Applicable environmental regulatory requirements such as those mandated by the Environmental Protection Agency (EPA) or the Washington Administrative Codes (WAC) shall be incorporated in Quality Assurance Project Plans (QAPjP), as required. (DE-AC27-01RV14136; Management Requirement)

2.1.2.6.4 Supplemental Quality Assurance Plans (QAPs) may be required and developed for specific project activities as needed to apply additional quality assurance regulatory standards and/or guidance and/or address unique/specific work scope or consensus standards. (Management Requirement)

2.1.2.6.4.1 Quality Assurance Plans may be used provided the following criteria has been met:

2.1.2.6.4.1.1 The requirements of these plans are implemented in project procedures.

2.1.2.6.4.1.2 The applicable Integrated Safety Management (ISM) process(s) and criteria have been met and the plans are compliant with the safety basis.

2.1.2.6.4.1.3 Application of the graded approach has been accomplished in accordance with project procedures.

2.1.2.6.4.1.4 Approvals by the responsible project manager, the Manager of Quality and Performance Assurance, and DOE (if applicable) in addition to concurrence by the affected organizations, such as Engineering and Operations.

2.1.2.6.5 This manual is designed to integrate with the following DOE Policies:

2.1.2.6.5.1 DOE P 450.4, *Safety Management System Policy*, dated 10-15-96, see Policy Q-05.1, *Instructions, Procedures, and Drawings*. (DOE 414.1C, Attachment 2, 2(a)(4)(a))

2.1.2.6.5.2 DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*, see Appendix A. (DOE 414.1C, Attachment 2, 2(a)(4)(d))

2.1.2.7 Flowdown of Quality Assurance Program Requirements

2.1.2.7.1 In accordance with the principles of ISMS, Authorization Basis requirements must flow from their source down into working level documents. Policy Q-05.1, *Instructions, Procedures, and Drawings* requires ISMS core functions and guiding principals be considered for written procedures or instructions, as applicable to the

type of work being conducted. The project Quality Assurance program shall be applied, with appropriate grading of controls to the scope of work defined in BNI's contractual Authorization Basis. This manual serves to reflect the quality assurance requirements imposed by regulation and by contract and to provide the basis for their flowdown and implementation via implementing level documents.

Policy Q-02.2 Management Assessment

2.2.1 Purpose and Applicability

2.2.1.1 This policy identifies the requirements for establishing and performing periodic management assessments of the adequacy and effective implementation of the Quality Assurance program. (Management Requirement)

2.2.1.2 This policy applies to organizations subject to or conducting management assessments to ensure that managers assess their management processes and identify and correct problems that may hinder the organization or its subcontractors from achieving its objectives. (DOE O 414.1C, Attachment 2, 3(i); DOE O 226.1A, Attachment 1, 1, 2(b)(1), Appendix A, 1(f); 10 CFR 830.122, (i))

2.2.1.3 Results from Management Assessment are identified and tracked in accordance with Policy Q-15.1, *Control of Nonconforming Items*, or Policy Q-16.1, *Corrective Action*, as appropriate. (QARD, Rev 18, 2.2.6.D)

2.2.2 Requirements

2.2.2.1 Independent Assessment of the Quality Assurance Program

2.2.2.1.1 Management shall regularly assess the adequacy and effective implementation of the Quality Assurance program. (NQA-1-2000, RQMT 2, 100(c); QARD, Rev 18, 2.2.6)

2.2.2.2 Management Assessment

2.2.2.2.1 Management assessments shall: (QARD, Rev. 18, 2.2.6, 2.2.6.C)

2.2.2.2.1.1 Be planned and documented, and performed annually. (QARD, Rev. 18, 2.2.6.B)

2.2.2.2.1.2 Be performed by personnel outside the quality assurance organization. (QARD, Rev. 18, 2.2.6.A)

2.2.2.2.1.3 Evaluate the scope, status, and adequacy of the Quality Assurance program. (QARD, Rev. 18, 2.2.6.C.2)

2.2.2.2.1.4 Evaluate the adequacy of resources and personnel provided to achieve and ensure quality. (QARD, Rev. 18, 2.2.6.C.1)

2.2.2.2.1.5 Evaluate the effectiveness of the Quality Assurance program. (QARD, Rev. 18, 2.2.6.C.3)

2.2.2.2.1.6 Evaluate the programmatic compliance to the Quality Assurance program. (QARD, Rev. 18, 2.2.6.C.4)

2.2.2.3 Self Assessment

2.2.2.3.1 Self assessments shall be used to evaluate performance at all levels periodically and to determine the effectiveness of policies, requirements, and standards and the implementation status. (DOE Order 414.1C, Criterion 9; DOE O 226.1A, Attachment 1, Appendix A, 2(a))

2.2.2.3.2 Self assessments shall be developed (scope and review criteria) and performed based on the nature of the facility/activity being assessed and the hazards and risks to be controlled. (DOE O 226.1A, Attachment 1, Appendix A, 2(a)(1))

2.2.2.3.3 Support organizations shall perform self assessments of their performance and the adequacy of their processes. (DOE O 226.1A, Attachment 1, Appendix A, 2(a)(3))

2.2.2.3.4 The WTP, at all levels, shall assess the implementation and adequacy of their processes, including analysis of the collective results of lower-level self assessments. (DOE O 226.1A, Attachment 1, Appendix A, 2(a)(4))

2.2.2.3.5 Self assessments that focus on hands-on work and the implementation of administrative processes shall involve workers, supervisors, and managers to encourage identification and resolution of deficiencies at the lowest level practicable (e.g., workplace inspections and post-job reviews). (DOE O 226.1A, Attachment 1, Appendix A, 2(a)(2))

2.2.2.3.6 Self assessments results shall be documented commensurate with the significance of and risks associated with activities being evaluated. (DOE O 226.1A, Attachment 1, Appendix A, 2(a)(5))

Policy Q-02.3 Quality Assurance Surveillance

2.3.1 Purpose and Applicability

2.3.1.1 This policy identifies the requirements for performing quality assurance surveillances, both internal and external. Surveillances are a management tool used to help evaluate the Quality Assurance program adequacy, effectiveness, compliance, implementation and maintenance. In addition, surveillances can also be used to identify continuous improvement opportunities. (Management Requirement)

2.3.1.2 This policy applies to the Quality Assurance organization. (Management Requirement)

2.3.2 Requirements

2.3.2.1 Surveillances shall be scheduled in a manner to provide coverage, consistency, and coordination of ongoing work, at a frequency commensurate with the status and importance of the work. (QARD, Rev 18, 2.2.5.A)

2.3.2.2 Surveillances shall be performed by personnel who are knowledgeable about, and not directly responsible for, the work under surveillance. (QARD, Rev 18, 2.2.5.B)

2.3.2.3 Conditions adverse to quality identified during the surveillance process will be dispositioned by the responsible organization in accordance with Policy Q-15.1, *Control of Nonconforming Items,* or Policy Q-16.1, *Corrective Action*, as appropriate. (Management Requirement)

2.3.2.4 Surveillances shall be documented in a report to appropriate management. (QARD, Rev 18, 2.2.5.C)

Policy Q-02.4 Personnel Training and Qualification

2.4.1 Purpose and Applicability

2.4.1.1 This policy identifies the requirements for the indoctrination, training, and qualification of personnel. (Management Requirement)

2.4.1.2 This policy applies to all WTP organizations and personnel. (Management Requirement)

2.4.1.3 Appendix A, Policy Q-02.4, *Personnel Training and Indoctrination,* provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

2.4.2 Requirements

2.4.2.1 General

2.4.2.1.1 Each organization shall provide for indoctrination, training, and formal qualification, as necessary, of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained. (NQA-1-2000, RQMT 2, 100 (b); QARD, Rev 18, 2.2.11, 2.2.11.A.1, 2.2.11.B.2; NQA-1A-1983, Basic Requirements, 2)

2.4.2.1.2 Training documentation shall include the objective, content of the training, attendees, and date of attendance. Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. (NQA-1-2000, RQMT 2, 500; QARD, Rev 18, 2.2.11.A.2)

2.4.2.1.3 Personnel who manage and perform assurance functions must possess experience, knowledge, skills, and abilities commensurate with their responsibilities. (DOE O 226.1A, Attachment 1, 2(e))

2.4.2.2 Indoctrination and Training

2.4.2.2.1 Indoctrination and training shall be commensurate with the scope, complexity, and importance of the activities, and the education, experience, and proficiency of the personnel. (NQA-1-2000, RQMT 2, 200; QARD, Rev 18, 2.2.11.A.3)

2.4.2.2.2 Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. (NQA-1-2000, RQMT 2, 201; QARD, Rev 18, 2.2.11.A.7)

2.4.2.2.3 The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in

technology, methods, or job responsibilities. (NQA-1-2000, RQMT 2, 202; QARD, Rev 18, 2.2.11.A.1, 2.2.11.A.3, 2.2.11.A.7)

2.4.2.3 Formal Qualification Requirements

2.4.2.3.1 The responsible organization shall designate those activities that require formal qualification of personnel and the minimum requirements for such personnel. (NQA-1-2000, RQMT 2, 300)

2.4.2.3.2 The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform the activities identified in Section 2.4.2.2, "Indoctrination and Training". (NQA-1-2000, RQMT 2, 300; QARD, Rev 18, 2.2.11.A.6)

Policy Q-02.5 Qualification and Certification of Auditors

2.5.1 Purpose and Applicability

2.5.1.1 This policy identifies the requirements for the initial and continuing qualification and certification of Quality Assurance auditors and lead auditors. (Management Requirement)

2.5.1.2 This policy applies to the Quality Assurance organization and other organizations supporting quality assurance audits. (Management Requirement)

2.5.1.3 Appendix A, Policy Q-02.5, *Qualification and Certification of Auditors*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

2.5.2 Requirements

2.5.2.1 General

2.5.2.1.1 Auditors and lead auditors shall be trained to the requirements of Policy Q-02.4, *Personnel Training and Qualification*, and meet the requirements of this policy. (QARD, Rev 18, 2.2.11.C, 18.2.7.C, 18.2.13; NQA-1A-1983, Sup Req 2S-3, 2.1; DOE O 226.1A, Attachment 1, 2(f))

2.5.2.1.2 Management may delegate qualification examination activities to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration. (NQA-1-2000, RQMT 2, 400(b); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 5.2)

2.5.2.1.2.1 The auditing organization shall maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. (NQA-1-2000, RQMT 2, 400(b); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 5.2)

2.5.2.1.2.2 Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the auditing organization in accordance with this policy. (NQA-1-2000, RQMT 2, 400(b); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 5.2)

2.5.2.1.3 Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. (NQA-1-2000, RQMT 2, 500)

2.5.2.1.4 Records of personnel qualification, including indoctrination, training, requalification for auditors and lead auditors performing audits, shall be established and maintained by the project. (NQA-1-2000, RQMT 2, 500; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.1)

2.5.2.2 Auditor Training and Indoctrination

2.5.2.2.1 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. (NQA-1-2000, RQMT 2, 304; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1)

2.5.2.2.2 Competence of personnel for performing the various auditing functions shall be developed by one or more of the following methods: (NQA-1-2000, RQMT 2, 304; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1)

2.5.2.2.2.1 Orientation to provide a working knowledge and understanding of the Quality Assurance program requirements, and the auditing organization's procedures for implementing audits and reporting results. (NQA-1-2000, RQMT 2, 304(a); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1(a))

2.5.2.2.2.2 General and specialized training in audit performance, where the general training shall include fundamentals such as objectives, characteristics, organization, performance, and results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. (NQA-1-2000, RQMT 2, 304(b); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1(b))

2.5.2.2.2.3 On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits. (NQA-1-2000, RQMT 2, 304(c); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1(c))

2.5.2.3 Lead Auditor Qualifications and Certifications

2.5.2.3.1 A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating corrective actions. (NQA-1-2000, RQMT 2, 303; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3)

2.5.2.3.2 An individual shall meet the requirements of this policy prior to being designated as a lead auditor. (NQA-1-2000, RQMT 2, 303; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3)

2.5.2.3.3 Communication

2.5.2.3.3.1 The prospective lead auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the lead auditor's manager. (NQA-1-2000, RQMT 2, 303.1; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.1)

2.5.2.3.4 Lead Auditor Training

2.5.2.3.4.1 Prospective lead auditors shall receive training to the extent necessary to assure auditing competence including: (NQA-1-2000, RQMT 2, 303.2; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2)

2.5.2.3.4.1.1 Knowledge and understanding of this manual, requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable. (NQA-1-2000, RQMT 2, 303.2(a); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2.1)

2.5.2.3.4.1.2 General structure of the Quality Assurance program as a whole, and applicable elements as defined in this manual. (NQA-1-2000, RQMT 2, 303.2(b); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2.2)

2.5.2.3.4.1.3 Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings. (NQA-1-2000, RQMT 2, 303.2(c); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2.3)

2.5.2.3.4.1.4 Planning audits of activities affecting quality. (NQA-1-2000, RQMT 2, 303.2(d); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2.4)

2.5.2.3.4.1.5 On-the-job training to include applicable elements of the audit program. (NQA-1-2000, RQMT 2, 303.2(e); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.2.5)

2.5.2.3.5 Audit Participation

2.5.2.3.5.1 Prospective lead auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification and certification. (NQA-1-2000, RQMT 2, 303.3; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.3)

2.5.2.3.6 Lead Auditor Examination

2.5.2.3.6.1 Prospective lead auditors shall pass an examination, which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof. (NQA-1-2000, RQMT 2, 303.4; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 3.4)

2.5.2.3.7 Lead Auditor Maintenance of Proficiency

2.5.2.3.7.1 Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to the Quality Assurance program and program auditing; or participation in Quality Assurance training program(s). (NQA-1-2000, RQMT 2, 303.5; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 4.1)

2.5.2.3.7.2 Based on annual assessment, management may extend the qualification, require retraining, or require requalification. (NQA-1-2000, RQMT 2, 303.5; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 4.1)

2.5.2.3.8 Lead Auditor Requalification

2.5.2.3.8.1 Lead auditors who fail to maintain their proficiency for a period of two years or more shall be require requalification. (NQA-1-2000, RQMT 2, 303.6; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 4.2)

2.5.2.3.8.2 Requalification shall include retraining in accordance with the requirements of Section 2.5.2.3.4, "Lead Auditor Training", of this policy, reexamination in accordance with the requirements of Section 2.5.2.3.6, "Lead Auditor Examination", of this policy, and participation as an auditor in at least one nuclear quality assurance audit. (NQA-1-2000, RQMT 2, 303.6; QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 4.2)

2.5.2.3.9 Lead Auditor Certification of Qualification

2.5.2.3.9.1 Each lead auditor shall be certified by the auditing organization as being qualified to lead audits. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 5.1, 5.2, 6.2)

2.5.2.3.9.2 The qualification of lead auditor personnel shall be certified in writing and shall document the following information: (NQA-1-2000, RQMT 2, 400(a); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2)

2.5.2.3.9.2.1 Employer's name. (NQA-1-2000, RQMT 2, 400(a)(1); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2(a))

2.5.2.3.9.2.2 Identification of person being certified. (NQA-1-2000, RQMT 2, 400(a)(2); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2(b))

2.5.2.3.9.2.3 Activities certified to perform. (NQA-1-2000, RQMT 2, 400(a)(3))

2.5.2.3.9.2.4 Basis of qualification to include: (NQA-1-2000, RQMT 2, 400(a)(4); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2(d))

2.5.2.3.9.2.4.1 Education, experience, indoctrination, and training. (NQA-1-2000, RQMT 2, 400(a)(4)(a); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2(d))

2.5.2.3.9.2.4.2 Test results, where applicable. (NQA-1-2000, RQMT 2, 400(a)(4)(b))

2.5.2.3.9.2.4.3 Capability demonstration results. (NQA-1-2000, RQMT 2, 400(a)(4)(c))

2.5.2.3.9.2.5 Results of periodic evaluation. (NQA-1-2000, RQMT 2, 400(a)(5))

2.5.2.3.9.2.6 Results of physical examinations, when required. (NQA-1-2000, RQMT 2, 400(a)(6))

Policy Q-02.5 Qualification and Certification of Auditors

2.5.2.3.9.2.7 Signature of employer's designated representative responsible for such certification. (NQA-1-2000, RQMT 2, 400(a)(7); QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.2(e))

2.5.2.3.9.2.8 Date of certification or recertification and certification expiration. (NQA-1-2000, RQMT 2, 400(a)(8); QARD, Rev 18, 2.2.11.C; NQA-1A-983, Sup Req 2S-3, 6.2(c))

2.5.2.3.9.3 The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. (NQA-1-2000, RQMT 2, 400(b))

Policy Q-02.6 Qualification and Certification of Inspection and Test, including NDE, Personnel

2.6.1 Purpose and Applicability

2.6.1.1 This policy identifies the requirements for the initial and continuing qualification and certification of personnel performing inspections and tests, including non-destructive examinations (NDE). (Management Requirement)

2.6.1.2 This policy applies to organizations and personnel performing inspections and tests to confirm acceptability of items and activities. (Management Requirement)

2.6.1.3 Appendix A, Policy Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel,* provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities.* (QARD, Rev. 18, 2.1, 2.2.2)

2.6.2 Requirements

2.6.2.1 Qualification of Inspection and Test Personnel

2.6.2.1.1 Personnel performing inspections and tests, including NDE, shall be trained in accordance with the requirements of Policy Q-02.4, *Personnel Training and Qualification* and meet the requirements of this policy. (Management Requirement)

2.6.2.1.2 The initial capabilities of an inspection and test candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. (NQA-1-2000, RQMT 2, 302; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.5)

2.6.2.1.3 The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. (NQA-1-2000, RQMT 2, 302; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.6)

2.6.2.1.4 Reevaluation of independent inspection and test personnel job performance shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of this policy. (NQA-1-2000, RQMT 2, 302; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.6)

2.6.2.1.4.1 If, during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. (NQA-1-2000, RQMT 2, 302; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.6)

2.6.2.1.5 Any person who has not performed inspection or testing activities in the qualified area for a period of one year shall be reevaluated. (NQA-1-2000, RQMT 2, 302; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.6)

2.6.2.2 Certification of Inspection and Test Personnel

2.6.2.2.1 The qualification of inspection and test personnel shall be certified in writing by the responsible organization and document the following information: (NQA-1-2000, RQMT 2, 400(a); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7)

2.6.2.2.1.1 Employer's name. (NQA-1-2000, RQMT 2, 400(a)(1); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(a))

2.6.2.2.1.2 Identification of the person being certified. (NQA-1-2000, RQMT 2, 400(a)(2); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(b))

2.6.2.2.1.3 Activities certified to perform. (NQA-1-2000, RQMT 2, 400(a)(3); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(c))

2.6.2.2.1.4 Basis of qualification, such as: (NQA-1-2000, RQMT 2, 400(a)(4); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(d))

2.6.2.2.1.4.1 Education, experience, indoctrination, and training. (NQA-1-2000, RQMT 2, 400(a)(4)(a); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(d)(1))

2.6.2.2.1.4.2 Test results, where applicable. (NQA-1-2000, RQMT 2, 400(a)(4)(b); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(d)(2))

2.6.2.2.1.4.3 Capability demonstration results. (NQA-1-2000, RQMT 2, 400(a)(4)(c); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(d)(3))

2.6.2.2.1.5 Results of periodic evaluations. (NQA-1-2000, RQMT 2, 400(a)(5); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(e))

2.6.2.2.1.6 Results of physical examinations, when required. (NQA-1-2000, RQMT 2, 400(a)(6); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(f))

2.6.2.2.1.7 Signature of the employer's designated representative who is responsible for such certification. (NQA-1-2000, RQMT 2, 400(a)(7); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(g))

2.6.2.2.1.8 Date of certification or recertification and certification expiration. (NQA-1-2000, RQMT 2, 400(a)(8); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.7(h))

2.6.2.2.2 The responsible organization shall identify any special physical characteristics needed in the performance of each activity including the need for initial and subsequent physical examinations. (NQA-1-2000, RQMT 2, 400(b); QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 2.8)

2.6.2.2.3 Management may delegate formal qualification examination activities to an independent certifying agency, but shall retain responsibility for the examination and its administration. (NQA-1-2000, RQMT 2, 400(b))

2.6.2.2.4 Integrity of examinations shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. (NQA-1-2000, RQMT 2, 400(b))

2.6.2.2.5 Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be maintained by the employer in accordance with the requirements of this policy. (NQA-1-2000, RQMT 2, 400(b))

2.6.2.2.6 Records of personnel training and/or qualification for test and inspection activities shall be established and maintained by WTP. (NQA-1-2000, RQMT 2, 500; QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Req 2S-3, 3.1)

2.6.2.2.7 Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. (NQA-1-2000, RQMT 2, 500)

2.6.2.3 Qualifications for NDE Personnel

2.6.2.3.1 Qualification requirements for personnel performing NDE inspections and tests to verify conformance are as follows: (NQA-1-2000, RQMT 2, 300)

2.6.2.3.1.1 Personnel who perform NDE including radiographic, magnetic particle, ultrasonic, liquid penetrant, electromagnetic, neutron radiography, leak testing, and acoustic emission to verify conformance to specified requirements shall be qualified to procedures that meet the requirements of any edition of the American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition through 2001 Edition, all-inclusive, and its applicable supplements. (NQA-1-2000, RQMT 2, 301; Equivalency Evaluation CCN 066347; QARD, Rev 18, 2.2.11.D, 9.2.3.A, 9.2.3.B, 9.2.3.C)

2.6.2.3.1.1.1 In lieu of the three-year certification interval specified in SNT-TC-1A, December 1988 Edition, Level III Nondestructive Examination personnel may be recertified on a five-year interval. When required by the implementing code, visual testing will be subject to these same requirements. (Equivalency Evaluation CCN 066347; QARD, Rev 18, 2.2.11.D)

Policy Q-03.1 Design Control

3.1.1 Purpose and Applicability

3.1.1.1 This policy identifies the requirements for ensuring that designs are defined, controlled, and verified. (Management Requirement)

3.1.1.2 This policy applies to design activities for the WTP. (Management Requirement)

3.1.1.3 Appendix A, Policy Q-03.1, *Design Control*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

3.1.2 Requirements

3.1.2.1 General

3.1.2.1.1 The design shall be defined, controlled, and verified. (NQA-1-2000, RQMT 3, 100; QARD, Rev 18, 3.1(a), 3.2.1)

3.1.2.1.2 Design inputs shall be specified on a timely basis and translated into design documents. (NQA-1-2000, RQMT 3, 100; QARD, Rev 18, 3.2.1, 3.2.1.B)

3.1.2.1.3 Design interfaces shall be identified and controlled. (NQA-1-2000, RQMT 3, 100; QARD, Rev 18, 3.2.7.A)

3.1.2.1.4 Design adequacy shall be verified by individuals other than those who designed the item or computer program. (NQA-1-2000, RQMT 3, 100; QARD, Rev 18, 3.2.1, 3.2.4.G)

3.1.2.1.5 Design changes shall be governed by control measures commensurate with those applied to the original design. (NQA-1-2000, RQMT 3, 100; QARD, Rev 18, 3.2.6.A)

3.1.2.1.6 Design documentation and records shall include not only final design documents, such as drawings and specifications and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design. (NQA-1-2000, RQMT 3, 900; QARD, Rev 18, 3.2.2.B)

3.1.2.2 Design Input

3.1.2.2.1 Applicable design inputs shall be identified and documented, and their selection reviewed and approved. (NQA-1-2000, RQMT 3, 200; QARD, Rev 18, 3.2.1.A)

3.1.2.2.2 The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for

making design decisions, accomplishing design verification measures, and evaluating design changes. (NQA-1-2000, RQMT 3, 200; QARD, Rev 18, 3.2.1.B)

3.1.2.3 Interface Control

3.1.2.3.1 Design information transmitted across interfaces shall identify the status of the design information or document provided and identify incomplete items which require further evaluation, review, or approval. (NQA-1-2000, RQMT 3, 700; QARD, Rev 18, 3.2.7.B, 3.2.7.C, 3.2.7.D)

3.1.2.3.2 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document. (NQA-1-2000, RQMT 3, 700; QARD, Rev 18, 3.2.7.E)

3.1.2.4 Design Process

3.1.2.4.1 The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements. (NQA-1-2000, RQMT 3, 300(a); QARD, Rev 18, 3.2.2.A)

3.1.2.4.2 Design documents shall support facility design, construction, and operation. (NQA-1-2000, RQMT 3, 300(a); QARD, Rev 18, 3.2.2.B)

3.1.2.4.3 Appropriate technical and quality assurance standards shall be identified and documented, and their selection reviewed and approved. (QARD, Rev 18, 3.2.1, 3.2.2.C)

3.1.2.4.4 Changes or deviations from specified quality assurance and technical standards, including the reasons for the change or deviation, shall be identified, evaluated, approved, documented, and controlled. (QARD, Rev 18, 3.2.2.D, 3.2.6.E)

3.1.2.4.5 The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. (NQA-1-2000, RQMT 3, 300(b); QARD, Rev 18, 3.2.2.E)

3.1.2.4.6 Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. (NQA-1-2000, RQMT 3, 300(b); QARD, Rev 18, 3.2.2.F)

3.1.2.4.7 The final design shall: (NQA-1-2000, RQMT 3, 300(c); QARD, Rev 18, 3.2.2.G)

3.1.2.4.7.1 Be relatable to the design input by documentation in sufficient detail to permit design verification. (NQA-1-2000, RQMT 3, 300(c)(1); QARD, Rev 18, 3.2.2.G.1)

3.1.2.4.7.2 Specify required inspections and tests and include or reference appropriate acceptance criteria. (NQA-1-2000, RQMT 3, 300(c)(2); QARD, Rev 18, 3.2.2.J)

3.1.2.4.7.3 Identify assemblies and/or components that are part of the item being designed. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II; QARD, Rev 18, 3.2.2.G.2)

3.1.2.5 Commercial Grade Items

3.1.2.5.1 When an assembly or component part, identified in Paragraph 3.1.2.4.7.3, above, is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented and in accordance with Policy Q-07.1, *Control of Purchased Items and Services*. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II; QARD, Rev 18, 3.2.2.H)

3.1.2.5.2 Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended function. ("Critical" added to "characteristics" in accordance with NQA-1-2000, RQMT 3, 300(C)(3), as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, Safety Requirements Document, Volume II)

3.1.2.5.3 If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, Safety Requirements Document, Volume II; QARD, Rev 18, 3.2.2.H)

3.1.2.6 Distribution and Use of Design Documents

3.1.2.6.1 The distribution and use of design documents shall be controlled in accordance with Policy Q-06.1, Document Control. (QARD, Rev 18, 3.2.2.L)

3.1.2.7 Design Analyses

3.1.2.7.1 Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. (NQA-1-2000, RQMT 3, 400; QARD, Rev 18, 3.2.3.C)

3.1.2.7.2 To the extent required below, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application. Preverified computer programs shall be controlled in accordance with the requirements of this manual. (NQA-1-2000, RQMT 3, 401; QARD, Rev 18, 3.2.3.E.6)

3.1.2.7.2.1 The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. (NQA-1-2000, RQMT 3, 401(a); QARD, Rev 18, 3.2.3.E.6(a))

3.1.2.7.2.2 The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application. (NQA-1-2000, RQMT 3, 401(b); QARD, Rev 18, 3.2.3.E.6(b))

3.1.2.7.2.3 Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes. (QARD, Rev 18, 3.2.3.E.7)

3.1.2.7.3 Computer software shall be developed or procured, qualified, and used in accordance with Policy Q-03.2, *Software Quality*. (QARD, Rev 18, 3.1.C)

3.1.2.7.4 Design analyses shall be planned, controlled, and documented. (QARD, Rev 18, 3.2.3.A)

3.1.2.7.5 Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. (QARD, Rev 18, 3.2.3.B)

3.1.2.7.6 Documentation of design analyses shall include: (NQA-1-2000, RQMT 3, 402; QARD, Rev 18, 3.2.3.E)

3.1.2.7.6.1 Identification of the originator, reviewer, and approver. (QARD, Rev 18, 3.2.3.D, 3.2.3.E.8)

3.1.2.7.6.2 The objective of the analyses. (NQA-1-2000, RQMT 3, 402(a); QARD, Rev 18, 3.2.3.E.1)

3.1.2.7.6.3 Design inputs and their sources. (NQA-1-2000, RQMT 3, 402(b); QARD, Rev 18, 3.2.3.E.2)

3.1.2.7.6.4 Results of literature searches or other applicable background data. (NQA-1-2000, RQMT 3, 402(c); QARD, Rev 18, 3.2.3.E.3)

3.1.2.7.6.5 Assumptions and indication of those assumptions that must be verified as the design proceeds. (NQA-1-2000, RQMT 3, 402(d); QARD, Rev 18, 3.2.1.E, 3.2.3.E.4)

3.1.2.7.6.6 Identification of any computer calculation, including: identification of the computer type, computer program name, and revision; inputs; outputs; evidence of or reference to computer program verification; and the basis (or reference thereto) supporting application of the computer program to the specific physical problem. (NQA-1-2000, RQMT 3, 402(e); QARD, Rev 18, 3.2.3.E.5)

3.1.2.7.6.7 Review and approval. (NQA-1-2000, RQMT 3, 402(f); QARD, Rev 18, 3.2.3.E.8)

3.1.2.8 Design Verification

3.1.2.8.1 The responsible design organization shall identify and document the particular design verification method(s) used. (NQA-1-2000, RQMT 3, 500(a))

3.1.2.8.2 The results of design verification shall be documented with the identification of the verifier clearly indicated. (NQA-1-2000, RQMT 3, 500(a); QARD, Rev 18, 3.2.4.E)

3.1.2.8.3 Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. (NQA-1-2000, RQMT 3, 500(a); QARD, Rev 18, 3.2.4.G)

3.1.2.8.4 Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met, such as when insufficient data exist. (NQA-1-2000, RQMT 3, 500(b); QARD, Rev 18, 3.2.4.H, 3.2.4.H.1)

3.1.2.8.4.1 In those cases, the unverified portion of the design shall be clearly identified and controlled. (NQA-1-2000, RQMT 3, 500(b); QARD, Rev 18, 3.2.4.H.1)

3.1.2.8.4.2 In all cases the design verification shall be completed prior to relying upon SSCs or computer programs to perform its function and before installation becomes irreversible (i.e., requires extensive demolition and rework). (NQA-1-2000, RQMT 3, 500(b); QARD, Rev 18, 3.2.4.H.2, 3.2.4.H.3)

3.1.2.8.5 If the design is modified to resolve verification findings, the modified design shall be verified prior to release for use. (NQA-1-2000, RQMT 3, 500(c); QARD, Rev 18, 3.2.4.K)

3.1.2.8.6 The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. (NQA-1-2000, RQMT 3, 500(d); QARD, Rev 18, 3.2.4.B)

3.1.2.8.6.1 Where the design has been subjected to a verification process in accordance with this policy, the verification process need not be duplicated for identical designs. (NQA-1-2000, RQMT 3, 500(d); QARD, Rev 18, 3.2.4.I)

3.1.2.8.6.2 However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. (NQA-1-2000, RQMT 3, 500(d); QARD, Rev 18, 3.2.4.J.1)

3.1.2.8.6.3 Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. (NQA-1-2000, RQMT 3, 500(d); QARD, Rev 18, 3.2.4.J.2)

3.1.2.8.6.4 The original design and associated verification documentation shall be referenced in records of subsequent application of the design. (NQA-1-2000, RQMT 3, 500(d); QARD, Rev 18, 3.2.4.J.3)

3.1.2.8.7 Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing. (NQA-1-2000, RQMT 3, 501; QARD, Rev 18, 3.2.4.A)

3.1.2.8.8 Design Reviews

3.1.2.8.8.1 Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable: (NQA-1-2000, RQMT 3, 501.1; QARD, Rev 18, 3.2.5.A)

3.1.2.8.8.1.1 Were the design inputs correctly selected? (NQA-1-2000, RQMT 3, 501.1(a); QARD, Rev 18, 3.2.5.A.1)

3.1.2.8.8.1.2 Are assumptions necessary to perform the design activity adequately described and reasonable? (NQA-1-2000, RQMT 3, 501.1(b); QARD, Rev 18, 3.2.5.A.2)

3.1.2.8.8.1.3 Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed? (NQA-1-2000, RQMT 3, 501.1(b); QARD, Rev 18, 3.2.5.A.2)

3.1.2.8.8.1.4 Were appropriate design methods and computer programs used? (NQA-1-2000, RQMT 3, 501.1(c); QARD, Rev 18, 3.2.5.A.3)

3.1.2.8.8.1.5 Were the design inputs correctly incorporated into the design? (NQA-1-2000, RQMT 3, 501.1(d); QARD, Rev 18, 3.2.5.A.4)

3.1.2.8.8.1.6 Is the design output reasonable compared to design inputs? (NQA-1-2000, RQMT 3, 501.1(e); QARD, Rev 18, 3.2.5.A.5)

3.1.2.8.8.1.7 Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions? (NQA-1-2000, RQMT 3, 501.1(f); QARD, Rev 18, 3.2.5.A.6)

3.1.2.8.8.1.8 Have suitable materials, parts, processes, and inspection and testing criteria been specified? (NQA-1-2000, RQMT 3, 501.1(g))

3.1.2.8.9 Alternate Calculations

3.1.2.8.9.1 Alternate calculations shall use alternate methods to verify the correctness of original calculations or analyses. (NQA-1-2000, RQMT 3, 501.2; QARD, Rev 18, 3.2.5.B)

3.1.2.8.9.2 The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed. (NQA-1-2000, RQMT 3, 501.2; QARD, Rev 18, 3.2.5.B)

3.1.2.8.10 Qualification Tests

3.1.2.8.10.1 Qualification tests shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions, including consideration of operating modes and environmental conditions. (NQA-1-2000, RQMT 3, 501.3; QARD, Rev 18, 3.2.5.C.4)

3.1.2.8.10.2 Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. (NQA-1-2000, RQMT 3, 501.3; QARD, Rev 18, 3.2.5.C.5)

3.1.2.8.10.3 When tests are being performed on models or mockups, scaling laws shall be established, verified, and approved. (NQA-1-2000, RQMT 3, 501.3; QARD, Rev 18, 3.2.5.C.8)

3.1.2.8.10.4 The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design. (NQA-1-2000, RQMT 3, 501.3; QARD, Rev 18, 3.2.5.C.9)

3.1.2.8.10.5 Qualification testing shall be conducted in accordance with Policy Q-011.1, *Test Control.* (Management Requirement)

3.1.2.9 Design Change Control

3.1.2.9.1 Design changes shall be controlled according to the following requirements: (QARD, Rev 18, 3.2.6)

3.1.2.9.1.1 Changes to design inputs, final designs, field changes, nonconforming items dispositioned "use-as-is" or "repair", and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design. (NQA-1-2000, RQMT 3, 600(a); QARD, Rev 18, 3.2.1.D, 3.2.6.A, 3.2.6.B)

3.1.2.9.1.2 These measures shall include evaluation of effects of those changes on the overall design and on any analyses upon which the design is based. (NQA-1-2000, RQMT 3, 600(a); QARD, Rev 18, 3.2.4.K)

3.1.2.9.1.3 The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. (NQA-1-2000, RQMT 3, 600(a))

3.1.2.9.1.4 The design organization approving the change shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design. (NQA-1-2000, RQMT 3, 600(a); QARD, Rev 18, 3.2.6.B.2)

3.1.2.9.1.5 When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. (NQA-1-2000, RQMT 3, 600(b))

3.1.2.9.1.6 Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary. (NQA-1-2000, RQMT 3, 600(c); QARD, Rev 18, 3.2.6.C)

3.1.2.9.1.7 Design deficiencies, that could adversely affect safety or Waste Acceptance Impacting SSCs, shall be documented in accordance with Policy Q-16.1,

Corrective Action. Additionally, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items shall be controlled in accordance with Policy Q-15.1, *Control of Nonconforming Items*. (QARD, Rev 18, 3.2.6.D; Management Requirement)

3.1.2.10 Software Design Control

3.1.2.10.1 The requirements of Policy Q-03.2, *Software Quality*, shall apply to computer software design control and shall be used in conjunction with Sections 3.1.2.1, "General", 3.1.2.3, "Interface Control" and 3.1.2.5, "Design Analyses", of this policy. (NQA-1-2000, RQMT 3, 800)

3.1.2.11 Configuration Management of Operating Facilities

3.1.2.11.1 Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. (NQA-1-2000, RQMT 3, 601)

3.1.2.11.2 These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. (NQA-1-2000, RQMT 3, 601)

3.1.2.11.3 Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed. (NQA-1-2000, RQMT 3, 601.1)

3.1.2.11.4 The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility and maintained for the life of the facility. (NQA-1-2000, RQMT 3, 601.2)

3.1.2.11.5 The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources. (NQA-1-2000, RQMT 3, 601.3)

3.1.2.11.6 Interface controls shall include the integration of activities of organizations that can affect the approved configuration. (NQA-1-2000, RQMT 3, 601.4)

3.1.2.11.7 Documentation shall identify the design bases and the approved configuration for the approved modes of operation. (NQA-1-2000, RQMT 3, 601.5)

3.1.2.11.8 Measures shall be established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases. (NQA-1-2000, RQMT 3, 601.6)

3.1.2.11.9 The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases. (NQA-1-2000, RQMT 3, 601.7)

3.1.2.11.10 Approval by the design authority shall be required prior to implementation of a change to the design bases. (NQA-1-2000, RQMT 3, 601.8)

3.1.2.11.11 The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents which reflect the operational status of the facility. (NQA-1-2000, RQMT 3, 601.9)

3.1.2.11.12 The process utilized to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation. (NQA-1-2000, RQMT 3, 601.9)

Policy Q-03.2 Software Quality

3.2.1 Purpose and Applicability

3.2.1.1 This policy establishes the requirements for computer software design control. (NQA-1-2000, RQMT 3, 800; Management Requirement)

3.2.1.2 Appendix E, *Supplement to Policy Q-03.2, Software Quality,* provides the requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of Appendix E shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software life cycle management. Appendix E supplements the requirements of this policy and shall be used in conjunction with applicable requirements of this policy when and to the extent specified in Appendix E, Section 3.2.2.2, "Software Graded Approach". (NQA-1-2000, Subpart 2.7, 100; QARD, Rev 18, Supplement I, I.1.A, I.1.B)

3.2.1.3 Embedded software that is integral to the operations, maintenance, or calibration of measuring and test equipment, that is verified or validated in conjunction with hardware as a unit, and has not been developed or modified for the project is controlled by Policy Q-12.1, *Control of Measuring and Test Equipment*, and is exempt from the requirements of this policy. (QARD, Rev 18, Supplement I, I.1.C)

3.2.1.4 Computer program testing shall be performed and shall be in accordance with Policy Q-11.1, *Test Control,* Section, 11.1.2.5, "Computer Program Test Procedures". (NQA-1-2000, RQMT 3, 801.5; QARD, Rev 18, Supplement I, I.2.3.B.4(e))

3.2.1.5 Appendix A, Policy Q-03.2, *Software Quality*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

Appendix F to this Quality Assurance Manual provides requirements related to software quality other than those provided in main policies and Appendices A and E. Appendix F encompasses the requirements previously included in 24590-WTP-QAM-QA-01-001 and applies to work activities identified in 24590-WTP-PL-IT-08-0001, *IS&T Project Plan for Implementation of 24590-WTP-QAM-QA-06-001 rev 2a*, Rev 0. This plan was developed to communicate the project plan for implementation of the software quality requirements of the new 24590-WTP-QAM-QA-06-001, *Quality Assurance Manual.* The scope of this plan includes the Software Plan, Guide, Procedures, and Forms as identified in the Project Schedule (Appendix A to the plan). The plan defines five efforts:

- To perform a safety software pre-survey to determine the types and sources of safety software
- To modify the existing procedures, guides and forms to include the new QAM requirement reference and to switch to the software designations Levels D, E, or F
- To extensively modify and develop plans, procedures, guides, and forms in order to implement safety software designation Levels A, B, and C
- Modify automated systems that support procedure driven process
- Develop Training for WTP Staff who have procedural responsibility

The requirements of 24590-WTP-QAM-QA-01-001, Policies 03.1 and 03.2, and 24590-WTP-QAM-QA-06-001, will coexist for the duration of 24590-WTP-PL-IT-08-0001. The procedures subject to the plan will remain compliant with the software quality requirements of 24590-WTP-QAM-QA-01-001, Policy 3.2, Software Quality, until reissued, in accordance with the plan schedule, as compliant with the applicable policies of 24590-WTP-QAM-QA-06-001.

3.2.2 Requirements

3.2.2.1 Software Design Process

3.2.2.1.1 The software design process shall be documented, approved by the responsible design organization, and controlled. (NQA-1-2000, RQMT 3, 801)

3.2.2.1.2 Identification of Software Design Requirements

3.2.2.1.2.1 Software design requirements shall be identified and documented and their selection reviewed and approved. (NQA-1-2000, RQMT 3, 801.1; QARD, Rev 18, Supplement I, I.2.3.A.2, I.2.3.B.1)

3.2.2.1.2.2 The software requirements shall identify the major components in addition to the operating system, function, attributes, interfaces, performance requirements, installation considerations, design inputs/outputs, ranges, and any design constraints of the computer program. (NQA-1-2000, RQMT 3, 801.1; QARD, Rev 18, Supplement I, I.2.3.A, I.2.3.A.1, I.2.3.B.2, I.2.3.B.4, I.2.3.B.4(a), I.2.3.B.4(b), I.2.3.B.4(c))

3.2.2.1.3 Software Design

3.2.2.1.3.1 The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. (NQA-1-2000, RQMT 3, 801.2)

3.2.2.1.3.2 The documentation shall include, as applicable, numerical methods, mathematical models, control flow, physical models, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design. (NQA-1-2000, RQMT 3, 801.2; QARD, Rev 18, Supplement I, I.2.3.B.4, I.2.3.B.4(b))

3.2.2.1.4 Implementation of Software Design

3.2.2.1.4.1 The software design shall be translated into computer program(s), using the programming organization's or design organization's programming standards and conventions. (NQA-1-2000, RQMT 3, 801.3; QARD, Rev 18, Supplement I, I.2.3.B.4(d), I.2.3.C.1)

3.2.2.1.5 Software Design Verification

3.2.2.1.5.1 Software design verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. (NQA-1-2000, RQMT 3, 801.4; QARD, Rev 18, Supplement 1, I.2.1.B.7)

3.2.2.1.5.2 The results of the verification shall be documented with the identification of the verifier indicated. (NQA-1-2000, RQMT 3, 801.4; QARD, Rev 18, Supplement I, I.2.1.B)

3.2.2.1.5.3 Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. (NQA-1-2000, RQMT 3, 801.4)

3.2.2.1.5.4 The extent of verification and the methods chosen are a function of the following: (NQA-1-2000, RQMT 3, 801.4)

3.2.2.1.5.4.1 The complexity of the software. (NQA-1-2000, RQMT 3, 801.4(a))

3.2.2.1.5.4.2 The degree of standardization. (NQA-1-2000, RQMT 3, 801.4(b))

3.2.2.1.5.4.3 Similarity with previously proved software. (NQA-1-2000, RQMT 3, 801.4(c))

3.2.2.1.5.4.4 Importance to safety. (NQA-1-2000, RQMT 3, 801.4(d))

3.2.2.2 Software Configuration Management

3.2.2.2.1 Configuration Identification

3.2.2.2.1.1 Software configuration management includes, but is not limited to, configuration identification, change control, and status control. (NQA-1-2000, RQMT 3, 802; QARD, Rev 18, Supplement I, I.2.4.A)

3.2.2.2.1.2 Configuration items shall be maintained under configuration management until the software is retired. (NQA-1-2000, RQMT 3, 802; QARD, Rev 18, Supplement I, I.2.3.G)

3.2.2.2.1.3 A software baseline shall be established at the completion of each activity of the software life cycle process. (NQA-1-2000, RQMT 3, 802.1)

3.2.2.2.1.4 Approved changes created subsequent to a baseline shall be added to the baseline. (NQA-1-2000, RQMT 3, 802.1)

3.2.2.2.1.5 A baseline shall define the most recently approved software configuration. (NQA-1-2000, RQMT 3, 802.1)

3.2.2.2.1.6 A labeling system for configuration item and the proposed, in-process, or approved status shall be implemented that: (NQA-1-2000, RQMT 3, 802.1; QARD, Rev 18, Supplement I, I.2.4.E, I.2.4.G.1, I.2.4.G.2)

3.2.2.2.1.6.1 Uniquely identifies each configuration item and provides traceability to the related documentation. (NQA-1-2000, RQMT 3, 802.1(a); QARD, Rev 18, Supplement I, I.2.4.E.2, I.2.4.E.3)

3.2.2.2.1.6.2 Identifies changes to configuration items by revision. (NQA-1-2000, RQMT 3, 802.1(b); QARD, Rev 18, Supplement I, I.2.4.E.2, I.2.4.E.3, I.2.4.G.3)

3.2.2.2.1.6.3 Provides the ability to uniquely identify each configuration of the revised software available for use. (NQA-1-2000, RQMT 3, 802.1(c); QARD, Rev 18, Supplement I, I.2.4.E.3, I.2.4.G)

3.2.2.2.2 Change Control

3.2.2.2.2.1 Changes to software shall be formally documented. (NQA-1-2000, RQMT 3, 802.2)

3.2.2.2.2.2 The documentation shall include: (NQA-1-2000, RQMT 3, 802.2; QARD, Rev 18, Supplement I, I.2.4.F.2)

3.2.2.2.2.2.1 A description of the change. (NQA-1-2000, RQMT 3, 802.2(a); QARD, Rev 18, Supplement I, I.2.4.F.2)

3.2.2.2.2.2.2 The rationale for the change. (NQA-1-2000, RQMT 3, 802.2(b); QARD, Rev 18, Supplement I, I.2.4.F.2)

3.2.2.2.2.2.3 The identification of affected software baselines. (NQA-1-2000, RQMT 3, 802.2(c); QARD, Rev 18, Supplement I, I.2.4.F.2)

3.2.2.2.2.3 The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. (NQA-1-2000, RQMT 3, 802.2; QARD, Rev 18, Supplement I, I.2.4.F.3)

3.2.2.2.2.4 Only authorized changes shall be made to software baselines. (NQA-1-2000, RQMT 3, 802.2)

3.2.2.2.2.5 Appropriate verification activities shall be performed for the change. (NQA-1-2000, RQMT 3, 802.2; QARD, Rev 18, Supplement I, I.2.4.F.5)

3.2.2.2.2.6 The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained. (NQA-1-2000, RQMT 3, 802.2; QARD, Rev 18, Supplement I, I.2.4.F.5)

3.2.2.2.2.7 Appropriate acceptance testing shall be performed for the change. (NQA-1-2000, RQMT 3, 802.2; QARD, Rev 18, Supplement I, I.2.4.F.5, I.2.4.F.6)

3.2.2.2.3 Configuration Status Control

3.2.2.2.3.1 The status of configuration items resulting from software design shall be maintained current. (NQA-1-2000, RQMT 3, 802.3)

3.2.2.2.3.2 Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls shall also provide for notification of this information to affected organizations. (NQA-1-2000, RQMT 3, 802.3; QARD, Rev 18, Supplement I, I.2.4.F.1, I.2.4.F.4, I.2.5.C.4)

Policy Q-04.1 Procurement Document Control

4.1.1 Purpose and Applicability

4.1.1.1 This policy identifies the requirements (based on the complexity and importance of the item or service being procured (Q/CM) as described in Policy Q-02.1, *Quality Assurance Program*, Section 2.1.2.2, "Graded Approach") to ensure that procurement documents, and changes thereto, contain appropriate technical and quality assurance requirements. (QARD, Rev 18, 4.1.A; Management Requirement)

4.1.1.2 This policy applies to organizations and employees involved in the processing of documents for the procurement of items and services. (Management Requirement)

4.1.1.3 Appendix A, Policy Q-04.1, *Procurement Document Control*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

4.1.2 Requirements

4.1.2.1 General

4.1.2.1.1 Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. (NQA-1-2000, RQMT 4, 100; QARD, Rev 18, 4.2.1, 4.2.1.B.1)

4.1.2.1.2 To the extent necessary, procurement documents shall require suppliers to provide, upon request, a documented quality assurance program consistent with the applicable requirements (e.g., 10 CFR 830, DOE O 414.1C, NQA-1, QARD, etc.) of this manual. The extent of the quality assurance program shall depend on the scope, nature, type and use, or complexity of the item or service being procured. (NQA-1-2000, RQMT 4, 100; QARD, Rev 18, 4.2.1.C.1)

4.1.2.1.3 The purchaser may permit some or all supplier work to be performed under the purchaser's quality assurance program. In this case, procurement documents shall specify that the purchaser's implementing documents are applicable to the supplier, and that the purchaser shall provide these applicable documents to them. (QARD, Rev 18, 4.2.1.C.3, 5.2.C, 5.2.D; Management Requirement)

4.1.2.1.4 Procurement processes shall prevent introduction of S/CIs by: (DOE O 414.1C, Attachment 2, 4(b)(2))

4.1.2.1.4.1 Identifying technical and quality assurance requirements in procurement specifications. (DOE O 414.1C, Attachment 2, 4(b)(2)(a))

4.1.2.1.4.2 Accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices. (DOE O 414.1C, Attachment 2, 4(b)(2)(b))

4.1.2.1.4.3 Inspecting inventory and storage areas to identify, control, and disposition S/CIs. (DOE O 414.1C, Attachment 2, 4(b)(2)(c))

4.1.2.1.4.4 Ensuring procurement process controls include provisions for preventing the procurement of S/CIs in accordance with Policy Q-15.2, *Control of Suspect/Counterfeit Items*. (QARD, Rev 18, 4.2.1.J; Management Requirement)

4.1.2.1.5 The distribution and use of procurement documents and changes thereto shall be controlled in accordance with Policy Q-06.1, *Document Control.* (QARD, Rev 18, 4.2.4)

4.1.2.1.6 Software acquisition includes software and/or software services procured in accordance with this policy and Policy Q-07.1, *Control of Purchased Items and Services*. (NQA-1-2000, Subpart 2.7, 300)

4.1.2.1.7 Procurement documents shall identify requirements for supplier's reporting of software errors to the purchaser and, as appropriate, the purchaser's reporting of software errors to the supplier. (NQA-1-2000, Subpart 2.7, 301; QARD, Rev 18, Supplement I, I.2.6.A.3)

4.1.2.2 Procurement Document Contents

4.1.2.2.1 Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the purchaser. (NQA-1-2000, RQMT 4, 200)

4.1.2.2.1.1 Procurement documents shall include a statement of the scope of work to be performed by the supplier. (NQA-1-2000, RQMT 4, 201; QARD, Rev 18, 4.2.1.A)

4.1.2.2.1.2 Technical requirements shall be specified in the procurement documents. (NQA-1-2000, RQMT 4, 202; QARD, Rev 18, 4.2.1.B)

4.1.2.2.1.2.1 These requirements shall be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished. (NQA-1-2000, RQMT 4, 202; QARD, Rev 18, 4.2.1.B.2)

4.1.2.2.1.2.2 The procurement documents shall identify tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier. (NQA-1-2000, RQMT 4, 202; QARD, Rev 18, 4.2.1.B.3)

4.1.2.2.1.3 Quality assurance program requirements shall be specified in procurement documents. (NQA-1-2000, RQMT 4, 203; QARD, Rev 18, 4.2.1.C)

4.1.2.2.1.3.1 These requirements shall be consistent with the importance and/or complexity of the item or service being procured. (NQA-1-2000, RQMT 4, 203; QARD, Rev 18, 4.2.1.C.1)

4.1.2.2.1.3.2 The procurement documents shall require the supplier to incorporate the appropriate quality assurance program requirements in sub-tier procurement documents. (NQA-1-2000, RQMT 4, 203; QARD, Rev 18, 4.2.1.C.2; 10 CFR 830.121, (c)(4))

4.1.2.2.1.3.3 These requirements shall include provisions for establishing hold points beyond which work cannot proceed without purchaser authorization. (QARD, Rev 18, 4.2.1.E)

4.1.2.2.1.4 The procurement documents shall provide for access to the supplier's and sub-tier supplier's facilities and records for surveillance, inspection, verification, or audit by the purchaser, its designated representative, and others authorized by the purchaser. (NQA-1-2000, RQMT 4, 204; QARD, Rev 18, 4.2.1.D; DOE O 226.1A, Attachment 1, 2(h))

4.1.2.2.1.5 The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. (NQA-1-2000, RQMT 4, 205; QARD, Rev 18, 4.2.1.F)

4.1.2.2.1.6 The time of submittal shall also be established. (NQA-1-2000, RQMT 4, 205; QARD, Rev 18, 4.2.1.F)

4.1.2.2.1.7 When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed. (NQA-1-2000, RQMT 4, 205; QARD, Rev 18, 4.2.1.F)

4.1.2.2.1.8 The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances. (NQA-1-2000, RQMT 4, 206; QARD, Rev 18, 4.2.1.G)

4.1.2.2.1.9 The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies. (NQA-1-2000, RQMT 4, 207; QARD, Rev 18, 4.2.1.H)

4.1.2.3 Procurement Document Review and Approval

4.1.2.3.1 A review of the procurement documents, and changes thereto, shall be made and documented prior to award/issuance to assure that documents transmitted to prospective supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. (NQA-1-2000, RQMT 4, 300; QARD, Rev 18, 4.2.2.A, 4.2.2.B)

4.1.2.3.2 Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the supplier. (NQA-1-2000, RQMT 4, 300; QARD, Rev 18, 4.2.3.B)

4.1.2.3.3 Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements

and intent of the procurement documents. (NQA-1-2000, RQMT 4, 300; QARD, Rev 18, 4.2.2.D)

4.1.2.4 Procurement Document Changes

4.1.2.4.1 Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents. (NQA-1-2000, RQMT 4, 400; QARD, Rev 18, 4.2.3.A)

Policy Q-05.1 Instructions, Procedures, and Drawings

5.1.1 Purpose and Applicability

5.1.1.1 This policy identifies the requirements to ensure that activities are prescribed by and performed in accordance with instructions, procedures, and drawings (e.g. implementing documents) of the type appropriate to the circumstances. (QARD, Rev 18, 5.1; 5.2.A, 5.2.2.A; Management Requirement)

5.1.1.2 This policy applies to project organizations responsible for the development, review, approval, maintenance, use, and cancellation of new and revised instructions, procedures, and drawings for activities. (Management Requirement)

5.1.1.3 Appendix A, Policy Q-05.1, *Instructions, Procedures, and Drawings*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

5.1.2 Requirements

5.1.2.1 Activities affecting items and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. (NQA-1-2000, RQMT 5, 100; QARD, Rev 18, 5.2.A; 5.2.2.A.3)

5.1.2.2 The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results, including: (NQA-1-2000, RQMT 5, 100)

5.1.2.2.1 Responsibilities and organizational interfaces of the organizations affected by the document. (QARD, Rev 18, 5.2.2.A.1)

5.1.2.2.2 A sequential description of the work to be performed, if necessary to satisfactorily complete the work, including controls for altering the sequence. (QARD, Rev 18, 2.2.4, 5.2.2.A.2)

5.1.2.2.3 Methods for documenting that the work was performed as specified. (QARD, Rev 18, 5.2.2.A.4)

5.1.2.3 The need for and the level of detail in written procedures or instructions shall be determined based on the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience). (NQA-1-2000, RQMT 5, 100; QARD, Rev 18, 5.2.2.B)

5.1.2.4 The following ISMS core functions and guiding principals shall be considered for written procedures or instructions, as applicable: (414.1C, Attachment 2, 2(a)(4); QARD, Rev 18, 2.2.1.B.1)

5.1.2.4.1 Scope of work, hazards identification, and hazard controls. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.2 How work will be performed within those controls. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.3 How continuous feedback and improvements are implemented. (414.1C, Attachment 2, 2(a)(4); DOE O 226.1A, Attachment 1, 2(b)(3), Appendix A, 1(b)(3), 4)

5.1.2.4.4 Clear worker and line management responsibilities. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.5 Required training (including qualification and certification) and experience. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.6 Prioritized activities. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.7 Standards and requirements (safety, technical, and quality). (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.8 Hazard controls are tailored to the work performed. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.9 Detecting and preventing quality problems. (414.1C, Attachment 2, 3(c)(1))

5.1.2.4.10 Work and operations authorizations required. (414.1C, Attachment 2, 2(a)(4))

5.1.2.4.11 Worker involvement. (414.1C, Attachment 2, 2(a)(4))

5.1.2.5 As applicable, contractual agreements, AB, and other regulatory requirements, including applicable local, state, and federal laws shall be considered for written procedures or instructions. (414.1C, Attachment 2, 2(a)(4); DE-AC27-01RV14136)

5.1.2.6 Instructions, procedures and drawings are reviewed, approved, and controlled in accordance with Policy Q-06.1, *Document Control.* (QARD, Rev 18, 5.2.3)

5.1.2.7 Quality assurance records generated by the implementing document shall be identified for retention and turnover. (QARD, Rev 18, 5.2.2.A.5, Management Requirement)

5.1.2.8 Quality assurance records are maintained in accordance with Policy Q-17.1, *Quality Assurance Records.* (Management Requirement)

Policy Q-06.1 Document Control

6.1.1 Purpose and Applicability

6.1.1.1 This policy establishes requirements to ensure documents that specify technical or quality requirements or prescribe activities affecting quality, including changes thereto, are reviewed for adequacy, approved for release, distributed for use at the location where the work is being performed, and used at the work location. (QARD, Rev 18, 6.1)

6.1.1.2 This policy applies to organizations and personnel involved in the preparation, issuance, control, and revision of documents. (Management Requirement)

6.1.1.3 Appendix A, Policy Q-06.1, *Document Control*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

6.1.2 Requirements

6.1.2.1 General

6.1.2.1.1 The preparation, issue, and change of documents that specify quality or technical requirements, or prescribe activities affecting quality such as instructions, procedures, and drawings, shall be controlled to ensure that correct documents are being employed. (NQA-1-2000, RQMT 6, 100; QARD, Rev 18, 4.2.2.F, 6.2.1.A)

6.1.2.1.2 Documents defined above, including changes thereto, shall be reviewed for adequacy and approved for issue by authorized personnel. (NQA-1-2000, RQMT 6, 100; QARD, Rev 18, 6.2.6.A)

6.1.2.1.3 Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements (technical, safety, and quality). (QARD, Rev 18, 6.2.3.A; Management Requirement)

6.1.2.2 Distribution and Use of Documents

6.1.2.2.1 The distribution and use of documents, including changes and editorial corrections to documents, shall include the following controls: (NQA-1-2000, RQMT 6, 200)

6.1.2.2.1.1 The documents to be controlled shall be identified. (NQA-1-2000, RQMT 6, 200(a))

6.1.2.2.1.2 The distribution of controlled documents for use at the appropriate location shall be specified. (NQA-1-2000, RQMT 6, 200(b))

6.1.2.2.1.3 Individuals responsible for the preparation, review, approval, and distribution of controlled documents shall be identified. (NQA-1-2000, RQMT 6, 200(c))

6.1.2.2.2 Controlled documents will be reviewed for completeness and approved prior to distribution. (NQA-1-2000, RQMT 6, 200(d))

6.1.2.2.3 A method shall be established to ensure the correct documents are being used. (NQA-1-2000, RQMT 6, 200(e))

6.1.2.3 Major Document Changes

6.1.2.3.1 Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated as affected organizations. (NQA-1-2000, RQMT 6, 301)

6.1.2.3.2 The reviewing organization shall have access to pertinent background data or information upon which to base their approval. (NQA-1-2000, RQMT 6, 301)

6.1.2.4 Minor Document Changes

6.1.2.4.1 Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. (NQA-1-2000, RQMT 6, 302; QARD, Rev 18, 6.2.8)

6.1.2.4.2 To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated. (NQA-1-2000, RQMT 6, 302)

Policy Q-07.1 Control of Purchased Items and Services

7.1.1 Purpose and Applicability

7.1.1.1 This policy identifies the requirements, (based on the complexity and importance of the item or service being procured as described in Policy Q-02.1, *Quality Assurance Program*, Section 2.1.2.2, "Graded Approach") for planning and executing procurement of items and services (Q/CM) to assure conformance with specified requirements. (DOE O 414.1C)

7.1.1.2 This policy applies to organizations responsible for planning and executing procurements. (Management Requirement)

7.1.1.3 Appendix A, Policy Q-07.1, *Control of Purchased Items and Services*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

7.1.2 Requirements

7.1.2.1 General

7.1.2.1.1 The procurement of items and services (Q/CM) shall be controlled to assure conformance with specified requirements. Such control shall provide for the following, as appropriate: (NQA-1-2000, RQMT 7, 100)

7.1.2.1.1.1 Source evaluation and selection. (NQA-1-2000, RQMT 7, 100)

7.1.2.1.1.2 Evaluation of objective evidence of quality furnished by the supplier. (NQA-1-2000, RQMT 7, 100)

7.1.2.1.1.3 Source inspection. (NQA-1-2000, RQMT 7, 100)

7.1.2.1.1.4 Audit. (NQA-1-2000, RQMT 7, 100)

7.1.2.1.1.5 Examination of items or services upon delivery or completion. (NQA-1-2000, RQMT 7, 100)

7.1.2.1.2 Records shall be established and maintained to indicate the performance of the following functions: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.1.2.1 Supplier evaluation and selection. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.1.2.2 Acceptance of items or services. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.1.2.3 Supplier nonconformances to procurement document requirements, including their evaluation and disposition. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.1.2.4 Utilization and acceptance of commercial grade items. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.1.2.5 Supplier deficiencies shall be documented and controlled in accordance with the applicable requirements of Policy Q-15.1, *Control of Nonconforming Items*, Policy Q-15.2, *Control of Suspect/Counterfeit Items* and Q-16.1, *Corrective Action*, or in accordance with the suppliers applicable program. (Management Requirement)

7.1.2.2 Supplier Evaluation and Selection

7.1.2.2.1 Prior to awarding a contract, the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results shall be documented and shall include one or more of the criteria listed below: (NQA-1-2000, RQMT 7, 200; QARD, Rev 18, 7.2.2.A; 7.2.2.C, 7.2.2.D)

7.1.2.2.1.1 Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability. (NQA-1-2000, RQMT 7, 200(a); QARD, Rev 18, 7.2.2.C.1, 7.2.3.B.5)

7.1.2.2.1.2 Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated. (NQA-1-2000, RQMT 7, 200(b); QARD, Rev 18, 7.2.2.C.2)

7.1.2.2.1.3 Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program. (NQA-1-2000, RQMT 7, 200(c); QARD, Rev 18, 7.2.2.C.3)

7.1.2.2.2 Source verification shall be performed by personnel qualified in accordance with Policy Q-02.4, *Personnel Training and Qualification.* (Management Requirement)

7.1.2.2.3 Subcontractors or suppliers qualified by Bechtel or Washington Group International (WGI) may be selected without further evaluation as delineated above, provided the subcontractors or suppliers are qualified for the intended services. Before initiation of work, supplier's quality assurance programs will be evaluated against project quality assurance requirements. (Management Requirement)

7.1.2.3 Proposal Bid Evaluation

7.1.2.3.1 The proposal/bid evaluation process shall include a determination of the suppliers' capability to conform to the technical and quality assurance requirements (procurement documents). (NQA-1-2000, RQMT 7, 300)

7.1.2.3.2 Prior to award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation. (NQA-1-2000, RQMT 7, 300; QARD, Rev 18, 7.2.3.C)

7.1.2.4 Control of Supplier Generated Documents

7.1.2.4.1 Controls shall be implemented to assure that the submittal and evaluation of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. (NQA-1-2000, RQMT 7, 400; QARD, Rev 18, 7.2.5.A, 7.2.5.B)

7.1.2.5 Acceptance of Items and Services

7.1.2.5.1 Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. (NQA-1-2000, RQMT 7, 501; QARD, Rev 18, 7.2.6.A)

7.1.2.5.2 Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the WTP site prior to installation or use. (NQA-1-2000, RQMT 7, 501; QARD, Rev 18, 7.2.6.B)

7.1.2.5.3 Purchaser methods used to accept an item or service from a supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the WTP, or a combination of these methods. (NQA-1-2000, RQMT 7, 502; QARD, Rev 18, 7.2.6.C, 7.2.6.C.1, 7.2.6.C.2)

7.1.2.6 Certificate of Conformance

7.1.2.6.1 When a Certificate of Conformance is used the following minimum requirements must be met: (NQA-1-2000, RQMT 7, 503; QARD, Rev 18, 7.2.7)

7.1.2.6.1.1 The certificate shall identify the purchased material or equipment, such as by the purchase order number. (NQA-1-2000, RQMT 7, 503(a); QARD, Rev 18, 7.2.7.A)

7.1.2.6.1.2 The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. (NQA-1-2000, RQMT 7, 503(b); QARD, Rev 18, 7.2.7.B)

7.1.2.6.1.2.1 This may be accomplished by either including a list of the specific requirements, or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, along with a suitable certificate. (NQA-1-2000, RQMT 7, 503(b))

7.1.2.6.1.2.2 The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment. (NQA-1-2000, RQMT 7, 503(b); QARD, Rev 18, 7.2.7.B)

7.1.2.6.1.3 The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances. (NQA-1-2000, RQMT 7, 503(c); QARD, Rev 18, 7.2.7.C)

7.1.2.6.1.4 The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the purchaser's or supplier's quality assurance program. (NQA-1-2000, RQMT 7, 503(d); QARD, Rev 18, 7.2.7.D)

7.1.2.6.1.5 The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser or supplier's quality assurance program. (NQA-1-2000, RQMT 7, 503(e); QARD, Rev 18, 7.2.7.E)

7.1.2.6.1.6 Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance. (NQA-1-2000, RQMT 7, 503(f); QARD, Rev 18, 7.2.7.F)

7.1.2.7 Source Verification

7.1.2.7.1 When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service. (NQA-1-2000, RQMT 7, 504)

7.1.2.7.2 Source verification shall include monitoring, witnessing, or observing selected activities. (NQA-1-2000, RQMT 7, 504; QARD, Rev 18, 7.2.8)

7.1.2.7.3 Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. (NQA-1-2000, RQMT 7, 504)

7.1.2.7.4 Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier. (NQA-1-2000, RQMT 7, 504; QARD, Rev 18, 7.2.8.C)

7.1.2.8 Receiving Inspection

7.1.2.8.1 When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier and ensure any outstanding issues have been resolved. (NQA-1-2000, RQMT 7, 505; QARD, Rev 18, 7.2.9, 7.2.9.A; Management Requirement)

7.1.2.8.1.1 The inspection shall be performed in accordance with inspection implementing documents. (QARD, Rev 18, 7.2.9.B)

7.1.2.8.1.2 The inspection shall be planned and executed according to the requirements of Policy Q-10.1, *Inspection.* (QARD, Rev 18, 7.2.9.D)

7.1.2.8.2 Purchased items shall be examined for potential suspect/counterfeit part characteristics, in accordance with Policy Q-15.2, *Control of Suspect/Counterfeit Items*. If identified as a potential suspect/counterfeit part, they shall be evaluated and, as appropriate, dispositioned as nonconforming items. (DOE O 414.1C, Attachment 2(4))

7.1.2.8.3 Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. (NQA-1-2000, RQMT 7, 505; QARD, Rev 18, 7.2.9.C)

7.1.2.8.4 Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. (NQA-1-2000, RQMT 7, 505; QARD, Rev 18, 7.2.9.E)

7.1.2.9 Post-Installation Testing

7.1.2.9.1 When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier. (NQA-1-2000, RQMT 7, 506; QARD, Rev 18, 7.2.10.A)

7.1.2.9.2 The test shall be in accordance with the requirements of Policy Q-11.1, *Test Control*. (QARD, Rev 18, 7.2.10.B)

7.1.2.10 Acceptance of Services Only

7.1.2.10.1 In cases involving procurement of services only, such as third party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any or all of the following methods: (NQA-1-2000, RQMT 7, 507)

7.1.2.10.1.1 Technical verification of data produced. (NQA-1-2000, RQMT 7, 507(a))

7.1.2.10.1.2 Surveillance and/or audit of the activity. (NQA-1-2000, RQMT 7, 507(b))

7.1.2.10.1.3 Review of objective evidence for conformance to the procurement document requirements. (NQA-1-2000, RQMT 7, 507(c))

7.1.2.11 Control of Supplier Nonconformances

7.1.2.11.1 Methods for control and disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements shall include the following: (NQA-1-2000, RQMT 7, 600; QARD, Rev 18, 7.2.11)

7.1.2.11.1.1 Evaluation of nonconforming items. (NQA-1-2000, RQMT 7, 600(a); QARD, Rev 18, 7.2.11.A)

7.1.2.11.1.2 Supplier submittal of nonconformance notice to the purchaser for approval as directed by the purchaser. These submittals shall include supplier-recommended disposition (e.g., use as-is or repair), and technical justification. (NQA-1-2000, RQMT 7, 600(b); QARD, Rev 18, 7.2.11.B)

7.1.2.11.1.3 Nonconformances to the procurement requirements or purchaser approved documents which consist of one or more of the following, shall be submitted to the purchaser for approval of the recommended disposition: (NQA-1-2000, RQMT 7, 600(b); QARD, Rev 18, 7.2.11.B)

7.1.2.11.1.3.1 Technical or material requirement is violated. (NQA-1-2000, RQMT 7, 600(b)(1); QARD, Rev 18, 7.2.11.B.1)

7.1.2.11.1.3.2 A requirement in supplier documents, which have been approved by the purchaser is violated. (NQA-1-2000, RQMT 7, 600(b)(2); QARD, Rev 18, 7.2.11.B.2)

7.1.2.11.1.3.3 Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework. (NQA-1-2000, RQMT 7, 600(b)(3); QARD, Rev 18, 7.2.11.B.3)

7.1.2.11.1.3.4 The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired. (NQA-1-2000, RQMT 7, 600(b)(4); QARD, Rev 18, 7.2.11.B.4)

7.1.2.11.1.4 Purchaser disposition of the supplier's recommendation. (NQA-1-2000, RQMT 7, 600(c); QARD, Rev 18, 7.2.11.C)

7.1.2.11.1.5 Verification of the implementation of the disposition. (NQA-1-2000, RQMT 7, 600(d); QARD, Rev 18, 7.2.11.D)

7.1.2.11.1.6 Maintenance of records of supplier-submitted nonconformances. (NQA-1-2000, RQMT 7, 600(e); QARD, Rev 18, 7.2.11.E)

7.1.2.12 Commercial Grade Items/Services (CGI/CGS)

7.1.2.12.1 General

7.1.2.12.1.1 When CGIs or CGSs are utilized, the dedicating entity can utilize the requirements of Section 7.1.2.12, "Commercial Grade Items/Services" for procurement and acceptance of items or services as an acceptable alternative to the above policy, except that supplier evaluation and selection, where determined necessary by the purchaser, shall be in accordance with Section 7.1.2.2, "Supplier Evaluation and Selection" of this policy. The applicable requirements of this manual shall apply to dedication activities for acceptance. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.1.2 Sampling plans utilized to select items for special test(s), inspection(s), and / or analysis shall have an adequate technical basis based on established standards that consider lot traceability, homogeneity, and the complexity of the item. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2 Commercial Grade Utilization

7.1.2.12.2.1 The utilization of CGIs or CGSs shall include the following: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2.1.1 Technical evaluation to determine that the item or service performs a safety function. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2.1.2 Confirmation that the item or service meets the commercial grade definition criteria. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2.1.3 Identification of the critical characteristics, including acceptance criteria. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2.1.4 Selection, performance, and documentation of the dedication method(s) for determining compliance with acceptance criteria. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.2.2 When one or more critical characteristics for acceptance cannot be verified by the dedication methods, the requirements of this section shall not be utilized to procure and accept the CGI or CGS. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.3 Commercial Grade Critical Characteristics

7.1.2.12.3.1 Critical characteristic selection for acceptance shall address the following: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.3.1.1 Identifiable and measurable attributes or variables appropriate for the safety function. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.3.1.2 Criteria related to the location of the item in the facility or criteria addressing the most severe location of the item in the facility, unless controls are in place to prevent usage in undesignated locations. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4 Commercial Grade Dedication

7.1.2.12.4.1 The dedicating entity shall provide reasonable assurance that the CGI or CGS meets the acceptance criteria for the identified critical characteristics. The four methods that can be used to accept commercial grade items or services are:

(NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.1.1 Special tests, inspections, and/or analyses performed in accordance with the requirements of Policy Q-03.1, Q-10.1, and/or Q-11.1 as appropriate. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II; Management Requirement)

7.1.2.12.4.1.2 Commercial grade survey of the supplier (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.1.3 Source verification (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.1.4 Acceptable supplier/item performance record. If this method is used, it shall be used in combination with one or more of the other commercial grade items or service acceptance methods described in this section. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.2 The four acceptance methods provide, either individually or in combination, a means to reasonably ensure that a CGI which is received meets the requirements of the item specified. The results of employing each method shall be documented by the purchaser. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.3 Prior to acceptance of the CGI or CGS, the dedicating entity shall determine the following, as applicable: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.3.1 Damage was not sustained during shipment. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.3.2 The item or service has satisfied the specified acceptance criteria for the identified critical characteristics. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.4.3.3 Specified documentation was received and is acceptable. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5 Commercial Grade Survey

7.1.2.12.5.1 A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following: (NQA-1-2000,

as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.1.1 Identification of the item(s), or product line, or service included within the scope of the survey. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.1.2 Identification of the critical characteristics to be controlled by the supplier. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.1.3 Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.1.4 Identification of the survey methods or verification activities performed with results obtained. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.1.5 Documentation of the adequacy of the supplier's processes and controls. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.2 A commercial grade survey shall not be employed as a basis for accepting CGIs or CGSs from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls as a part of the purchase order or control requirements for the CGI or CGS and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.5.3 The dedicating entity shall establish the survey frequency for reconfirming the previous survey information for application to additional purchases. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6 Commercial Grade Source Verification

7.1.2.12.6.1 Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location. Commercial grade source verification shall be performed in accordance with Section 7.1.2.7, "Source Verification" of this policy, including a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity, and shall include or address the following: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6.1.1 Identification of the item(s) or service(s) included within the scope of the source verification. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6.1.2 Identification of the critical characteristics, including acceptance criteria, to be controlled by the supplier. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6.1.3 Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6.1.4 Identification of the activities witnessed during the source verification and the results obtained. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.6.1.5 Documentation of the adequacy of the supplier's processes and controls. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7 Commercial Grade Acceptable Supplier Item/Services Performance Records

7.1.2.12.7.1 An acceptable supplier/item/service performance record shall include the following: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.1.1 Identification of the supplier/item/service being evaluated. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.1.2 Identification of previously established critical characteristics specific to the supplier/item/service. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.1.3 Identification of industry data examined to evaluate the supplier/item/service. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.1.4 Identification of basis for determining that industry data substantiates acceptability of the supplier/item/service. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.1.5 Documentation of the adequacy and acceptance of the supplier/item/service performance record. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.2 An acceptable supplier/item/service performance record shall not be employed unless: (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.2.1 The established historical record is based on industry-wide performance data that are directly applicable to the critical characteristics and the intended facility application, i.e., a single source of information is not adequate to demonstrate satisfactory performance. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.2.2 The manufacturer/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.7.3 Continued application of an acceptable supplier/item/service performance record shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

7.1.2.12.8 Commercial Grade Supplier Deficiency Correction

7.1.2.12.8.1 Deficiencies identified in the supplier's processes and controls, identified in the dedication process, shall be corrected by the supplier and verified by the dedicating entity, if the specified dedication process is to be used to verify an identified critical characteristic. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

Policy Q-08.1 Identification and Control of Items

8.1.1 Purpose and Applicability

8.1.1.1 This policy identifies the requirements for identifying and controlling items (including consumables and partially fabricated assemblies) to assure that only correct and accepted items are used or installed. (QARD, Rev 18, 8.1.A)

8.1.1.2 This policy applies to organizations involved in identifying and controlling items during research and development, design, procurement, construction, fabrication, commissioning, operation and maintenance phases of facilities for which BNI has responsibility. (Management Requirement)

8.1.1.3 Appendix A, Policy Q-08.1, *Identification and Control of Items*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

8.1.2 Requirements

8.1.2.1 General

8.1.2.1.1 Controls shall be established to assure that only correct and accepted items are used or installed. (NQA-1-2000, RQMT 8, 100)

8.1.2.2 Identification

8.1.2.2.1 Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures identification is established and maintained. (NQA-1-2000, RQMT 8, 100; QARD, Rev 18, 8.2.1.A)

8.1.2.2.2 Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. (NQA-1-2000, RQMT 8, 201; QARD, Rev 18, 8.2.1.B)

8.1.2.2.3 This identification shall relate an item to an applicable design or other pertinent specifying document. (NQA-1-2000, RQMT 8, 201; QARD, Rev 18, 8.2.1.C)

8.1.2.3 Physical Identification

8.1.2.3.1 Physical identification shall be used to the maximum extent possible. (NQA-1-2000, RQMT 8, 202; QARD, Rev 18, 8.2.2.A)

8.1.2.3.2 If physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or procedural control). (NQA-1-2000, RQMT 8, 202; QARD, Rev 18, 8.2.2.A)

8.1.2.3.3 Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. (NQA-1-2000, RQMT 8, 202; QARD, Rev 18, 8.2.2.B.1, 8.2.2.B.2)

8.1.2.3.4 Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted. (NQA-1-2000, RQMT 8, 202; QARD, Rev 18, 8.2.2.B.3, 8.2.2.B.4)

8.1.2.4 Traceability

8.1.2.4.1 When codes, standards, or specifications include specific identification or traceability requirements (e.g., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control. (NQA-1-2000, RQMT 8, 301; QARD, Rev 18, 8.2.3.A)

8.1.2.5 Limited Life Items

8.1.2.5.1 Items having a limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired. (NQA-1-2000, RQMT 8, 302)

8.1.2.6 Maintaining Identification of Stored Items

8.1.2.6.1 Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: (NQA-1-2000, RQMT 8, 303; QARD, Rev 18, 8.2.3.D)

8.1.2.6.1.1 Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging. (NQA-1-2000, RQMT 8, 303(a); QARD, Rev 18, 8.2.3.D.1)

8.1.2.6.1.2 Protection of identifications on items subject to excessive deterioration due to environmental exposure. (NQA-1-2000, RQMT 8, 303(b); QARD, Rev 18, 8.2.3.D.2)

8.1.2.6.1.3 Provisions for updating existing plant records. (NQA-1-2000, RQMT 8, 303(c); QARD, Rev 18, 8.2.3.D.3)

Policy Q-09.1 Control of Special Processes

9.1.1 Purpose and Applicability

9.1.1.1 This section establishes the requirements to ensure that special processes are controlled. (Management Requirement)

9.1.1.2 This policy applies to organizations performing special processes. (Management Requirement)

9.1.1.3 Appendix A, Policy Q-09.1, *Control of Special Processes*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

9.1.2 Requirements

9.1.2.1 Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements. (NQA-1-2000, RQMT 9, 100; QARD, Rev 18, 9.1.A)

9.1.2.2 Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. (NQA-1-2000, RQMT 9, 201; QARD, Rev 18, 9.2.1.A)

9.1.2.3 Special process instructions shall include or reference:

9.1.2.3.1 Procedure, personnel, and equipment qualification requirements. (NQA-1-2000, RQMT 9, 201; QARD, Rev 18, 9.2.2.C)

9.1.2.3.2 Conditions necessary for accomplishment of the process. (NQA-1-2000, RQMT 9, 201; QARD, Rev 18, 9.2.2.D)

9.1.2.3.3 Proper equipment, controlled parameters of the process, specified environment, and calibration requirements. (NQA-1-2000, RQMT 9, 201; QARD, Rev 18, 9.2.2.D)

9.1.2.3.4 Requirements of applicable codes and standards, including acceptance criteria for the process. (NQA-1-2000, RQMT 9, 202; QARD, Rev 18, 9.2.2.E)

9.1.2.3.5 The necessary requirements for qualifications of personnel, procedures, or equipment for special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards. (NQA-1-2000, RQMT 9, 203; QARD, Rev 18, 9.2.1.A)

9.1.2.4 Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process. (NQA-1-2000, RQMT 9, 400)

Policy Q-10.1 Inspection

10.1.1 Purpose and Applicability

10.1.1.1 This policy identifies the requirements for specifying, planning, performing, and reporting inspections used to verify the acceptance of items or activities. The inspection process is designed to prevent the inadvertent acceptance and use of nonconforming items. (QARD, Rev. 18, 10.1; Management Requirement)

10.1.1.2 This policy applies to organizations performing inspections used to verify acceptance of items and activities. (Management Requirement)

10.1.1.3 Appendix A, Policy Q-10.1, *Inspection*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

10.1.2 Requirements

10.1.2.1 General

10.1.2.1.1 Inspections required to verify conformance of an item or activity to specified requirements or the continued acceptability of items in service shall be planned and executed. (NQA-1-2000, RQMT 10, 100)

10.1.2.1.2 Characteristics subject to inspection and inspection methods shall be specified. (NQA-1-2000, RQMT 10, 100)

10.1.2.1.3 Inspection results shall be documented. (NQA-1-2000, RQMT 10, 100)

10.1.2.1.4 Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. (NQA-1-2000, RQMT 10, 100)

10.1.2.2 Inspection Requirements

10.1.2.2.1 Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. (NQA-1-2000, RQMT 10, 200)

10.1.2.3 Inspection Hold Points

10.1.2.3.1 If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. (NQA-1-2000, RQMT 10, 300; QARD, Rev 18, 10.2.3.A)

10.1.2.3.2 Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point. (NQA-1-2000, RQMT 10, 300; QARD, Rev 18, 10.2.3.B)

10.1.2.4 Planning

10.1.2.4.1 Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. (NQA-1-2000, RQMT 10, 401)

10.1.2.4.2 When sampling procedures are used, they shall be based on valid statistical methods. (NQA-1-2000, RQMT 10, 402; QARD, Rev 18, 10.2.4)

10.1.2.5 In-Process Inspection and Monitoring

10.1.2.5.1 Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. (NQA-1-2000, RQMT 10, 500; QARD, Rev 18, 10.2.5.A)

10.1.2.5.2 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. (NQA-1-2000, RQMT 10, 500; QARD, Rev 18, 10.2.5.A)

10.1.2.5.3 Both inspection and process monitoring shall be provided when control is inadequate without both. (NQA-1-2000, RQMT 10, 500; QARD, Rev 18, 10.2.5.B)

10.1.2.6 Final Inspections

10.1.2.6.1 Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. (NQA-1-2000, RQMT 10, 601; QARD, Rev 18, 10.2.6.C)

10.1.2.6.2 Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. (NQA-1-2000, RQMT 10, 602; QARD, Rev 18, 10.2.6.A)

10.1.2.6.3 Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability. (NQA-1-2000, RQMT 10, 603; QARD, Rev 18, 10.2.6.D)

10.1.2.6.4 Appropriate records shall be established, maintained and, as a minimum, identify the following: (NQA-1-2000, RQMT 10, 700; QARD, Rev 18, 10.2.8)

10.1.2.6.4.1 Item inspected. (NQA-1-2000, RQMT 10, 700(a); QARD, Rev 18, 10.2.8.A)

10.1.2.6.4.2 Date of inspection. (NQA-1-2000, RQMT 10, 700(b); QARD, Rev 18, 10.2.8.B)

10.1.2.6.4.3 The name or unique identifier of the inspector who documented, evaluated, and determined acceptability. (NQA-1-2000, RQMT 10, 700(c); QARD, Rev 18, 10.2.8.C)

10.1.2.6.4.4 The name of the data recorder, as applicable. (QARD, Rev 18, 10.2.8.D)

10.1.2.6.4.5 Type of observation or method of inspection. (NQA-1-2000, RQMT 10, 700(d); QARD, Rev 18, 10.2.8.E)

10.1.2.6.4.6 The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance. (QARD, Rev 18, 10.2.8.F)

10.1.2.6.4.7 Results indicating acceptability of characteristics inspected. (NQA-1-2000, RQMT 10, 700(e); QARD, Rev 18, 10.2.8.G)

10.1.2.6.4.8 Measuring and test equipment used during the inspection, including the identification number and the most recent calibration date. (QARD, Rev 18, 10.2.8.H)

10.1.2.6.4.9 Reference to information on action taken in connection with nonconformances. (NQA-1-2000, RQMT 10, 700(f); QARD, Rev 18, 10.2.8.I)

Policy Q-11.1 Test Control

11.1.1 Purpose and Applicability

11.1.1.1 This policy identifies the requirements for planning and executing tests that are used to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service. The test control process is designed to prevent the use of failed or untested items. (QARD, Rev 18, 11.1.A; Management Requirement)

11.1.1.2 This policy applies to organizations and personnel involved in performing tests used to verify conformance of an item to specified requirements to demonstrate satisfactory performance for service. (Management Requirement)

11.1.1.3 Appendix A, Policy Q-11.1, *Test Control*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

11.1.2 Requirements

11.1.2.1 General

11.1.2.1.1 Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. (NQA-1-2000, RQMT 11, 100)

11.1.2.1.2 Characteristics to be tested and test methods to be employed shall be specified. (NQA-1-2000, RQMT 11, 100)

11.1.2.1.3 Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated. (NQA-1-2000, RQMT 11, 100)

11.1.2.2 Test Requirements

11.1.2.2.1 Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. (NQA-1-2000, RQMT 11, 200(a); QARD, Rev 18, 11.2.2.C)

11.1.2.2.2 Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, operational tests, computer program tests such as software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. (NQA-1-2000, RQMT 11, 200(a); QARD, Rev 18, 11.1.A.2)

11.1.2.2.3 Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. (NQA-1-2000, RQMT 11, 200(a))

11.1.2.2.4 The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance. (NQA-1-2000, RQMT 11, 200(a))

11.1.2.2.5 Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements. (NQA-1-2000, RQMT 11, 200(b); QARD, Rev 18, 11.1.A.1, 11.2.2.D)

11.1.2.2.6 If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority and the organization responsible for the facility is required prior to performing the test. (NQA-1-2000, RQMT 11, 200(c); Management Requirement)

11.1.2.3 Test Procedures

11.1.2.3.1 Test procedures shall include or reference the test configuration and test objectives. (NQA-1-2000, RQMT 11, 300(a); QARD, Rev 18, 11.2.2.B)

11.1.2.3.2 Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. (NQA-1-2000, RQMT 11, 300(a); QARD, Rev 18, 11.2.2.B)

11.1.2.3.3 Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, including accuracy requirements, trained personnel, condition of test equipment and the completeness of the item to be tested, suitable environmental conditions, and provisions for data acquisition and storage. (NQA-1-2000, RQMT 11, 300(a); QARD, Rev 18, 11.2.1.E)

11.1.2.4 Use of Other Testing Documents

11.1.2.4.1 As an alternative to Section 11.1.2.3, "Test Procedures" above, appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria can be used. (NQA-1-2000, RQMT 11, 300(b); QARD, Rev 18, 11.2.3.A)

11.1.2.5 Computer Program Test Procedures

11.1.2.5.1 The following requirements apply instead of Sections 11.1.2.3, "Test Procedures" and 11.1.2.4, "Use of Other Testing Documents" to testing of computer programs, and as appropriate, the computer hardware and operating system. (NQA-1-2000, RQMT 11, 400)

11.1.2.5.2 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. (NQA-1-2000, RQMT 11, 400(a); QARD, Supplement I, I.2.3.D.3)

11.1.2.5.2.1 For those computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces

correct results. (NQA-1-2000, RQMT 11, 400(a); QARD, Supplement I, I.2.3.B.4(e), I.2.3.B.4(f), I.2.3.B.4(g))

11.1.2.5.2.2 For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. (NQA-1-2000, RQMT 11, 400(a); QARD, Supplement I, I.2.3.B.4(g))

11.1.2.5.3 The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature. (NQA-1-2000, RQMT 11, 400(a); QARD, Supplement I, I.2.3.D.5)

11.1.2.5.4 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer platform, or when there are significant changes in the operating system. (NQA-1-2000, RQMT 11, 400(b); QARD, Supplement I, I.2.3.E.5)

11.1.2.5.5 Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance. (NQA-1-2000, RQMT 11, 400(b); QARD, Supplement I, I.2.3.E.5)

11.1.2.6 Test Results

11.1.2.6.1 Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. (NQA-1-2000, RQMT 11, 500; QARD, Rev 18, 11.2.4.A)

11.1.2.6.2 Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization. (NQA-1-2000, RQMT 11, 500)

11.1.2.7 Test Documentation

11.1.2.7.1 Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. (NQA-1-2000, RQMT 11, 600)

Policy Q-12.1 Control of Measuring and Test Equipment

12.1.1 Purpose and Applicability

12.1.1.1 This policy identifies the requirements for controlling measuring and test equipment. (Management Requirement)

12.1.1.2 This policy applies to organizations that use or calibrate measuring and test equipment for determining acceptance of items and activities, process monitoring, data collection, or other activities affecting quality. (Management Requirement)

12.1.1.3 Software developed or modified by the user shall be controlled in accordance with Policy Q-03.2, *Software Quality*. (QARD, Rev 18, 12.2.1.A)

12.1.1.4 Appendix A, Policy Q-12.1, *Control of Measuring and Test Equipment*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

12.1.2 Requirements

12.1.2.1 General

12.1.2.1.1 Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits. (NQA-1-2000, RQMT 12, 100; QARD, Rev 18, 12.1)

12.1.2.1.2 Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. (NQA-1-2000, RQMT 12, 200; QARD, Rev 18, 12.2.2.B)

12.1.2.1.3 Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform their intended function. (NQA-1-2000, RQMT 12, 400)

12.1.2.2 Calibration

12.1.2.2.1 Measuring and test equipment shall be calibrated at prescribed time periods or usage. A calibration or calibration check shall be performed whenever the accuracy of the equipment is suspect or the equipment is removed from service. (NQA-1-2000, RQMT 12, 301; QARD, Rev 18, 12.2.1.A, 12.2.1.E, 12.2.1.E.1, 12.2.1.E.2)

12.1.2.2.2 Calibration shall be against certified equipment having known valid relationships to nationally recognized standards. (NQA-1-2000, RQMT 12, 301; QARD, Rev 18, 12.2.1.A)

12.1.2.2.2.1 If no nationally recognized standards exist, the basis for calibration shall be documented. (NQA-1-2000, RQMT 12, 301; QARD, Rev 18, 12.2.1.A)

12.1.2.3 Control

12.1.2.3.1 Calibration procedures shall identify or reference required accuracy. (NQA-1-2000, RQMT 12, 302)

12.1.2.3.2 Methods and frequency of checking accuracy shall be defined in procedures. (NQA-1-2000, RQMT 12, 302)

12.1.2.3.3 The calibration method and interval of calibration for measuring and test equipment shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, degree of use, precision, and other conditions affecting capability. (NQA-1-2000, RQMT 12, 302; QARD, Rev 18, 12.2.1.D)

12.1.2.3.4 Out-of-calibration measuring and test equipment shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated. (NQA-1-2000, RQMT 12, 302; QARD, Rev 18, 12.2.3.B, 12.2.3.B.1)

12.1.2.3.5 If any measuring and test equipment is consistently found out of calibration during the re-calibration process, it shall be repaired or replaced. (NQA-1-2000, RQMT 12, 302; QARD, Rev 18, 12.2.3.C)

12.1.2.3.5.1 When measuring and test equipment are found to be out of calibration, an evaluation commensurate with the significance of the condition shall be made and documented including the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. (NQA-1-2000, RQMT 12, 302.1; QARD, Rev 18, 12.2.3.B.2, 12.2.3.B.2(a), 12.2.3.B.2(b))

12.1.2.3.5.2 Measuring and test equipment shall be properly handled and stored to maintain accuracy. (NQA-1-2000, RQMT 12, 302.2; QARD, Rev 18, 12.2.5.A)

12.1.2.3.5.3 Equipment shall be suitably marked or otherwise identified to indicate calibration status. (NQA-1-2000, RQMT 12, 302.3; QARD, Rev 18, 12.2.1.F)

12.1.2.3.5.4 If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Policy Q-15.1, *Control of Nonconforming Items*. (QARD, Rev 18, 12.2.3.B.2(c))

12.1.2.3.5.5 Inspections or tests shall be repeated for items determined to be suspect. (QARD, Rev 18, 12.2.3.B.2(c))

12.1.2.4 Commercial Devices

12.1.2.4.1 Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy. (NQA-1-2000, RQMT 12, 303; QARD, Rev 18, 12.2.6)

Policy Q-13.1 Handling, Storage, and Shipping

13.1.1 Purpose and Applicability

13.1.1.1 This policy identifies the requirements for handling, storing, cleaning, packaging, shipping, housekeeping, and preservation of items and consumables, in accordance with design and procurement requirements, to prevent damage or loss and to minimize deterioration. (QARD, Rev 18, 13.1)

13.1.1.2 This policy applies to organizations that handle, store, clean, package, ship, and preserve items. (Management Requirement)

13.1.2 Requirements

13.1.2.1 General

13.1.2.1.1 Handling, storage, cleaning, packaging, shipping, housekeeping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. (NQA-1-2000, RQMT 13, 100; QARD, Rev 18, 13.2.1.A)

13.1.2.1.2 These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity. (NQA-1-2000, RQMT 13, 100; QARD, Rev 18, 13.2.1.A)

13.1.2.1.3 When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified. (NQA-1-2000, RQMT 13, 200; QARD, Rev 18, 13.2.2.A, 13.2.2.B)

13.1.2.1.4 When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. (NQA-1-2000, RQMT 13, 300; QARD, Rev 18, 13.2.1.B)

13.1.2.1.5 Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. (NQA-1-2000, RQMT 13, 400; QARD, Rev 18, 13.2.2.C)

13.1.2.1.6 Special handling tools and equipment shall be inspected and tested periodically or prior to use as necessary to ensure performance. (NQA-1-2000, RQMT 13, 400; QARD, Rev 18, 13.2.2.D)

13.1.2.1.7 Operators of special handling and lifting equipment shall be experienced or trained to use the equipment. (NQA-1-2000, RQMT 13, 500; QARD, Rev 18, 13.2.2.E)

13.1.2.2 Marking and Labeling

13.1.2.2.1 Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls. (NQA-1-2000, RQMT 13, 600; QARD, Rev 18, 13.2.3.A, 13.2.3.B)

Policy Q-14.1 Inspection, Test, and Operating Status

14.1.1 Purpose and Applicability

14.1.1.1 This policy establishes the requirements to identify the inspection, test, and operating status of items throughout fabrication, construction, installation, and testing. (QARD, Rev 18, 14.1)

14.1.1.2 This policy applies to organizations involved in the application and maintenance of status indicators to prevent inadvertent installation, use, or operation of items. (Management Requirement)

14.1.2 Requirements

14.1.2.1 The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. (NQA-1-2000, RQMT 14, 100; QARD, Rev 18, 14.2.2.A)

14.1.2.2 Status shall be maintained through legible indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. (NQA-1-2000, RQMT 14, 100; QARD, Rev 18, 14.2.2.B, 14.2.2.C)

14.1.2.3 The authority for application and removal of tags, markings, labels, and stamps shall be specified. (NQA-1-2000, RQMT 14, 100; QARD, Rev 18, 14.2.2.D)

14.1.2.4 Status indicators shall also provide for indicating the operating status of systems and components, such as by tagging valves and switches, to prevent inadvertent operation or changes in operating status. These indicators shall be placed at all locations where operation of the item can be initiated, such as control panels, switches, breakers, valves, or systems. (NQA-1-2000, RQMT 14, 100; QARD, Rev 18, 14.2.2.E)

14.1.2.5 Items that have satisfactorily passed required inspections and tests shall be identified. (QARD, Rev 18, 14.2.1.A)

14.1.2.6 The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests. (QARD, Rev 18, 14.2.1.B)

Policy Q-15.1 Control of Nonconforming Items

15.1.1 Purpose and Applicability

15.1.1.1 This policy identifies the requirements for controlling items that do not conform to specified requirements, including suspect/counterfeit items, to prevent their inadvertent installation or use. (QARD Rev 18, 15.1.A; Management Requirement)

15.1.1.2 The requirements identified in this policy are not required when nonconforming items are discovered while in an in-process status. These items shall be under work process control procedures and are re-worked within the scope of the work process control to meet existing design requirements. (Management Requirement)

15.1.1.3 Appendix A, Policy Q-15.1, *Control of Nonconforming Items*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities.* (QARD, Rev. 18, 2.1, 2.2.2)

15.1.2 Requirements

15.1.2.1 General

15.1.2.1.1 Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. (NQA-1-2000, RQMT 15, 100; QARD Rev 18, 15.1.A)

15.1.2.1.2 Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. (NQA-1-2000, RQMT 15, 100)

15.1.2.1.3 The responsibility and authority for the evaluation and disposition of nonconforming items and the records produced shall be defined. (NQA-1-2000, RQMT 15, 402)

15.1.2.1.4 Nonconformances shall be tracked and trended in accordance with the requirements of Policy Q-16.1, *Corrective Action.* (QARD, Rev 18, 15.2.1.B)

15.1.2.2 Identification

15.1.2.2.1 Nonconforming items shall be identified by legible and easily recognizable marking, tagging, segregation, or other methods not detrimental to the item, on either the item, the container, or the package containing the item. (NQA-1-2000, RQMT 15, 200; QARD Rev 18, 15.2.2.A, 15.2.2.B)

15.1.2.3 Segregation

15.1.2.3.1 Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. (NQA-1-2000, RQMT 15, 300(a); QARD Rev 18, 15.2.3.A)

15.1.2.3.2 When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of the nonconforming item. (NQA-1-2000, RQMT 15, 300(b); QARD Rev 18, 15.2.3.B)

15.1.2.4 Disposition Control

15.1.2.4.1 Nonconforming items shall be evaluated and recommended dispositions shall be proposed. (NQA-1-2000, RQMT 15, 401; QARD Rev 18, 15.2.1.D)

15.1.2.4.2 Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel. (NQA-1-2000, RQMT 15, 401; QARD Rev 18, 15.2.1.H)

15.1.2.4.3 Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing. (NQA-1-2000, RQMT 15, 402)

15.1.2.4.4 Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information. (NQA-1-2000, RQMT 15, 403)

15.1.2.4.5 A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. (NQA-1-2000, RQMT 15, 404; QARD Rev 18, 15.2.4.A)

15.1.2.4.6 The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use-as-is shall be documented. (NQA-1-2000, RQMT 15, 404; QARD Rev 18, 15.2.4.B)

15.1.2.4.7 Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. (NQA-1-2000, RQMT 15, 404)

15.1.2.4.8 Required as-built records shall reflect the use-as-is or repair condition. (NQA-1-2000, RQMT 15, 404)

15.1.2.4.9 Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria. (NQA-1-2000, RQMT 15, 405; QARD Rev 18, 15.2.4.D)

Policy Q-15.2 Control of Suspect/Counterfeit Items

15.2.1 Purpose and Applicability

15.2.1.1 This policy identifies the requirements for identifying, analyzing, and dispositioning Suspect/Counterfeit Items (S/CIs) and preventing S/CIs from being supplied through the collection, analysis, and dissemination of S/CI information. (DOE O 414.1C, Attachment 2, 4(a))

15.2.1.2 This policy applies to organizations and personnel involved in engineering, design, procurement, testing, inspection, installation, and maintenance. (DOE O 414.1C, Attachment 2, 4(a)(1))

15.2.2 Requirements

15.2.2.1 General

15.2.2.1.1 Prevention of the introduction and use of S/CIs shall be managed utilizing work process controls, such as engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned. (DOE O 414.1C, Attachment 2, 4(a)(1))

15.2.2.1.2 Procedures that implement the S/CI program shall include the following elements. (DOE O 414.1C, Attachment 2, 4(b))

15.2.2.1.2.1 Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment. (DOE O 414.1C, Attachment 2, 4(b)(1))

15.2.2.1.2.2 Identification and disposal of S/CIs onsite. (DOE O 414.1C, Attachment 2, 4(a)(3))

15.2.2.1.2.3 Inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. (DOE O 414.1C, Attachment 2, 4(b)(3); Management Requirement)

15.2.2.1.2.4 Controls shall ensure that the uses of S/CIs are restricted to only those items that have been found acceptable through engineering analysis and a formal disposition process. (DOE O 414.1C, Attachment 2, 4(a)(4))

15.2.2.1.2.5 A listing of S/CIs of concern shall be developed to collect, maintain and disseminate SC/I information. The list shall be up-to-date, accurate using all available sources including: (DOE O 414.1C, Attachment 2, 4(a)(5))

15.2.2.1.2.5.1 Government Industry Data Exchange Program. (DOE O 414.1C, Attachment 2, 4(a)(5)(a))

15.2.2.1.2.5.2 Institute of Nuclear Power Operations. (DOE O 414.1C, Attachment 2, 4(a)(5)(b))

15.2.2.1.2.5.3 DOE Occurrence Reporting and Processing System. (DOE O 414.1C, Attachment 2, 4(a)(5)(c))

15.2.2.1.2.5.4 DOE S/CI website. (DOE O 414.1C, Attachment 2, 4(a)(5)(d))

15.2.2.1.2.6 Procurement processes that prevent introduction of S/CIs by: (DOE O 414.1C, Attachment 2, 4(b)(2))

15.2.2.1.2.6.1 Identifying technical and QA requirements in procurement specifications. (DOE O 414.1C, Attachment 2, 4(b)(2)(a))

15.2.2.1.2.6.2 Accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices. (DOE O 414.1C, Attachment 2, 4(b)(2)(b))

15.2.2.1.2.6.3 Assuring that inventory and storage areas are periodically inspected to identify S/CI. (DOE O 414.1C, Attachment 2, 4(b)(2)(c))

15.2.2.1.2.7 Controls that provide for identification, inspection, documentation, evaluation, segregation when practical, notification of relevant organizations, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards. (DOE O 414.1C, Attachment 2, 4(b)(3))

15.2.2.1.2.8 Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the public and workers cost/benefit impact, and a schedule for replacement (if required). (DOE O 414.1C, Attachment 2, 4(b)(4))

15.2.2.1.2.9 Controls that ensure S/CIs in non-safety applications identified during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications. (DOE O 414.1C, Attachment 2, 4(b)(5))

15.2.2.1.2.10 Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation. (DOE O 414.1C, Attachment 2, 4(b)(6))

15.2.2.1.2.11 Testing procured or installed S/CIs as necessary using approved engineering test methods. (DOE O 414.1C, Attachment 2, 4(b)(7))

15.2.2.1.2.12 Controls that ensure S/CIs identified by WTP personnel are reported to responsible DOE/NNSA line management office, the Office of Environment, Safety and Health, and the Office of the Inspector General. (DOE O 414.1C, Attachment 2, 4(b)(8))

15.2.2.1.2.13 Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention. (DOE O 414.1C, Attachment 2, 4(b)(9))

15.2.2.2 Training

15.2.2.2.1 Managers, supervisors, and workers shall receive initial and continuing training on S/CI processes and controls (including prevention, detection, and disposition of S/CIs). (DOE O 414.1C, Attachment 2, 4(a)(2))

Policy Q-16.1 Corrective Action

16.1.1 Purpose and Applicability

16.1.1.1 This policy identifies the requirements for ensuring that conditions adverse to safety, health, quality, security, and the environment are promptly identified, controlled, documented, evaluated, corrected, and trended. (DOE O 226.1A, Attachment 1, 2(a), 2(b)(4), 2(c), Appendix A, 1(a), 1(b); QARD, Rev 18, 16.1)

16.1.1.2 This policy applies to all organizations responsible for achieving, maintaining, and verifying the adequacy of items, services, and activities of facilities, programs, and projects. (Management Requirement)

16.1.1.3 This policy provides for the identification of problems, recommendations and/or opportunities for improvement. For adverse conditions, this policy provides the requirements for causal analysis, identification of corrective actions and recurrence controls, corrective action tracking and monitoring, closure of corrective actions and verification of effectiveness, and trend analysis. (DOE O 226.1A, Attachment 1, Appendix A, 1(b)(4), 5, 5(a))

16.1.1.4 This policy applies to conditions identified by employees in performance of their routine duties including internal independent audits, surveillances, and management assessments and to conditions identified by external agencies. (DOE O 226.1A, Attachment 1, Appendix A, 1(b)(4), 5(c))

16.1.1.5 Adverse conditions include any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances, as defined in Appendix C, *Glossary*. A significant adverse condition is one, if uncorrected, could have a serious effect on safety or operability. (QARD, Rev 18, 16.2.1; Management Requirement)

16.1.2 Requirements

16.1.2.1 Communication

16.1.2.1.1 Processes for communication of adverse conditions shall be established using a graded approach as described in Policy Q-02.1, *Quality Program*. These communication processes shall provide: (DOE O 226.1A, Attachment 1, Appendix A, 5(d))

16.1.2.1.1.1 Sufficient technical basis to permit informed decisions.

16.1.2.1.1.2 Provisions for communicating and documenting dissent.

16.1.2.1.1.3 Provisions for resolving disputes.

16.1.2.1.1.4 Provisions for independent technical reviews of significant conditions.

16.1.2.2 Classification

16.1.2.2.1 Problems, recommendations and/or opportunities for improvement that do not meet the definition of an adverse condition are routed to the appropriate responsible organization and/or reporting program for resolution or improvement and are not subject to the requirements of adverse conditions within this policy. (DOE O 414.1C, Attachment 2, 3(c)(4); Management Requirement)

16.1.2.2.2 Adverse conditions and significant adverse conditions shall be classified as such, and corrective actions shall be taken accordingly. (QARD, Rev 18, 16.2.2.A, 16.2.2.B, 16.2.2.B.1, 16.2.2.B.2, DOE O 226.1A, Attachment 1, Appendix A, 5(a)(1), Management Requirement)

16.1.2.2.3 Regardless of classification, results shall be reviewed for inclusion in the WTP Lessons Learned Program. (DOE O 226.1A, Attachment 1, 2(b)(5), Appendix A, 1(b)(5), 6)

16.1.2.3 Adverse Conditions

16.1.2.3.1 The identification of cause and corrective action for adverse conditions shall be documented, tracked, and reported to appropriate levels of management responsible for the condition, utilizing a graded approach as described in Policy Q-02.1, *Quality Assurance Program*, Section 2.1.2.2, "Graded Approach". (DOE O 414.1C, Attachment 2, 3(c); NQA-1-2000, RQMT 16, 100, QARD, Rev 18, 16.2.3.A, DOE O 226.1A, Attachment 1, Appendix A, 5(a)(5))

16.1.2.3.2 Adverse conditions shall be identified promptly and corrected as soon as practical. (NQA-1-2000, RQMT 16, 100, QARD, Rev 18, 16.2.3.B)

16.1.2.3.3 Responsible management shall determine the extent of the adverse condition and complete corrective action, including assigning responsibilities and establishing milestones to ensure timely completion of actions, utilizing a graded approach as described in Policy Q-02.1, *Quality Assurance Program*, Section 2.1.2.2, "Graded Approach". (QARD, Rev 18, 16.2.3.B, DOE O 226.1A, Attachment 1, Appendix A, 5(a)(2), 5(a)(6), 5(a)(7), 5(a)(8), 5(a)(11), Management Requirement)

16.1.2.4 Significant Adverse Conditions

16.1.2.4.1 Criteria for determining a significant adverse condition shall be established. (QARD, Rev 18, 16.2.4.A)

16.1.2.4.2 Significant adverse conditions shall be documented and reported to management responsible for the condition and their upper management. (QARD, Rev 18, 16.2.4.B)

16.1.2.4.3 Significant adverse conditions shall be evaluated for a stop work condition by Quality Assurance management to determine if stopping work is warranted, provided the stop work does not hinder the resolution of the condition. (QARD, Rev 18, 16.2.4.C, DOE O 226.1A, Attachment 1, Appendix A, 5(b), Management Requirement)

16.1.2.4.3.1 Quality Assurance management shall issue stop work orders to responsible management after a stop work condition has been identified. Criteria for resuming work shall be established in the stop work order. (QARD, Rev 18, 16.2.4.C.1, Management Requirement)

16.1.2.4.3.2 Quality Assurance management shall take appropriate action to lift and close (in part or total) the stop work issued by the Quality Assurance organization based on the resolution of the related significant adverse condition. (QARD, Rev 18, 16.2.4.C.2)

16.1.2.4.4 Responsible management shall perform investigative action to determine the extent of the condition, and document the results. (QARD, Rev 18, 16.2.4.D, Management Requirement)

16.1.2.4.5 Responsible management shall determine, document, and complete remedial action. (QARD, Rev 18, 16.2.4.E)

16.1.2.4.6 Responsible management shall determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical. (QARD, Rev 18, 16.2.4.F, DOE O 226.1A, Attachment 1, Appendix A, 5(a)(4))

16.1.2.5 Corrective Action Completion

16.1.2.5.1 Completion of corrective actions shall be verified. (NQA-1-2000, RQMT 16, 100; DOE O 226.1A, Attachment 1, Appendix A, 5(a)(9))

16.1.2.5.2 Processes shall be established to verify the implementation of corrective actions prior to closeout of the documentation associated with adverse conditions in accordance with the graded approach as described in Policy Q-02.1, *Quality Assurance Program*, Section 2.1.2.2, "Graded Approach". (QARD, Rev 18, 16.2.5; DOE O 226.1A, Attachment 1, Appendix A, 5(a)(10))

16.1.2.6 Trending

16.1.2.6.1 Criteria shall be established for determining trends. (QARD, Rev 18, 16.2.6.A)

16.1.2.6.2 Reports of nonconformances and adverse conditions shall be evaluated to identify trends. (QARD, Rev 18, 16.2.6.B)

16.1.2.6.3 Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of trends and assists in identifying root cause. (QARD, Rev 18, 16.2.6.C)

16.1.2.6.4 Trend evaluations shall be promptly distributed to affected organization management for review and appropriate corrective action. (QARD, Rev 18, 16.2.6.D)

Policy Q-17.1 Quality Assurance Records

17.1.1 Purpose and Applicability

17.1.1.1 This policy identifies the requirements for the generation, authentication, and maintenance of quality assurance records that furnish documentary evidence that items or activities meet specified requirements and are designated as quality assurance records. (Management Requirement)

17.1.1.2 This policy applies to organizations and personnel who prepare or process documents designated as quality assurance records. (Management Requirement)

17.1.1.3 Appendix A, Policy Q-17.1, *Quality Assurance Records*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

17.1.2 Requirements

17.1.2.1 General

17.1.2.1.1 Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. (NQA-1-2000, RQMT 17, 100; QARD, Rev 18, 17.1.A)

17.1.2.1.2 Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. (NQA-1-2000, RQMT 17, 100; QARD, Rev 18, 17.1.A)

17.1.2.1.3 Requirements and responsibilities for these activities shall be documented. (NQA-1-2000, RQMT 17, 100)

17.1.2.2 Generation of Quality Assurance Records

17.1.2.2.1 Quality assurance records shall be legible and complete. (NQA-1-2000, RQMT 17, 200(a); QARD, Rev 18, 17.2.2.B)

17.1.2.2.2 Quality assurance records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required. (NQA-1-2000, RQMT 17, 200(b); QARD, Rev 18, 17.2.2.B)

17.1.2.3 Authentication of Quality Assurance Records

17.1.2.3.1 Documents shall be considered valid quality assurance records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. (NQA-1-2000, RQMT 17, 300; QARD, Rev 18, 17.2.2.D)

17.1.2.4 Classification of Quality Assurance Records

17.1.2.4.1 Quality assurance records shall be classified as lifetime or nonpermanent. (NQA-1-2000, RQMT 17, 400)

17.1.2.4.2 Lifetime quality assurance records are those that meet one or more of the following criteria: (NQA-1-2000, RQMT 17, 401.1)

17.1.2.4.2.1 Those which would be of significant value in demonstrating capability for safe operation. (NQA-1-2000, RQMT 17, 401.1(a))

17.1.2.4.2.2 Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item. (NQA-1-2000, RQMT 17, 401.1(b))

17.1.2.4.2.3 Those which would be of significant value in determining the cause of an accident or malfunction of an item. (NQA-1-2000, RQMT 17, 401.1(c))

17.1.2.4.2.4 Those which would provide required baseline data for in-service inspections. (NQA-1-2000, RQMT 17, 401.1(d))

17.1.2.4.2.5 Project personnel exposure quality assurance records. (DEAR 952.223-75 Preservation of Individual Occupational Radiation Exposure Records (APR 1984))

17.1.2.4.3 Nonpermanent quality assurance records are those quality assurance records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime quality assurance records. (NQA-1-2000, RQMT 17, 402)

17.1.2.5 Receipt Control of Quality Assurance Records

17.1.2.5.1 The organization responsible for the receipt of quality assurance records shall designate a person or position responsible for receiving records. (NQA-1-2000, RQMT 17, 500; QARD, Rev 18, 17.2.4.A)

17.1.2.5.2 The designee shall be responsible for organizing and implementing a system of receipt control of quality assurance records for temporary storage. (NQA-1-2000, RQMT 17, 500; QARD, Rev 18, 17.2.4.A)

17.1.2.6 Storage of Quality Assurance Records

17.1.2.6.1 Quality assurance records shall be protected from damage, deterioration, or loss. (NQA-1-2000, RQMT 17, 800(a); QARD, Rev 18, 17.2.4.C, 17.2.6.B)

17.1.2.6.2 Quality assurance records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: (NQA-1-2000, RQMT 17, 600(a); QARD, Rev 18, 17.2.6.B.1)

17.1.2.6.2.1 Natural disasters such as winds, floods, or fires. (NQA-1-2000, RQMT 17, 600(a)(1); QARD, Rev 18, 17.2.6.B.1)

17.1.2.6.2.2 Environmental conditions such as high and low temperatures and humidity. (NQA-1-2000, RQMT 17, 600(a)(2); QARD, Rev 18, 17.2.6.B.1)

17.1.2.6.2.3 Infestation of insects, mold, rodents, or other pests. (NQA-1-2000, RQMT 17, 600(a)(3); QARD, Rev 18, 17.2.6.B.1)

17.1.2.6.3 Dual facilities, containers, or combination thereof shall be provided for records storage if a single facility, container, or combination thereof is not capable of providing adequate protection. (NQA-1-2000, RQMT 17, 600(b))

17.1.2.6.4 Provisions shall be made for specially processed quality assurance records (e.g., photographs, negatives, microfilm, and magnetic and optical media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, moisture, and humidity. (NQA-1-2000, RQMT 17, 800(d); CCN 066347; QARD, Rev 18, 17.2.6.B.3)

17.1.2.7 Retention and Disposition of Quality Assurance Records

17.1.2.7.1 Quality assurance record retention periods shall be documented. (NQA-1-2000, RQMT 17, 700(a); QARD, Rev 18, 17.2.8.A)

17.1.2.7.2 Quality assurance records shall be maintained for their retention periods. (NQA-1-2000, RQMT 17, 700(b); QARD, Rev 18, 17.2.8.A)

17.1.2.7.3 Lifetime quality assurance records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. (NQA-1-2000, RQMT 17, 401.2)

17.1.2.7.4 Quality assurance records shall be retained in accordance with their classifications. (NQA-1-2000, RQMT 17, 500)

17.1.2.7.5 The retention period for nonpermanent quality assurance records shall be established in writing. (NQA-1-2000, RQMT 17, 500)

17.1.2.7.6 Quality assurance records retained by suppliers shall be retained in accordance with procurement document requirements. (QARD, Rev 18, 17.2.8.C)

17.1.2.8 Retrieval of Quality Assurance Records

17.1.2.8.1 Quality assurance records shall be retrievable. (NQA-1-2000, RQMT 17, 800(b); QARD, Rev 18, 17.2.7.A)

17.1.2.9 Correcting Information in Quality Assurance Records

17.1.2.9.1 The methods for quality assurance record changes shall be documented. (NQA-1-2000, RQMT 17, 800(c))

Policy Q-18.1 Audit (Independent Assessment)

18.1.1 Purpose and Applicability

18.1.1.1 This policy identifies the requirements for performing audits (independent assessment), both internal and external. Audits are used to verify compliance with and to determine the effectiveness of the quality assurance program implementation and maintenance, and to identify continuous improvement opportunities. (QARD, Rev 18, 18.1.A; DOE O 226.1A, Attachment 1, Appendix A, 1(b)(1); Management Requirement)

18.1.1.2 This policy applies to those organizations involved in or subject to the performance of audits. (QARD, Rev 18, 18.1.B; Management Requirement)

18.1.1.3 Appendix A, Policy Q-18.1, *Audit (Independent Assessment)*, provides additional requirements for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2)

18.1.2 Requirements

18.1.2.1 Audits

18.1.2.1.1 Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. (NQA-1-2000, RQMT 18, 100; QARD, Rev 18, 18.2.1; DOE O 226.1A, Attachment 1, Appendix A, 2(b)(4))

18.1.2.1.2 Audits shall concentrate on performance and observation of work activities and the results of process implementation. (DOE O 226.1A, Attachment 1, Appendix A, 2(b)(5))

18.1.2.1.3 These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. (NQA-1-2000, RQMT 18, 100; QARD, Rev 18, 18.2.6, 18.2.8.B)

18.1.2.1.4 Audit results shall be documented and reported to and reviewed by responsible management. (NQA-1-2000, RQMT 18, 100)

18.1.2.1.5 Follow-up action shall be taken where indicated. (NQA-1-2000, RQMT 18, 100)

18.1.2.2 Scheduling Audits

18.1.2.2.1 Audits shall be scheduled in a manner to provide coverage and coordination with on-going activities, based on the status and importance of the activity. (NQA-1-2000, RQMT 18, 200; QARD, Rev 18, 18.2.2.A, 18.2.2.B; DOE O 226.1A, Attachment 1, Appendix A, 2(b)(1))

18.1.2.2.2 Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. (NQA-1-2000, RQMT 18, 200; QARD, Rev 18, 18.2.2.D)

18.1.2.3 Audit Planning

18.1.2.3.1 The auditing organization shall develop an audit plan for each audit. (NQA-1-2000, RQMT 18, 301; QARD, Rev 18, 18.2.5.A; DOE O 226.1A, Attachment 1, Appendix A, 2(b)(1))

18.1.2.3.2 This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. (NQA-1-2000, RQMT 18, 301; QARD, Rev 18, 18.2.5.A)

18.1.2.3.3 Audits to measure item and service quality shall be planned and conducted to measure the adequacy of work performance and to promote improvement. (DOE O 414.1C, Attachment 2, 3(j)(1))

18.1.2.4 Audit Team Independence

18.1.2.4.1 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. (NQA-1-2000, RQMT 18, 302; QARD, Rev 18, 18.2.6; DOE O 226.1A, Attachment 1, Appendix A, 2(b))

18.1.2.5 Selection of an Audit Team

18.1.2.5.1 Lead auditors and auditors shall be qualified and certified in accordance with Policy Q-02.5, *Qualification and Certification of Auditors*. (QARD, Rev 18, 18.2.7.C, 18.2.13; NQA-1A-1983, Supp RQMT 2S-3, 5.1, 5.2; DOE O 226.1A, Attachment 1, 2(f), Appendix A, 2(b)(2))

18.1.2.5.2 Technical specialists shall be trained in accordance with Policy Q-02.4, *Personnel Training and Qualification*. (QARD, Rev 18, 18.2.13; NQA-1A-1983, Supp RQMT 2S-3, 5.1; DOE O 226.1A, Attachment 1, Appendix A, 2(b)(3))

18.1.2.5.3 An audit team shall be identified prior to the beginning of each audit. (NQA-1-2000, RQMT 18, 303; QARD, Rev 18, 18.2.7.A)

18.1.2.5.4 This team shall contain one or more auditors, one being designated Lead Auditor who organizes and directs the audit. (NQA-1-2000, RQMT 18, 303; QARD, Rev 18, 18.2.7.B; DOE O 226.1A, Attachment 1, Appendix A, 2(b)(3))

18.1.2.6 Performing Audits

18.1.2.6.1 Elements selected for audit shall be evaluated against specified requirements. (NQA-1-2000, RQMT 18, 400; QARD, Rev 18, 18.2.8.C)

18.1.2.6.2 Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. (NQA-1-2000, RQMT 18, 400; QARD, Rev 18, 18.2.8.D)

18.1.2.6.3 Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. (NQA-1-2000, RQMT 18, 400; QARD, Rev 18, 18.2.8.E)

18.1.2.7 Reporting

18.1.2.7.1 The audit report shall be signed or otherwise endorsed by the lead auditor and issued to the audited organization. (NQA-1-2000, RQMT 18, 500; QARD, Rev 18, 18.2.9)

18.1.2.7.2 The contents of the audit report shall: (NQA-1-2000, RQMT 18, 500; QARD, Rev 18, 18.2.9)

18.1.2.7.2.1 Describe the audit scope. (NQA-1-2000, RQMT 18, 500(a); QARD, Rev 18, 18.2.9.A)

18.1.2.7.2.2 Identify auditors and persons contacted. (NQA-1-2000, RQMT 18, 500(b); QARD, Rev 18, 18.2.9.B, 18.2.9.C)

18.1.2.7.2.3 Summarize audit results, including a statement on the effectiveness of the elements audited. (NQA-1-2000, RQMT 18, 500(c); QARD, Rev 18, 18.2.9.D)

18.1.2.7.2.4 Describe each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization in accordance with Policy Q-16.1, *Corrective Action*. (NQA-1-2000, RQMT 18, 500(d); QARD, Rev 18, 18.2.8.E, 18.2.8.F, 18.2.9.E, 18.2.10.A, 18.2.10.B)

18.1.2.7.2.5 Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action. (NQA-1-2000, RQMT 18, 800)

18.1.2.8 Response

18.1.2.8.1 Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of the actions taken or planned. (NQA-1-2000, RQMT 18, 600; QARD, Rev 18, 18.2.10.A, 18.2.10.B)

18.1.2.8.2 Audit responses shall be evaluated by or for the auditing organization. (NQA-1-2000, RQMT 18, 600; QARD, Rev 18, 18.2.11)

18.1.2.9 Follow-up Action

18.1.2.9.1 Follow-up action shall be taken to verify that corrective action is accomplished as scheduled in accordance with the requirements of Policy Q-15.1, *Control of Nonconforming Items* and Policy Q-16.1, *Corrective Action*. (NQA-1-2000, RQMT 18, 700; QARD, Rev 18, 18.2.12; DOE O 226.1A, Attachment 1, Appendix A, 5(a)(10), 5(a)(11))

Appendix A

Policy Q-01.1 – Immobilized High Level Waste (IHLW) Addenda

This appendix provides the IHLW requirements, in addition to those described in the policies of this manual, for items and activities identified in 24590-HLW-RPT-PR-01-001, *Waste Acceptance Impacting Items and Activities*. (QARD, Rev. 18, 2.1, 2.2.2, 2.2.3)

Planning activities for IHLW shall be performed and documented prior to the start of work.

These additional requirements are based on Office of Civilian Radioactive Waste Management, DOE/RW-0333P (Rev 18), *Quality Assurance Requirements and Description (QARD)*. The QARD requirements have been evaluated against NQA-1-2000 for equivalency. Where the QARD requirements are not equivalent with NQA-1-2000 and are not incorporated into the main policies of the manual, this appendix provides the additional quality requirements.

The following Appendix A policies provide additional IHLW requirements supplemental to the main policies of the manual. Where Appendix A requirements reference the requirements in the main policy, the corresponding Appendix A policies also apply.:

Q-02.4 *Personnel Training and Qualification*
Q-02.5 *Qualification and Certification of Auditors*
Q-02.6 *Qualification and Certification of Inspection and Test, including NDE, Personnel*
Q-03.1 *Design Control*
Q-03.2 *Software Quality*
Q-04.1 *Procurement Document Control*
Q-05.1 *Instructions, Procedures, and Drawings*
Q-06.1 *Document Control*
Q-07.1 *Control of Purchased Items and Services*
Q-08.1 *Identification and Control of Items*
Q-09.1 *Control of Special Processes*
Q-10.1 *Inspection*
Q-11.1 *Test Control*
Q-12.1 *Control of Measuring and Test Equipment*
Q-15.1 *Control of Nonconforming Items*
Q-17.1 *Quality Assurance Records*
Q-18.1 *Audit (Independent Assessment)*

The following base policies contain equivalent requirements to QARD, Revision 18, therefore, there are no additional Appendix A policies:

Q-01.1 *Organization*
Q-02.1 *Quality Assurance Program*
Q-02.2 *Management Assessment*
Q-02.3 *Surveillances*
Q-13.1 *Handling, Storage, and Shipping*
Q-14.1 *Inspection, Test, and Operating Status*

Q-15.2 *Control of Suspect/Counterfeit Items*
Q-16.1 *Corrective Action*

The following Appendix A IHLW requirements have no corresponding base QAM policies.

Q-02.7, *Special Reviews*
Supplement II, *Sample Control*
Supplement V, *Control of the Electronic Management of Information*

Appendix A
Policy Q-02.4 – Personnel Training and Qualification

A2.4.1 General

A2.4.1.1 Personnel indoctrination, training, and qualification processes shall be implemented in a manner that ensures the appropriate indoctrination, training, and qualification have been provided prior to performing waste acceptance impacting activities. (QARD, Rev 18, 2.2.11)

A2.4.1.2 Personnel shall be indoctrinated and trained as follows: (QARD, Rev 18, 2.2.11.A)

A2.4.1.2.1 Personnel that require certification are given proficiency tests. Acceptance criteria are developed to determine whether individuals are properly trained and qualified. (QARD, Rev 18, 2.2.11.A.4)

A2.4.1.2.2 Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change. (QARD, Rev 18, 2.2.11.A.5)

Appendix A
Policy Q-02.5 – Qualification and Certification of Auditors

A2.5.1 Qualification of Auditors

A2.5.1.1 Responsibility of Auditing Organization

A2.5.1.1.1 The Quality Assurance Organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 2.1)

A2.5.2 Records

A2.5.2.1 Updating of Lead Auditors' Records

A2.5.2.1.1 Records for each lead Auditor shall be maintained and updated annually. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Sup Req 2S-3, 6.3)

A2.5.3 Education and Experience for Lead Auditors

A2.5.3.1 The prospective Lead Auditor should have verifiable evidence that a minimum of ten (10) credits under the following scoring system have been accumulated. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2)

A2.5.3.1.1 **Education (4 Credits Maximum)**

A2.5.3.1.1.1 Associate degree from an accredited institution: score one (1) credit, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) credits, or (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.1)

A2.5.3.1.1.2 A bachelor's degree from an accredited institution: score two (2) credits, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) credits; in addition, score one (1) credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.1)

A2.5.3.1.2 **Experience (9 Credits Maximum)**

A2.5.3.1.2.1 Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) credit for each full year with a maximum of

five (5) credits for this aspect of experience. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.2)

A2.5.3.1.2.2 If two (2) years of this experience have been in the nuclear field, score one (1) additional credit; or if two (2) years of this experience have been in quality assurance, score two (2) additional credits; or if two (2) years of this experience have been in auditing, score three (3) additional credits, or if two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or if two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.2)

A2.5.3.1.3 Other Credentials of Professional Competence (2 Credits Maximum)

A2.5.3.1.3.1 For certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency or National Professional or Technical Society: score two (2) credits. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.3)

A2.5.3.1.4 Rights of Management (2 Credits Maximum)

A2.5.3.1.4.1 The Lead Auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing, which may not be explicitly called out in this Appendix. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses. (QARD, Rev 18, 2.2.11.C; NQA-1A-1983, Appendix 2A-3, 2.4)

Appendix A

Policy Q-02.6 – Qualification and Certification of Inspection and Test, including NDE, Personnel

A2.6.1 Qualification Requirements

A2.6.1.1 The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this policy are permitted to perform inspection and test activities. When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this policy may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.1)

A2.6.2 Personnel Selection

A2.6.2.1 Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.2)

A2.6.3 Indoctrination

A2.6.3.1 Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.3)

A2.6.4 Training

A2.6.4.1 The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Sup Rev 2S-1, 2.4)

A2.6.5 Functional Qualifications

A2.6.5.1 Three levels of qualification may be utilized depending on the complexity of the functions involved. The recommendations for each level are not limiting with regard to

organizational position or professional status but, rather, are limiting with regard to functional activities. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 2)

A2.6.5.2 Level I Personnel Capabilities

A2.6.5.2.1 A Level I person shall be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in user's written procedures. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 2.1)

A2.6.5.3 Level II Personnel Capabilities

A2.6.5.3.1 Level II person shall have all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person shall have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment as appropriate; in supervising or maintaining surveillance over the inspections and tests; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 2.2)

A2.6.5.4 Level III Personnel Capabilities

A2.6.5.4.1 A Level III person shall have all of the capabilities of a Level II person for the inspection or test category or class in question. In addition, the individual shall also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this policy. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 2.3)

A2.6.6 Education and Experience Qualifications

A2.6.6.1 These education and experience recommendations should be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3)

A2.6.6.2 Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency shall be documented. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3)

A2.6.6.3 Level I

A2.6.6.3.1 Two years of related experience in equivalent inspection or testing activities, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.1.1)

A2.6.6.3.2 High school graduation and six months of related experience in equivalent inspection or testing activities, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.1.2)

A2.6.6.3.3 Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.1.3)

A2.6.6.4 Level II

A2.6.6.4.1 One year of satisfactory performance as a Level I in the corresponding inspection or test category or class, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.2.1)

A2.6.6.4.2 High school graduation plus three years of related experience in equivalent inspection or testing activities, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.2.2)

A2.6.6.4.3 Completion of college level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.2.3)

A2.6.6.4.4 Graduation from a four-year college plus six months of related experience in equivalent inspection or testing activities. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.2.4)

A2.6.6.5 Level III

A2.6.6.5.1 Six years of satisfactory performance as a Level II in the corresponding inspection or test category or class, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.3.1)

A2.6.6.5.2 High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection or testing activities with at least two years as a Level II and with at least two years associated with nuclear facilities – or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.3.2)

A2.6.6.5.3 Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities – or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility, or (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.3.3)

A2.6.6.5.4 Graduation from a four-year college plus five years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities - or, if not, at least sufficient training to be

acquainted with the relevant quality assurance aspects of a nuclear facility. (QARD, Rev 18, 2.2.11.B; NQA-1A-1983, Appendix 2A-1, 3.3.4)

A2.6.7 Certification

A2.6.7.1 When required by codes, standards, and specifications, personnel who perform inspections shall be certified in accordance with the pertinent codes, standards, and specifications, (e.g., American Welding Society [Certified Welding Inspector], National Electric Code [Certified Electrical Inspector], American Concrete Institute [Concrete Construction Inspector, Concrete Transportation Inspector], etc.). Validity of these certifications shall be verified prior to performing inspections. (QARD, Rev 18, 2.2.11.B; QARD, Rev 18, 2.2.11.E)

A2.6.7.2 Implementing documents shall be established for the control and administration of nondestructive examination personnel training, examination, and certification. (QARD, Rev 18, 9.2.3.D)

Appendix A
Policy Q-02.7 – Special Reviews

A2.7.1 Readiness Reviews

A2.7.1.1 The need for readiness reviews shall be identified by WTP management for major scheduled or planned work to ensure program objectives are met. (QARD, Rev 18, 2.2.7)

A2.7.1.2 Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that: (QARD, Rev 18, 2.2.7)

A2.7.1.2.1.1 Work prerequisites have been satisfied. (QARD, Rev 18, 2.2.7.A)

A2.7.1.2.1.2 Personnel have been suitably trained and qualified. (QARD, Rev 18, 2.2.7.B)

A2.7.1.2.1.3 Appropriate implementing documents and management controls are available and approved. (QARD, Rev 18, 2.2.7.C)

Appendix A
Policy Q-03.1 – Design Control

A3.1.1 Interface Control

A3.1.1.1 Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSCs are compatible geometrically, functionally, and with processes and environment. (QARD, Rev 18, 3.2.7.B)

A3.1.2 Design Process

A3.1.2.1 The dimensional accuracy and completeness of design drawings and specifications shall be checked and documented. (QARD, Rev 18, 3.2.2.I)

A3.1.2.2 Design documents shall be reviewed by individuals or groups within the quality assurance organization that do not have direct responsibility for performing the work being verified, or by individuals or groups other than the one who generated the document and trained and qualified in quality assurance practices and concepts. Reviews shall be performed to assure that the documents are prepared, reviewed, and approved in accordance with implementing procedures and contain the necessary quality assurance requirements, such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented. Training and qualification of non-quality assurance organization individuals shall be in accordance with Policy Q-02.4, *Personnel Training and Qualification*. (QARD, Rev 18, 3.2.2.K)

A3.1.2.3 For commercial grade items, the critical characteristics to be verified and the acceptance criteria for those characteristics shall be documented. If a commercial grade assembly or component, prior to installation, is modified or selected by special inspection and/or testing to meet requirements that are more restrictive than the supplier's published product description, then the item shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference. (QARD, Rev 18, 3.2.2.H)

A3.1.3 Design Analyses

A3.1.3.1 Calculations shall be identifiable by subject (including SSC to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable and retrievable. (QARD, Rev 18, 3.2.3.D)

A3.1.4 Design Verification

A3.1.4.1 Guidelines or criteria shall be established and described for determining the method of design verification. (QARD, Rev 18, 3.2.4.C)

A3.1.4.2 The particular design verification method used shall be identified and documented. (QARD, Rev 18, 3.2.4.C)

A3.1.4.3 Procedural controls shall provide criteria for determining when design documents that reflect the commitments of the Safety Analysis Report receive formal design verification by interdisciplinary or multi-organizational teams or by a single individual (a signature and date are acceptable documentation). Design documents subject to procedural controls include, but are not limited to, specifications, calculations, associated computer software supporting a waste acceptance impacting function, system descriptions, parts of the Safety Analysis Report when used as a design document, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant. (QARD, Rev 18, 3.2.4.D)

A3.1.4.4 Responsibilities of the verifier, areas and features to be verified, pertinent considerations to be verified, and the extent of documentation shall be identified in procedures. (QARD, Rev 18, 3.2.4.F)

A3.1.4.5 In exceptional circumstances, this verification may be performed by the originator's immediate supervisor, provided: (QARD, Rev 18, 3.2.4.G)

A3.1.4.5.1 The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design. (QARD, Rev 18, 3.2.4.G.1)

A3.1.4.5.2 The supervisor is the only individual in the organization competent to perform the verification. (QARD, Rev 18, 3.2.4.G.2)

A3.1.4.5.3 The verification is not a cursory review. (QARD, Rev 18, 3.2.4.G.3)

A3.1.4.5.4 The determination to use the supervisor is documented and approved in advance by the supervisor's management. (QARD, Rev 18, 3.2.4.G.4)

A3.1.4.5.5 Quality assurance audits are conducted to evaluate the frequency and effectiveness of the use of supervisors as design verifiers. (QARD, Rev 18, 3.2.4.G.5)

A3.1.4.6 In cases where the design verification timing cannot be satisfied, as described in Policy 3.1.2.6 "Design Verification", the design verification may be deferred, providing that a justification for this action is documented and the unverified portion of the design output document and all design output documents based on the unverified portion are appropriately identified and controlled. (QARD, Rev 18, 3.2.4.H.1)

A3.1.5 Qualification Tests

A3.1.5.1 Where design adequacy is to be verified by qualification tests, the tests shall be identified. (QARD, Rev 18, 3.2.5.C.1)

A3.1.5.2 Prototype, component, or feature testing shall be performed as early as possible before the installation would become irreversible. (QARD, Rev 18, 3.2.5.C.2)

A3.1.5.3 The test configuration shall be defined and documented. (QARD, Rev 18, 3.2.5.C.3)

A3.1.5.4 Testing shall demonstrate the adequacy of system, structure, or component performance under conditions that simulate the full range, including the most adverse anticipated design conditions as determined by analysis. (QARD, Rev 18, 3.2.5.C.4)

A3.1.5.5 Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met. (QARD, Rev 18, 3.2.5.C.6)

A3.1.5.6 If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance. (QARD, Rev 18, 3.2.5.C.7)

A3.1.6 Design Change Control

A3.1.6.1 If an organization that originally was responsible for approving a particular design document is no longer responsible, a new responsible organization shall be designated. (QARD, Rev 18, 3.2.6.B.1)

A3.1.6.2 Measures shall be provided to ensure personnel are notified of design changes/modifications that may affect the performance of their duties. (QARD, Rev 18, 3.2.6.F)

A3.1.6.3 Prior to the issuance of a design change initiated after the construction authorization, the design changes shall be evaluated pursuant to applicable regulatory requirements. (QARD, Rev 18, 3.2.6.G)

A3.1.7 Sampling Plans

A3.1.7.1 The basis, including any supporting analyses for the use of sampling plans for items, barriers, and related activities, shall be documented. The following apply to the use of sampling plans: (QARD, Rev 18, 3.2.8)

A3.1.7.1.1 Sampling plans shall use a criterion that provides 95 percent confidence that there are only 5 percent defective items in a lot (95/5). (QARD, Rev 18, 3.2.8.A, CCN 148208)

A3.1.7.1.2 Lots sampled shall be essentially homogeneous. (QARD, Rev 18, 3.2.8.B)

A3.1.7.1.3 Sample plans shall be based on recognized standard practices. (QARD, Rev 18, 3.2.8.C)

Appendix A
Policy Q-03.2 – Software Quality

A3.2.1 Procurement

A3.2.1.1 Documentation as required by this policy shall be delivered or made available by the supplier to the purchaser. (QARD, Rev 18, Supplement 1, I.2.6.A.1)

A3.2.2 Software Design Control

A3.2.2.1 Software Requirements

A3.2.2.1.1 Software requirements shall include: (QARD, Rev 18, Supplement I. I.2.2.B)

A3.2.2.1.1.1 A description of the overall nature and purpose of the software. (QARD, Rev 18, Supplement I, I.2.2.B.1)

A3.2.2.1.1.2 The software products to which it applies. (QARD, Rev 18, Supplement I, I.2.2.B.2)

A3.2.2.1.1.3 Enough detail to either design the software or make an acquisition decision. (QARD, Rev 18, Supplement I, I.2.3.A.4)

A3.2.2.2 Software Design and Development Implementation

A3.2.2.2.1 User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable: (QARD, Rev 18, Supplement 1, I.2.3.C.3)

A3.2.2.2.1.1 Instructions that contain an introduction (e.g., purpose, scope, etc.), description of the user's interaction with the software, and a description of any required training necessary to use the software. (QARD, Rev 18, Supplement 1, I.2.3.C.3(a))

A3.2.2.2.1.2 Input and output specifications. (QARD, Rev 18, Supplement 1, I.2.3.C.3(b))

A3.2.2.2.1.3 Data files, input and output data, defaults, and file formats. (QARD, Rev 18, Supplement 1, I.2.3.C.3(c))

A3.2.2.2.1.4 A description of the allowable and tolerable ranges for inputs and outputs. (QARD, Rev 18, Supplement 1, I.2.3.C.3(d))

A3.2.2.2.1.5 Anticipated errors and how the user can respond. (QARD, Rev 18, Supplement 1, I.2.3.C.3(e))

A3.2.2.2.1.6 The hardware and software environments. (QARD, Rev 18, Supplement 1, I.2.3.C.3(f))

A3.2.2.2.1.7 Available sample problems. (QARD, Rev 18, Supplement 1, I.2.3.C.3(g))

A3.2.2.2.1.8 Installation procedures. (QARD, Rev 18, Supplement 1, I.2.3.C.3(h))

A3.2.2.2.2 Measures to mitigate the consequences of potential problems shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program. (QARD, Rev 18, Supplement 1, I.2.3.B.3)

A3.2.2.2.3 Software life cycles shall contain control points that, when reached, shall ensure specified software is documented, reviewed, and baselined. (QARD, Rev 18, Supplement I, I.2.1.A.3)

A3.2.3 Software Test Control

A3.2.3.1 Software Test

A3.2.3.1.1 The software validation documentation shall: (QARD, Rev 18, Supplement 1, I.2.3.D.6)

A3.2.3.1.1.1 Specify the hardware and software configurations. (QARD, Rev 18, Supplement 1, I.2.3.D.6(a))

A3.2.3.1.1.2 Be organized in a manner that allows traceability to both software requirements and design. (QARD, Rev 18, Supplement 1, I.2.3.D.6(b))

A3.2.3.1.1.3 Contain the results of the execution of the validation activity. (QARD, Rev 18, Supplement 1, I.2.3.D.6(c))

A3.2.3.1.1.4 Include the results of reviews and tests along with a summary of the status of the software (i.e., indication of incomplete design performance and application requirements). (QARD, Rev 18, Supplement 1, I.2.3.D.6(d))

A3.2.3.1.2 Failure to successfully execute the test cases shall be documented and reviewed to determine if modifications to the requirements, design, implementation, or test plans and cases are required. (QARD, Rev 18, Supplement 1, I.2.3.D.7)

A3.2.3.1.3 Testing shall demonstrate, as appropriate, that the computer program: (QARD, Rev 18, Supplement 1, I.2.3.D.4)

A3.2.3.1.3.1 Properly handles abnormal conditions and events as well as failures. (QARD, Rev 18, Supplement 1, I.2.3.D.4(a))

A3.2.3.1.3.2 Does not perform adverse unintended functions. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. (QARD, Rev 18, Supplement 1, I.2.3.D.4(b))

A3.2.3.1.3.3 Does not unexpectedly degrade the system either by itself or in combination with other functions or configuration items. (QARD, Rev 18, Supplement 1, I.2.3.D.4(c))

A3.2.3.1.4 Software validation activities shall be planned, performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use. (QARD, Rev 18, Supplement I, I.2.3.D.2)

A3.2.3.1.5 Software validation of modifications to released software shall be subjected to selective testing (i.e., regression) to detect unintended adverse effects introduced during the modification of the software, to verify that the modifications have not caused unintended adverse affects, and to verify that a modified software still meets specified requirements. (QARD, Rev 18, Supplement 1, I.2.3.D.8)

A3.2.3.2 Software Test Results

A3.2.3.2.1 Tests and test results from reviews and verifications shall be included in the acceptance test documentation. (QARD, Rev 18, Supplement 1, I.2.1.B.2(a))

A3.2.3.3 Software Acceptance Testing

A3.2.3.3.1 Further operations and maintenance activities shall consist of maintenance of the software: (QARD, Rev 18, Supplement 1, I.2.3.E.3)

A3.2.3.3.1.1 To remove latent errors (corrective maintenance). (QARD, Rev 18, Supplement 1, I.2.3.E.3(a))

A3.2.3.3.1.2 To respond to new or revised requirements (perfective maintenance). (QARD, Rev 18, Supplement 1, I.2.3.E.3(b))

A3.2.3.3.1.3 To adapt the software to changes in the operating environment (adaptive maintenance). (QARD, Rev 18, Supplement 1, I.2.3.E.3(c))

A3.2.3.3.2 Software modifications shall be approved, documented, verified and validated, and controlled. (QARD, Rev 18, Supplement 1, I.2.3.E.4)

A3.2.3.3.3 Tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of-development acceptance tests. (QARD, Rev 18, Supplement 1, I.2.1.B.2(b))

A3.2.3.4 Installation and Checkout

A3.2.3.4.1 Software installation and checkout activities shall be performed and documented when the software is installed on a computer or when there are changes in the operating system to ensure that the software installs properly and satisfies the requirements for its intended use. (QARD, Rev 18, Supplement 1, I.2.3.F.1)

A3.2.3.4.2 The software validation activities for the installation and checkout shall consist of: (QARD, Rev 18, Supplement 1, I.2.3.F.2)

A3.2.3.4.2.1 The execution of tests for installation. (QARD, Rev 18, Supplement 1, I.2.3.F.2(a))

A3.2.3.4.2.2 The documentation that the software was successfully installed and ready for operational use. (QARD, Rev 18, Supplement 1, I.2.3.F.2(b))

A3.2.4 Software Use

A3.2.4.1 User organizations control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process. (QARD, Rev 18, Supplement 1, I.2.8.A)

A3.2.4.2 Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved. (QARD, Rev 18, Supplement 1, I.2.8.B)

A3.2.4.3 If the intended use of the software item will require the use of inputs outside the ranges verified during validation testing, the appropriate baseline elements shall be reverified and revalidated for the expected range of inputs prior to continuing use. (QARD, Rev 18, Supplement 1, I.2.8.C)

A3.2.4.4 Documentation for the receipt of software obtained from Software Configuration Management shall be provided and maintained for software in operation or use. (QARD, Rev 18, Supplement 1, I.2.8.D)

A3.2.4.5 Controls shall be established to permit authorized access and prevent unauthorized access to computer systems. (QARD, Rev 18, Supplement 1, I.2.8.E)

A3.2.4.6 The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities shall be identified. (QARD, Rev 18, Supplement 1, I.2.2.B.3)

A3.2.5 Software Configuration Management

A3.2.5.1 Configuration items to be controlled shall include the following, as appropriate, documentation (e.g., plans, requirements, designs, user manuals, test reports, user information, etc.), computer program(s) (e.g., source, object, backup files, media, etc.), and related support software. (QARD, Rev 18, Supplement 1, I.2.4.D)

A3.2.6 Problem Reporting and Resolution

A3.2.6.1 Software shall not be used in activities unless it has been qualified, as appropriate, baselined and limited to copies obtained from Software Configuration Management. (QARD, Rev 18, Supplement I, I.2.3.E.1, I.2.3.E.2, I.2.4.B, I.2.5.B)

A3.2.7 Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 2b, Policy Q-03.2

Appendix F to this Quality Assurance Manual provides requirements related to software quality other than those provided in main policies and Appendices A and E. Appendix F encompasses the requirements previously included in 24590-WTP-QAM-QA-01-001 and applies to work activities identified in 24590-WTP-PL-IT-08-0001, *IS&T Project Plan for Implementation of 24590-WTP-QAM-QA-06-001 rev 2a*, Rev 0. This plan was developed to communicate the project plan for implementation of the software quality requirements of the new 24590-WTP-QAM-QA-06-001, *Quality Assurance Manual*. The scope of this plan includes the Software Plan, Guide, Procedures, and Forms as identified in the Project Schedule (Appendix A to the plan). The plan defines five efforts:

- To perform a safety software pre-survey to determine the types and sources of safety software
- To modify the existing procedures, guides and forms to include the new QAM requirement reference and to switch to the software designations Levels D, E, or F
- To extensively modify and develop plans, procedures, guides, and forms in order to implement safety software designation Levels A, B, and C
- Modify automated systems that support procedure driven process
- Develop Training for WTP Staff who have procedural responsibility

The requirements of 24590-WTP-QAM-QA-01-001, Policies 03.1 and 03.2, and 24590-WTP-QAM-QA-06-001, will coexist for the duration of 24590-WTP-PL-IT-08-0001. The procedures subject to the plan will remain compliant with the software quality requirements of 24590-WTP-QAM-QA-01-001, Policy 3.2, Software Quality, until reissued, in accordance with the plan schedule, as compliant with the applicable policies of 24590-WTP-QAM-QA-06-001.

Appendix A
Policy Q-04.1 – Procurement Document Control

A4.1.1 Procurement Document Preparation

A4.1.1.1 Spare parts shall be subject to quality assurance program controls, codes and standards, and technical requirements equal to or greater than the original requirements, or as required to preclude repetition of defects. (QARD, Rev 18, 4.2.1.H)

A4.1.1.2 Procurement documents shall include instructions relative to the performance of special processes. (QARD, Rev 18, 4.2.1.I)

A4.1.2 Procurement Document Review and Approval

A4.1.2.1 Reviews shall ensure that all applicable requirements delineated in Policy Q-04.1, *Procurement Document Control,* are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with the requirements. (QARD, Rev 18, 4.2.2.C)

A4.1.2.2 Procurement documents shall be reviewed by individuals or groups within the quality assurance organization that do not have direct responsibility for performing the work being verified, or by individuals or groups other than the one who generated the document that are trained and qualified in quality assurance practices and concepts and concur with these documents with respect to the quality assurance related aspects. The training and qualification of non-quality assurance organization individuals shall be in accordance with Policy Q-02.4, *Personnel Training and Qualification.* (QARD, Rev 18, 4.2.2.E)

A4.1.3 Procurement Document Change

A4.1.3.1 The evaluation shall consider the requirements of this section and additional or modified design criteria and analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished. (QARD, Rev 18, 4.2.3.B.1, 4.2.3.B.2, 4.2.3.B.3)

Appendix A
Policy Q-05.1 – Instructions, Procedures, and Drawings

A5.1.1 General

A5.1.1.1 Work shall be suspended if it cannot be accomplished as described in controlled implementing documents. (QARD, Rev 18, 5.2.B)

A5.1.2 Types of Implementing Documents

A5.1.2.1 The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. (QARD, Rev 18, 5.2.1)

A5.1.2.2 Design drawings, including as-built drawings, are developed and changes are controlled in accordance with the requirements of Policy Q-03.1, *Design Control*. (QARD, Rev 18, 5.2.1)

Appendix A
Policy Q-06.1 – Document Control

A6.1.1 Types of Documents

A6.1.1.1 Controlled documents shall include, but not be limited to design documents (including as-builts), procurement documents, procedures, instructions, quality assurance program description and requirements documents, and Safety Analysis Reports, including changes thereto. (QARD, Rev 18, 6.2.1.B)

A6.1.2 Reviewing Documents

A6.1.2.1 The responsibility for preparing documents shall be assigned to the appropriate organization. (QARD, Rev 18, 6.2.2)

A6.1.2.2 The organizational position responsible for approving the document for release shall be identified. (QARD, Rev 18, 6.2.4)

A6.1.2.3 Implementing documents and documents that specify technical or quality assurance requirements or prescribe activities that are governed by this quality assurance manual, including changes thereto, shall be reviewed prior to the start of work with respect to the following requirements and to any additional requirements specified by the applicable policies of this quality assurance manual. (QARD, Rev 18, 6.2.3)

A6.1.2.3.1 The review shall be performed by individuals other than the preparer. (QARD, Rev 18, 6.2.3.B)

A6.1.2.3.2 Reviewers shall be technically competent for the subject area of the document being reviewed. (QARD, Rev 18, 6.2.3.C)

A6.1.2.3.3 Reviewers shall have access to pertinent background data or information upon which to base their acceptance. (QARD, Rev 18, 6.2.3.D)

A6.1.2.4 Reviewers shall document acceptance. (QARD, Rev 18, 6.2.3.E)

A6.1.2.5 Reviewers include: (QARD, Rev 18, 6.2.3.F)

A6.1.2.5.1 Organizations or technical disciplines affected by the document as determined by the manager responsible for the implementing document. (QARD, Rev 18, 6.2.3.F.1)

A6.1.2.5.2 Individuals or groups within the quality assurance organization that do not have direct responsibility for performing the work being verified, or individuals or groups other than the one who generated the document that are trained and qualified in quality assurance practices and concepts and concur with these documents with respect to the quality assurance related aspects. The training and qualification of

non-quality assurance organization individuals shall be in accordance with Policy Q-02.4, *Personnel Training and Qualification.* (QARD, Rev 18, 6.2.3.F.2)

A6.1.2.6 Comments resulting from the review shall be documented and resolved to the satisfaction of the organization responsible for the document before approving the document. (QARD, Rev 18, 6.2.3.G)

A6.1.3 Distribution and Use of Documents

A6.1.3.1 A system shall be established to identify the current status of each document that is required to be controlled in accordance with this section. This system shall be made accessible to document users. (QARD, Rev 18, 6.2.5.A)

A6.1.3.2 The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work. (QARD, Rev 18, 6.2.5.B)

A6.1.3.3 Effective dates shall be established for approved implementing documents. (QARD, Rev 18, 6.2.5.C)

A6.1.3.4 The latest version (revision or change) of documents either in hardcopy or electronic media shall be available for use prior to the start of work at the location where the activity is performed. Documents shall be adhered to in the performance of work. (QARD, Rev 18, 6.2.5.D)

A6.1.4 Changes to Documents

A6.1.4.1 Changes shall be approved for release in a timely manner by the designated organizational position responsible for the document. (QARD, Rev 18, 6.2.6.B)

A6.1.4.2 Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire revised controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document. (QARD, Rev 18, 6.2.6.C)

A6.1.4.3 Implementing documents shall require that a history of changes to quality assurance program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed. (QARD, Rev 18, 6.2.6.D)

A6.1.4.4 Changes to documents, other than editorial corrections as delineated in Subsection A6.1.6, shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated as affected organizations. The reviewing organization shall have access to pertinent background data or information upon which to base their approval. (QARD, Rev 18, 6.2.6.E)

A6.1.5 Expedited Changes

A6.1.5.1 If an activity cannot be performed as prescribed in a document and the change process would cause unreasonable delays, an expedited change may be made at the work location by responsible management. (QARD, Rev 18, 6.2.7)

A6.1.5.1.1 After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the document being changed. (QARD, Rev 18, 6.2.7.A)

A6.1.5.1.2 Implementing documents shall describe the process to control expedited changes according to the following requirements. (QARD, Rev 18, 6.2.7.B)

A6.1.5.1.2.1 The level of management with the authority to make expedited changes shall be identified. (QARD, Rev 18, 6.2.7.B.1)

A6.1.5.1.2.2 The time limits for processing expedited changes through the normal change process shall be specified. (QARD, Rev 18, 6.2.7.B.2)

A6.1.5.1.2.3 An evaluation of the work shall be performed, if the normal review process results in a change that is different from the expedited change. (QARD, Rev 18, 6.2.7.B.3)

A6.1.6 Editorial Corrections

A6.1.6.1 The following items are considered editorial corrections: (QARD, Rev 18, 6.2.8.A)

A6.1.6.1.1 Correcting grammar or spelling. (QARD, Rev 18, 6.2.8.A.1)

A6.1.6.1.2 Renumbering sections or attachments that do not affect the chronological sequence of work. (QARD, Rev 18, 6.2.8.A.2)

A6.1.6.1.3 Changing the title or number of the document or the title or number of documents referenced in the procedure. (QARD, Rev 18, 6.2.8.A.3)

A6.1.6.1.4 Updating organizational titles. (QARD, Rev 18, 6.2.8.A.4)

A6.1.6.2 A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction. (QARD, Rev 18, 6.2.8.B)

A6.1.6.3 The organizational position responsible for approving the document for release shall approve editorial corrections. (QARD, Rev 18, 6.2.8.C)

Appendix A
Policy Q-07.1 – Control of Purchased Items and Services

A7.1.1 Procurement Planning

A7.1.1.1 Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall: (QARD, Rev 18, 7.2.1)

A7.1.1.1.1 Identify procurement methods and organizational responsibilities, including interfaces between design, procurement, and quality assurance organizations. (QARD, Rev 18, 7.2.1.A)

A7.1.1.1.2 Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished. (QARD, Rev 18, 7.2.1.B)

A7.1.1.1.3 Prior to the initiation of each individual activity identified in the succeeding paragraph, identify and document the sequence of actions and milestones, indicating the completion of these activities and the preparation of applicable procedures. (QARD, Rev 18, 7.2.1.C)

A7.1.1.1.4 Provide for the integration of the following activities: (QARD, Rev 18, 7.2.1.D)

A7.1.1.1.4.1 Procurement document preparation, review, and change control according to the requirements of Policy Q-04.1, *Procurement Document Control.* (QARD, Rev 18, 7.2.1.D.1)

A7.1.1.1.4.2 Selection of procurement sources. (QARD, Rev 18, 7.2.1.D.2)

A7.1.1.1.4.3 Proposal/bid evaluation and award. (QARD, Rev 18, 7.2.1.D.3)

A7.1.1.1.4.4 Evaluation of contractor/supplier performance. (QARD, Rev 18, 7.2.1.D.4)

A7.1.1.1.4.5 Verifications, including any hold and witness point notifications. (QARD, Rev 18, 7.2.1.D.5)

A7.1.1.1.4.6 Control of nonconformances. (QARD, Rev 18, 7.2.1.D.6)

A7.1.1.1.4.7 Corrective action. (QARD, Rev 18, 7.2.1.D.7)

A7.1.1.1.4.8 Acceptance of the item or service. (QARD, Rev 18, 7.2.1.D.8)

A7.1.1.1.4.9 Identification of quality assurance records. (QARD, Rev 18, 7.2.1.D.9)

A7.1.1.1.5 Be accomplished as early as practicable, and no later than the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process. (QARD, Rev 18, 7.2.1.E)

A7.1.1.1.6 Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance. (QARD, Rev 18, 7.2.1.F)

A7.1.1.1.7 Include participation of representatives from the technical organizations and the quality assurance organization. (QARD, Rev 18, 7.2.1.G)

A7.1.2 Source Evaluation and Selection

A7.1.2.1 The organizational responsibilities of the purchaser for source evaluation and selection shall be identified, including provisions for input from the quality assurance organization. (QARD, Rev 18, 7.2.2.B)

A7.1.3 Proposal/Bid Evaluation

A7.1.3.1 The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified organizations, including the quality assurance organization. (QARD, Rev 18, 7.2.3.A)

A7.1.3.2 The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured: (QARD, Rev 18, 7.2.3.B)

A7.1.3.2.1 Technical considerations. (QARD, Rev 18, 7.2.3.B.1)

A7.1.3.2.2 Quality assurance program requirements. (QARD, Rev 18, 7.2.3.B.2)

A7.1.3.2.3 Supplier's personnel. (QARD, Rev 18, 7.2.3.B.3)

A7.1.3.2.4 Supplier's production capability. (QARD, Rev 18, 7.2.3.B.4)

A7.1.3.2.5 Alternatives and exceptions. (QARD, Rev 18, 7.2.3.B.6, 7.2.3.B.7)

A7.1.3.3 Any deficiencies that would affect quality shall be corrected before starting quality affecting work. (QARD, Rev 18, 7.2.3.D)

A7.1.3.4 The supplier's quality assurance program description document shall be accepted by the purchaser prior to the start of work. (QARD, Rev 18, 7.2.3.E)

A7.1.4 Supplier Performance Evaluation

A7.1.4.1 The purchaser of items and services shall establish measures to interface with the supplier to verify performance. The measures shall include: (QARD, Rev 18, 7.2.4.A)

A7.1.4.1.1 Establishing an understanding between the purchaser and supplier regarding the requirements and specifications identified in the procurement documents. (QARD, Rev 18, 7.2.4.A.1)

A7.1.4.1.2 Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements. (QARD, Rev 18, 7.2.4.A.2)

A7.1.4.1.3 Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements. (QARD, Rev 18, 7.2.4.A.3)

A7.1.4.1.4 Identifying and processing necessary change information. (QARD, Rev 18, 7.2.4.A.4)

A7.1.4.1.5 Establishing the method to be used to document information exchanges between purchaser and supplier. (QARD, Rev 18, 7.2.4.A.5)

A7.1.4.1.6 Establishing the extent of source surveillance and inspection. (QARD, Rev 18, 7.2.4.A.6)

A7.1.4.2 Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. This evaluation shall be documented and based on: (QARD, Rev 18, 7.2.4.B)

A7.1.4.2.1 Review of supplier furnished documents and records (e.g., certificates of conformance, the American Society of Mechanical Engineers (ASME) Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, and corrective actions). (QARD, Rev 18, 7.2.4.B.1)

A7.1.4.2.2 Results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits from other sources (e.g., other customers, ASME, NRC) (QARD, Rev 18, 7.2.4.B.2)

A7.1.4.2.3 Operating experience of identical or similar products furnished by the same supplier. (QARD, Rev 18, 7.2.4.B.3)

A7.1.4.3 The extent of verifications, including planning, shall be a function of the relative importance, complexity, and quantity of items or services being procured and the supplier's quality performance. (QARD, Rev 18, 7.2.4.C)

A7.1.4.4 Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier activities. (QARD, Rev 18, 7.2.4.D)

A7.1.4.5 Verifications shall be conducted as early as practical and shall not relieve the supplier of their responsibility for the verification of quality achievement. Verifications shall include: (QARD, Rev 18, 7.2.4.E)

A7.1.4.5.1 The use of audits to evaluate the supplier's performance. (QARD, Rev 18, 7.2.4.E(i))

A7.1.4.5.2 Evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program. This documentation shall include, as appropriate, the documentation of source surveillance and inspections, audits, receiving inspection, nonconformances, dispositions, waivers, and corrective actions. (QARD, Rev 18, 7.2.4.E(ii))

A7.1.4.6 In order to determine the effectiveness of a supplier's quality assurance program, the purchasers of items and services shall evaluate documentation related to that effectiveness, such as surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective action as they relate to the scope of a procurement. (QARD, Rev 18, 7.2.4.F)

A7.1.5 Acceptance of Items or Services

A7.1.5.1 Methods for accepting supplier furnished items or services shall ensure that items or services comply with the purchaser's procurement document requirements and include one or more of the following, as appropriate to the items or services being procured: (QARD, Rev 18, 7.2.6.C)

A7.1.5.1.1 Technical verification of data produced (services only). (QARD, Rev 18, 7.2.6.C.3)

A7.1.5.1.2 Surveillance and/or audit of the activity (services only). (QARD, Rev 18, 7.2.6.C.4)

A7.1.5.1.3 Review of objective evidence (e.g., certifications, stress reports, etc.) for conformance to the procurement document requirements (services only). (QARD, Rev 18, 7.2.6.C.5)

A7.1.5.1.4 Purchaser shall accept items and services prior to installation or use. (QARD, Rev 18, 7.2.6.D)

A7.1.6 Source Verification

A7.1.6.1 Verification activities are planned and performed with quality assurance organization participation in accordance with written procedures to ensure conformance to procurement requirements. Procedures applicable to the method of procurement provide for: (QARD, Rev 18, 7.2.8.A)

A7.1.6.1.1 Specification of the characteristics or processes to be witnessed, inspected, or verified and the method of surveillance and the extent of documentation required. (QARD, Rev 18, 7.2.8.A.1)

A7.1.6.1.2 Audits, surveillance, or inspections to verify the effectiveness of the supplier's quality assurance program and quality control activities and to ensure that the supplier complies with quality assurance and technical requirements. (QARD, Rev 18, 7.2.8.A.2)

A7.1.6.2 Source verification shall be implemented to inspect, monitor, witness, or observe activities consistent with the supplier's planned fabrication, inspections, examinations, or tests, and shipments of items at predetermined points and performed at intervals consistent with the importance and complexity of the item. (QARD, Rev 18, 7.2.8.B)

A7.1.7 Commercial Grade Items

A7.1.7.1 General

A7.1.7.1.1 Where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, commercial grade items may be substituted for basic components, subject to the following to provide the necessary assurance that the dedicated item will perform its intended waste acceptance impacting function: (QARD, Rev 18, 7.2.12.A)

A7.1.7.1.1.1 The item's critical characteristics shall be specified in approved design and procurement documents. (QARD, Rev 18, 7.2.12.A.1)

A7.1.7.1.1.2 Verification of the item's critical characteristics shall be achieved by application of a dedication process to be performed by a specified dedicating entity. (QARD, Rev 18, 7.2.12.A.2)

A7.1.7.1.1.3 Implementing processes shall be developed to be consistent with Electric Power Research Institute (EPRI) Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07), EPRI NP-5652 (6/88), as endorsed and modified by NRC Generic Letters 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (3/89) and 91-05, Licensee Commercial-Grade Procurement and Dedication Programs (4/91). (QARD, Rev 18, 7.2.12.A.3)

A7.1.7.1.2 Definitions

A7.1.7.1.2.1 ***Commercial Grade Item***–An item that is not subject to design or specification requirements that are unique to nuclear facilities or activities, is used in applications other than nuclear facilities or activities, and is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturers published product description (e.g., catalog). (QARD, Rev. 18, *Glossary*)

A7.1.7.1.2.2 ***Critical Characteristics***–The important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function, or reasonable expectation that the item will perform its intended waste isolation function. (QARD, Rev. 18, *Glossary*)

A7.1.7.1.2.3 ***Dedicating Entity***–The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the U.S. Department of Energy itself. The dedicating entity is responsible for identifying and evaluating deviations, reporting

defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. (QARD, Rev. 18, *Glossary*)

A7.1.7.1.2.4 ***Dedication***–An acceptance process undertaken to provide: (QARD, Rev. 18, *Glossary*)

A7.1.7.1.2.4.1 Reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function or

A7.1.7.1.2.4.2 Reasonable expectation that the item will perform its intended function and, in this respect, is deemed equivalent to an item designed and manufactured under a QARD quality assurance program.

A7.1.7.1.2.4.3 This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by a purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following:

A7.1.7.1.2.4.3.1 Commercial grade surveys

A7.1.7.1.2.4.3.2 Product inspections or witnessing at hold points at the manufacturer's facilities, and

A7.1.7.1.2.4.3.3 Analyses of historical records for acceptable performance.

A7.1.7.1.2.4.4 In all cases, the dedication process shall be conducted in accordance with the applicable requirements of QARD. Final dedication of an item occurs after receipt inspection and final acceptance by the U.S. Department of Energy or its contractor, when the item is designated for use as a basic component.

Appendix A
Policy Q-08.1 - Identification and Control of Items

A8.1.1 General

A8.1.1.1 Computer software nonconformances shall be controlled in accordance with Policy Q-03.2, *Software Quality*. (QARD, Rev 18, 8.1.B)

A8.1.2 Identification

A8.1.2.1 Correct identification of items shall be verified and documented prior to release for fabrication, assembly, shipping, or installation. (QARD, Rev 18, 8.2.1.D)

A8.1.3 Traceability

A8.1.3.1 If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item. (QARD, Rev 18, 8.2.3.B)

A8.1.4 Limited Life Items

A8.1.4.1 If items, including consumables, have a limited calendar (shelf) life, operating life, or operating cycles, their use shall be subjected to methods established to: (QARD, Rev 18, 8.2.3.C)

A8.1.4.1.1 Uniquely identify them. (QARD, Rev 18, 8.2.3.C.1)

A8.1.4.1.2 Establish records identifying the calendar (shelf) life, operating life, and/or operating cycles remaining. (QARD, Rev 18, 8.2.3.C.2)

A8.1.4.1.3 Prevent the further use of such items, including consumables, which have reached the end of their calendar (shelf) life, operating life, or operating cycles. (QARD, Rev 18, 8.2.3.C.3)

Appendix A
Policy Q-09.1 – Control of Special Processes

A9.1.1 General

A9.1.1.1 Processes to be controlled as special processes shall meet the following criteria: (QARD, Rev 18, 9.2.1.B)

A9.1.1.1.1 The results are highly dependent on the control of the process. (QARD, Rev 18, 9.2.1.B.1.)

A9.1.1.1.2 The results are highly dependent on the skill of the operator. (QARD, Rev 18, 9.2.1.B.2)

A9.1.1.1.3 Quality of the results cannot be readily determined by inspection or test of the item. (QARD, Rev 18, 9.2.1.B.3)

A9.1.2 Personnel, Implementing Documents, and Equipment Qualifications

A9.1.2.1 Implementing documents (instructions, procedures, drawings, checklists, travelers, or other appropriate means) shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference: (QARD, Rev 18, 9.2.2)

A9.1.2.1.1 Organizational responsibilities, including those for the quality assurance organization, for the qualification of special process equipment and personnel. (QARD, Rev 18, 9.2.2.A)

A9.1.2.1.2 Provisions for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, personnel, and traceability between the item and the individual performing the special process. (QARD, Rev 18, 9.2.2.B, 9.2.2.D)

A9.1.2.1.3 Certificates of qualification shall clearly delineate the specific processes that personnel are qualified to perform and the criteria used to qualify personnel in each process. (QARD, Rev 18, 9.2.2.C)

A9.1.2.1.4 A requirement for the quality assurance organization to be involved in special process personnel, equipment, and process qualification to ensure satisfactory performance. This involvement includes, but is not limited to the performance of surveillances and audits. (QARD, Rev 18, 9.2.2.F)

Appendix A
Policy Q-10.1 – Inspection

A10.1.1 Inspection Planning

A10.1.1.1 Inspection planning shall be performed and documented. Inspection plans may be separate documents governed by procedural controls, or an integral part of approved implementing documents. (QARD, Rev 18, 10.2.1.A)

A10.1.1.2 Representatives of the interested technical organizations and the quality assurance organization shall participate in planning activities. (QARD, Rev 18, 10.2.1.B)

A10.1.1.3 Related codes, standards, specifications, and design documents shall be used to develop inspection plans. (QARD, Rev 18, 10.2.1.C)

A10.1.1.4 The elements of inspection plans shall identify: (QARD, Rev 18, 10.2.1.D)

A10.1.1.4.1 Characteristics to be inspected. (QARD, Rev 18, 10.2.1.D.1)

A10.1.1.4.2 Description of inspection or process monitoring that will be used. (QARD, Rev 18, 10.2.1.D.2)

A10.1.1.4.3 Identification of the organization responsible for performing the inspection. (QARD, Rev 18, 10.2.1.D.3)

A10.1.1.4.4 Acceptance criteria. (QARD, Rev 18, 10.2.1.D.4)

A10.1.1.4.5 Measuring and test equipment to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function. (QARD, Rev 18, 10.2.1.D.5)

A10.1.1.4.6 If applicable, identification of a sampling plan in accordance with the requirements of A10.1.3. (QARD, Rev 18, 10.2.1.D.6)

A10.1.1.4.7 Methods to record inspection results. (QARD, Rev 18, 10.2.1.D.7)

A10.1.2 Selecting Inspection Personnel to Perform Inspections

A10.1.2.1 The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of this section. (QARD, Rev 18, 10.2.2.A)

A10.1.2.2 Data recorders, equipment operators, or other inspection or test team members who are supervised by a qualified inspector shall not be required to be a qualified inspector. (QARD, Rev 18, 10.2.2.B)

A10.1.2.3 Inspections shall be performed by individuals other than those who performed the activity being inspected, and those individuals shall not report directly to the supervisor immediately responsible for performance of the work. (QARD, Rev 18, 10.2.2.C)

A10.1.3 Statistical Sampling

A10.1.3.1 The statistical sampling method shall comply with the sampling plan requirements delineated in Policy Q-03.1, *Design Control.* (QARD, Rev 18, 10.2.4)

A10.1.4 In-Process Inspections and Monitoring

A10.1.4.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. (QARD, Rev 18, 10.2.5.C)

A10.1.4.2 Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process or construction. (QARD, Rev 18, 10.2.5.D)

A10.1.5 Final Inspection

A10.1.5.1 Quality records not previously examined shall be examined for adequacy and completeness. (QARD, Rev 18, 10.2.6.B)

A10.1.6 Accepting Items

A10.1.6.1 The acceptance of inspection results shall be documented and approved by qualified and authorized personnel. (QARD, Rev 18, 10.2.7.A)

A10.1.6.2 The inspection status of an item shall be identified according to Policy Q-14.1, *Inspection, Test, and Operating Status.* (QARD, Rev 18, 10.2.7.B)

A10.1.7 Qualification and Certification of Inspection Personnel

A10.1.7.1 Personnel who perform inspections shall be qualified and certified in accordance with Policy 2.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel.* (QARD, Rev 18, 10.2.9)

Appendix A
Policy Q-11.1 – Test Control

A11.1.1 General

A11.1.1.1 Testing of computer software supporting a waste acceptance impacting function shall be performed in accordance with Policy 3.2, *Software Quality*. (QARD, Rev 18, 11.1.B)

A11.1.2 Test Planning

A11.1.2.1 Test planning shall require that test implementing documents provide for the following: (QARD, Rev 18, 11.2.1)

A11.1.2.1.1 Identification of the implementing documents to be developed to control and perform tests and provide criteria for: (QARD, Rev 18, 11.2.1.A)

A11.1.2.1.1.1 Determining the accuracy requirements of test equipment. (QARD, Rev 18, 11.2.1.A(i))

A11.1.2.1.1.2 Determining when tests are required and defining how and when testing activities are performed. (QARD, Rev 18, 11.2.1.A(ii))

A11.1.2.1.2 Provisions for performing prototype, component, or feature qualification testing, including design verification testing, as early as possible before the installation would become irreversible. (QARD, Rev 18, 11.2.1.B)

A11.1.2.1.3 Identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents. (QARD, Rev 18, 11.2.1.C)

A11.1.2.1.4 Identification of test methods to be employed and instructions for performing the test. (QARD, Rev 18, 11.2.1.D)

A11.1.2.1.5 Mandatory inspection hold points for witnessing by the organization placing the hold point. (QARD, Rev 18, 11.2.1.F)

A11.1.2.1.6 Methods to record data and results. (QARD, Rev 18, 11.2.1.G)

A11.1.2.1.7 Provisions for ensuring that test prerequisites have been met. (QARD, Rev 18, 11.2.1.H)

A11.1.2.1.8 Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the measuring and test equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function. (QARD, Rev 18, 11.2.1.I)

A11.1.3 Test Procedures

A11.1.3.1 Tests shall be performed in accordance with implementing documents that address the following requirements, as applicable: (QARD, Rev 18, 11.1.A.1, 11.2.2)

A11.1.3.1.1 Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel. (QARD, Rev 18, 11.2.2.A)

A11.1.4 Use of Other Testing Documents

A11.1.4.1 Other testing documents shall include adequate supplemental instructions, as required, to ensure the required quality of the testing work. (QARD, Rev 18, 11.2.3.B)

A11.1.5 Test Results

A11.1.5.1 The test status of an item shall be identified in accordance with Policy Q-14.1, *Inspection, Test, and Operating Status*. (QARD, Rev 18, 11.2.4.B)

A11.1.6 Test Documentation

A11.1.6.1 Test documentation shall identify the following: (QARD, Rev 18, 11.2.5)

A11.1.6.1.1 Item or work product tested. (QARD, Rev 18, 11.2.5.A)

A11.1.6.1.2 Date of test. (QARD, Rev 18, 11.2.5.B)

A11.1.6.1.3 Name of the tester and data recorders. (QARD, Rev 18, 11.2.5.C)

A11.1.6.1.4 Type of observation. (QARD, Rev 18, 11.2.5.D)

A11.1.6.1.5 Identification of test criteria or reference documents used to determine acceptance. (QARD, Rev 18, 11.2.5.E)

A11.1.6.1.6 Results and acceptability of the test. (QARD, Rev 18, 11.2.5.F)

A11.1.6.1.7 Actions taken in connection with any nonconformances noted. (QARD, Rev 18, 11.2.5.G)

A11.1.6.1.8 Name of the person evaluating and accepting the test results. (QARD, Rev 18, 11.2.5.H)

A11.1.6.1.9 Identification of the measuring and test equipment used during the test, including the identification number and the next calibration due date. (QARD, Rev 18, 11.2.5.I)

A11.1.7 Qualification and Certification of Test Personnel

A11.1.7.1 Personnel who direct tests shall be qualified and certified according to the requirements of Policy Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel.* (QARD, Rev 18, 11.2.6)

Appendix A
Policy Q-12.1 – Control of Measuring and Test Equipment

A12.1.1 Calibration

A12.1.1.1 Calibration standards shall have a greater accuracy than the required accuracy of standards being calibrated. (QARD, Rev 18, 12.2.1.B)

A12.1.1.1.1 If calibration standards with a greater accuracy than required of the standard being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements. (QARD, Rev 18, 12.2.1.B.1)

A12.1.1.1.2 The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified. (QARD, Rev 18, 12.2.1.B.2)

A12.1.1.2 Calibration standards used for the calibration of measuring and test equipment shall have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, shall have an accuracy that ensures that the equipment being calibrated will be within required tolerance. The basis of acceptance shall be approved by responsible management. The level of management authorized to perform this function shall be identified. (QARD, Rev 18, 12.2.1.C)

A12.1.1.3 Updates to software contained in measuring and test equipment that affect calibration shall require recalibration of the equipment prior to use. (QARD, Rev 18, 12.2.1.H)

A12.1.2 Control

A12.1.2.1 For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use. (QARD, Rev 18, 12.2.1.D)

A12.1.3 Documentation

A12.1.3.1 The use of measuring and test equipment shall be documented. (QARD, Rev 18, 12.2.2.A)

A12.1.3.2 As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration. (QARD, Rev 18, 12.2.2.C)

A12.1.3.3 Measuring and test equipment calibration documentation shall include the following information: (QARD, Rev 18, 12.2.7)

A12.1.3.3.1 Identification of the measuring or test equipment calibrated. (QARD, Rev 18, 12.2.7.A)

A12.1.3.3.2 Traceability to the calibration standard used for calibration. (QARD, Rev 18, 12.2.7.B)

A12.1.3.3.3 Calibration data. (QARD, Rev 18, 12.2.7.C)

A12.1.3.3.4 Identification of the individual performing the calibration. (QARD, Rev 18, 12.2.7.D)

A12.1.3.3.5 Identification of the date of calibration and the recalibration due date or interval, as appropriate. (QARD, Rev 18, 12.2.7.E)

A12.1.3.3.6 Results of the calibration and statement of acceptability. (QARD, Rev 18, 12.2.7.F)

A12.1.3.3.7 Reference to any actions taken in connection with out-of-calibration or nonconforming measuring and test equipment, including evaluation results and repeated inspections or tests, as appropriate. (QARD, Rev 18, 12.2.7.G)

A12.1.3.3.8 Identification of the implementing document (including revision level) used in performing the calibration. (QARD, Rev 18, 12.2.7.H)

A12.1.4 Out-of-Calibration Measuring and Test Equipment

A12.1.4.1 Measuring and test equipment shall be considered to be out-of-calibration and shall not be used until calibrated if any of the following conditions exist: (QARD, Rev 18, 12.2.3.A)

A12.1.4.1.1 The calibration due date or interval has passed without recalibration. (QARD, Rev 18, 12.2.3.A.1)

A12.1.4.1.2 The device produces results known to be in error. (QARD, Rev 18, 12.2.3.A.2)

A12.1.4.1.3 The calibration status cannot be determined. (QARD, Rev 18, 12.2.3.A.3)

A12.1.5 Lost Measuring and Test Equipment

A12.1.5.1 When measuring and test equipment is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated. (QARD, Rev 18, 12.2.4)

A12.1.5.1.1 The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. (QARD, Rev 18, 12.2.4.A)

A12.1.5.1.2 The evaluation shall be documented. (QARD, Rev 18, 12.2.4.B)

A12.1.5.1.3 If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Policy Q-15.1, *Control of Nonconforming Items*. (QARD, Rev 18, 12.2.4.C)

A12.1.6 Handling, Storage, and Use

A12.1.6.1 Selection of measuring and test equipment shall be controlled to ensure that such items are the proper type for the intended use. (QARD, Rev 18, 12.2.5.B)

A12.1.6.2 Calibrated measuring and test equipment shall be uniquely identified to provide traceability to its calibration data. (QARD, Rev 18, 12.2.1.G)

Appendix A
Policy Q-15.1 – Control of Nonconforming Items

A15.1.1 Documentation

A15.1.1.1 Nonconformances shall be documented and reported to the appropriate levels of management responsible for the conditions. In addition, organizations affected by the nonconformance shall be notified. (QARD, Rev 18, 15.2.1.A)

A15.1.1.2 Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria. (QARD, Rev 18, 15.2.1.C)

A15.1.1.3 Computer software nonconformances shall be controlled in accordance with Appendix E, *Supplement to Policy Q-03.2, Software Quality,* Section E3.2.2.7. (QARD, Rev 18, 15.1.B)

A15.1.2 Disposition Control

A15.1.2.1 The review shall include determining the need for corrective action according to the requirements of Policy Q-16.1, *Corrective Action.* (QARD, Rev 18, 15.2.1.D)

A15.1.2.2 Recommended dispositions shall be evaluated and approved by individuals who are independent of the work that produced the disposition. (QARD, Rev 18, 15.2.1.E)

A15.1.2.3 Personnel performing evaluations to determine a disposition as well as those evaluating a recommended disposition shall have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and access to pertinent background information. (QARD, Rev 18, 15.2.1.F)

A15.1.2.4 The responsibility and authority for reviewing, evaluating, and approving the disposition, and closing nonconformances shall be specified. (QARD, Rev 18, 15.2.1.G)

A15.1.2.5 Nonconformances shall be corrected or dispositioned before initiation of the preoperational test program on the item. (QARD, Rev 18, 15.2.1.I)

A15.1.2.6 Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. (QARD, Rev 18, 15.2.4.C)

A15.1.2.6.1 If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance. (QARD, Rev 18, 15.2.4.C.1)

A15.1.2.6.2 Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation, and when each document

or record is changed, the justification for the change shall identify the nonconformance documentation. (QARD, Rev 18, 15.2.4.C.2)

A15.1.2.7 Replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives. (QARD, Rev 18, 15.2.4.E)

A15.1.2.8 The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (i.e., inspect, test, or nondestructive examination) the item to verify acceptability. (QARD, Rev 18, 15.2.4.D)

Appendix A
Policy Q-17.1 – Quality Assurance Records

A17.1.1 Quality Assurance Records

A17.1.1.1 Specific quality assurance record types include, but are not limited to: (QARD, Rev 18, 17.2.1.A)

A17.1.1.1.1 Scientific, engineering, and operational data and logs; laboratory and field notebooks and logbooks; and data reduction documents. (QARD, Rev 18, 17.2.1.A.1)

A17.1.1.1.2 Results of reviews, inspections, tests, audits, and material analysis. (QARD, Rev 18, 17.2.1.A.2)

A17.1.1.1.3 Monitoring of work performance. (QARD, Rev 18, 17.2.1.A.3)

A17.1.1.1.4 Maintenance and modification procedures and related inspection results. (QARD, Rev 18, 17.2.1.A.4)

A17.1.1.1.5 Reportable occurrences. (QARD, Rev 18, 17.2.1.A.5)

A17.1.1.1.6 Quality assurance program changes that reduce commitments. (QARD, Rev 18, 17.2.1.A.6)

A17.1.1.1.7 Computer software supporting a waste acceptance impacting function. (QARD, Rev 18, 17.2.1.A.7)

A17.1.1.1.8 Qualification of personnel, procedures, and equipment. (QARD, Rev 18, 17.2.1.A.8)

A17.1.1.1.9 Documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, construction records, and as-built drawings. (QARD, Rev 18, 17.2.1.A.9)

A17.1.2 Creating Valid Quality Assurance Records

A17.1.2.1 Implementing documents shall: (QARD, Rev 18, 17.2.2.A)

A17.1.2.1.1 Identify those documents that will become quality assurance records. (QARD, Rev 18, 17.2.2.A.1)

A17.1.2.1.2 Identify the organization responsible for submitting the quality assurance records to the records management system. (QARD, Rev 18, 17.2.2.A.2)

A17.1.2.1.3 Individuals handling quality assurance records shall protect them from damage or loss until the records are submitted to the records management system. (QARD, Rev 18, 17.2.2.C)

A17.1.2.2 Quality record authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (e.g., magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted. (QARD, Rev 18, 17.2.2.D)

A17.1.2.3 Handwritten signatures shall not be required if the document is clearly identified as a statement of the reporting individual or organization. (QARD, Rev 18, 17.2.2.E)

A17.1.2.4 Quality assurance records may be originals or copies. (QARD, Rev 18, 17.2.2.F)

A17.1.3 Submission of Quality Assurance Records

A17.1.3.1 Quality assurance records shall be submitted to the records management system for receipt, processing, and storage. (QARD, Rev 18, 17.2.3)

A17.1.4 Receiving and Indexing Quality Assurance Records

A17.1.4.1 A receipt control system shall be established for quality assurance records according to the following requirements: (QARD, Rev 18, 17.2.4)

A17.1.4.1.1 A method shall be established for verifying that the quality assurance records received are in agreement with the transmittal document. (QARD, Rev 18, 17.2.4.B)

A17.1.4.1.2 Legibility and completeness of quality assurance records shall be verified. (QARD, Rev 18, 17.2.4.D)

A17.1.4.1.3 The receipt control system shall permit a current and accurate assessment of the status of quality assurance records during processing. (QARD, Rev 18, 17.2.4.E)

A17.1.4.1.4 Quality assurance records shall be indexed to ensure retrievability. The indexing system shall include: (QARD, Rev 18, 17.2.4.F)

A17.1.4.1.4.1 The location of the quality assurance records within the records management system. (QARD, Rev 18, 17.2.4.F.1)

A17.1.4.1.4.2 Identification of the item or related activity to which the quality assurance records pertain. (QARD, Rev 18, 17.2.4.F.2)

A17.1.4.1.4.3 The record retention times. (QARD, Rev 18, 17.2.4.F.3)

A17.1.5 Correcting Information in Quality Assurance

A17.1.5.1 Corrections to quality assurance records, including documents that will become quality assurance records, shall include the initials or signature of the person authorized to make the correction and the date the correction was made. (QARD, Rev 18, 17.2.5.A)

A17.1.5.2 Corrections to quality assurance records shall be approved by the originating organization. If the organization responsible for generating the record is no longer available, a new responsible organization shall be identified. (QARD, Rev 18, 17.2.5.B)

A17.1.6 Storing and Preserving Quality Assurance Records

A17.1.6.1 Quality assurance records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides: (QARD, Rev 18, 17.2.6.A)

A17.1.6.1.1 A description of the storage facility. (QARD, Rev 18, 17.2.6.A.1)

A17.1.6.1.2 A description of the filing system to be used. (QARD, Rev 18, 17.2.6.A.2)

A17.1.6.1.3 A method for verifying that the quality assurance records received are in agreement with the transmittal document and that the records are legible. (QARD, Rev 18, 17.2.6.A.3)

A17.1.6.1.4 A description of controls governing quality assurance record access, retrieval, and removal. (QARD, Rev 18, 17.2.6.A.4)

A17.1.6.1.5 A method for filing supplemental information. (QARD, Rev 18, 17.2.6.A.5)

A17.1.6.1.6 A method for disposition of superseded quality assurance records. (QARD, Rev 18, 17.2.6.A.6)

A17.1.6.2 Approved filing methods shall require quality assurance records to be firmly attached in binders or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the quality assurance record medium being stored. (QARD, Rev 18, 17.2.6.B.2)

A17.1.6.3 The storage area shall be protected from unauthorized entry, larceny, and vandalism. (QARD, Rev 18, 17.2.6.B.4)

A17.1.7 Retrieval of Quality Assurance Records

A17.1.7.1 Access to storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the quality assurance records. (QARD, Rev 18, 17.2.7.B)

A17.1.8 Turnover of Quality Assurance Records

A17.1.8.1 Suppliers shall submit to WTP records management, those quality assurance records being temporarily stored by suppliers that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete or, as items are released for shipment, or as prescribed by the purchaser. (QARD, Rev 18, 17.2.9.A)

A17.1.8.2 The records management organization shall inventory the submittal, acknowledge receipt, and process the quality assurance records. (QARD, Rev 18, 17.2.9.B)

A17.1.8.3 The responsible line organizations shall identify those quality assurance records in temporary storage to be submitted for long-term storage to the records management system in accordance with the following sections on long-term single storage facility or dual storage facilities. (QARD, Rev 18, 17.2.9.C)

A17.1.9 Temporary Storage Facility

A17.1.9.1 Temporary storage shall provide for the storage of quality assurance records during processing, review, or use until turnover to the DOE for disposition according to the following requirements: (QARD, Rev 18, 17.2.12)

A17.1.9.1.1 Quality assurance records shall be temporarily stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided. (QARD, Rev 18, 17.2.12.A)

A17.1.9.1.2 Single storage containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection. (QARD, Rev 18, 17.2.12.B)

A17.1.9.1.3 Procedures shall specify the maximum allowable time for the temporary storage of quality assurance records. (QARD, Rev 18, 17.2.12.C)

A17.1.10 Replacement of Quality Assurance Records

A17.1.10.1 Organizations originating quality assurance records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged quality assurance records. (QARD, Rev 18, 17.2.13)

Appendix A
Policy Q-18.1 – Audit (Independent Assessment)

A18.1.1 Scheduling Audits

A18.1.1.1 The following areas shall also be considered when scheduling audits:

A18.1.1.1.1 The preparation, review, approval, and control of early procurements. (QARD, Rev 18, 18.2.1.B)

A18.1.1.1.2 Indoctrination and training programs. (QARD, Rev 18, 18.2.1.C)

A18.1.1.1.3 Interface control. (QARD, Rev 18, 18.2.1.D)

A18.1.1.1.4 Corrective action, calibration, and nonconformance control systems. (QARD, Rev 18, 18.2.1.E)

A18.1.1.1.5 Development and control of computer software supporting a waste acceptance impacting function. (QARD, Rev 18, 18.2.1.G)

A18.1.1.1.6 The purchase of items, including ASME Code items. (QARD, Rev 18, 18.2.1.H)

A18.1.1.1.7 Audits of suppliers, including ASME Code suppliers. (QARD, Rev 18, 18.2.1.I)

A18.1.1.2 Audit Responses shall be evaluated by the auditing organization. (QARD, Rev 18, 18.2.11)

A18.1.2 Internal Audits

A18.1.2.1 Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work. (QARD, Rev 18, 18.2.2.A)

A18.1.2.2 Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work. (QARD, Rev 18, 18.2.2.B)

A18.1.2.3 Audits shall be scheduled (including performance-based audits) of applicable QARD elements to verify compliance and effectiveness. (QARD, Rev 18, 18.2.2.E, 18.2.2.F)

A18.1.2.4 Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. (QARD, Rev 18, 18.2.2.C)

A18.1.2.5 Internal audits shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter. (QARD, Rev 18, 18.2.2.E)

A18.1.3 External Audits

A18.1.3.1 External audits (audits of suppliers) shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work at a frequency commensurate with the status and importance of the work. (QARD, Rev 18, 18.2.3.A)

A18.1.3.2 External audits shall be scheduled, at a frequency commensurate with the status and importance of the work, to begin as early in the life of the work as practical and to continue at intervals consistent with the schedule for accomplishing the work. (QARD, Rev 18, 18.2.3.B, 18.2.3.B.1, 18.2.3.B.2, 18.2.3.B.3)

A18.1.3.3 The audit period (triennial or annual) shall begin when the audit is performed. (QARD, Rev 18, 18.2.3.C.1)

A18.1.3.4 External supplier audits for compliance and effectiveness shall be performed triennially (every third year) or at least once during the life of the work, whichever is shorter. Regularly scheduled external audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness (performance based). (QARD, Rev 18, 18.2.3.C, 18.2.3.D)

A18.1.3.4.1 The initial external audit shall be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a quality assurance program that has the required scope for purchases placed during the audit period. (QARD, Rev 18, 18.2.3.C.2)

A18.1.3.4.2 An audit of the modified requirements shall be performed when a major change in the contract scope, work methodology, or organization occurs. This audit shall start a new audit period. (QARD, Rev 18, 18.2.3.C.3)

A18.1.3.5 External audits may not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, and adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. Rationale for not performing audits for these items shall be documented. (QARD, Rev 18, 18.2.3.E)

A18.1.3.6 Pre-award surveys, if applicable, may serve as the first triennial audit, provided: (QARD, Rev 18, 18.2.3.F)

A18.1.3.6.1 The supplier is implementing the same quality assurance program for other contracts that is proposed for the purchaser's contract. (QARD, Rev 18, 18.2.3.F.1)

A18.1.3.6.2 The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit. (QARD, Rev 18, 18.2.3.F.2)

A18.1.4 Audit Schedule

A18.1.4.1 The audit schedule(s) shall be developed annually and revised periodically to ensure that coverage is maintained current. (QARD, Rev 18, 18.2.4)

A18.1.5 Audit Planning

A18.1.5.1 Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items. (QARD, Rev 18, 18.2.5.A)

A18.1.5.2 The scope of each internal audit shall be based on evaluation of implementing documents, activities, and items to be audited; results of previous audits; nature and frequency of previously identified deficiencies; and impact of significant changes in personnel, organization, or the quality assurance program. (QARD, Rev 18, 18.2.5.B)

A18.1.6 Selection of an Audit Team

A18.1.6.1 The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. (QARD, Rev 18, 18.2.6)

A18.1.6.2 The audit team shall include representatives from the quality assurance organization, and when appropriate, applicable technical specialists. (QARD, Rev 18, 18.2.7.A)

A18.1.6.3 Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes. Technical specialists, when used, shall be indoctrinated and trained in accordance with Policy Q-02.4, *Personnel Training and Qualification.* (QARD, Rev 18, 18.2.7.D)

A18.1.6.4 In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team. (QARD, Rev 18, 18.2.7.E)

A18.1.6.5 The lead auditor shall ensure, before starting the audit, that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited. (QARD, Rev 18, 18.2.7.F)

A18.1.7 Performing Audits

A18.1.7.1 The audit team leader shall ensure that the audit team is prepared before starting the audit. (QARD, Rev 18, 18.2.8.A)

A18.1.7.2 Audit results shall be documented by auditing personnel and reported to and reviewed by management having responsibility for the area audited. (QARD, Rev 18, 18.2.8.E)

Appendix A
Supplement II – Sample Control

S II.1 General

S II.1.1 This supplement establishes requirements for the control of physical samples. (QARD, Rev 18, Supplement II, II.1)

S II.2 Requirements

S II.2.1 General Requirements

S II.2.1.1 Samples shall be controlled and identified in a manner consistent with their intended use. (QARD, Rev 18, Supplement II, II.2.1(a))

S II.2.1.2 Controls shall identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use. (QARD, Rev 18, Supplement II, II.2.1(b))

S II.2.1.3 Controls shall include specifics on orientation relative to the location that was sampled, as appropriate. (QARD, Rev 18, Supplement II, II.2.1(c))

S II.2.2 Traceability

S II.2.2.1 Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents. (QARD, Rev 18, Supplement II, II.2.2(a))

S II.2.2.2 Sample traceability shall ensure that the sample can be traced at all times from its collection through final use and any post-test retention that may be appropriate. (QARD, Rev 18, Supplement II, II.2.2(b))

S II.2.3 Identification

S II.2.3.1 Identification shall be maintained on the samples or in a manner that ensures that identification is established and maintained. (QARD, Rev 18, Supplement II, II.2.3.A)

S II.2.3.2 Samples shall be identified from their initial collection through final use. (QARD, Rev 18, Supplement II, II.2.3.B)

S II.2.3.3 Sample identification shall be documented and checked before the sample is released for use or analysis. (QARD, Rev 18, Supplement II, II.2.3.C)

S II.2.3.4 Sample identification methods shall include use of physical markings. (QARD, Rev 18, Supplement II, II.2.3.D)

S II.2.3.5 If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to containers, or other procedural control). (QARD, Rev 18, Supplement II, II.2.3.E)

S II.2.3.6 Physical markings, when used, shall: (QARD, Rev 18, Supplement II, II.2.3.F)

S II.2.3.6.1 Be applied using materials and methods that provide a clear and legible identification. (QARD, Rev 18, Supplement II, II.2.3.F.1)

S II.2.3.6.2 Not detrimentally affect the sample content or form. (QARD, Rev 18, Supplement II, II.2.3.F.2)

S II.2.3.6.3 Be transferred to each identified sample part when the sample is subdivided. (QARD, Rev 18, Supplement II, II.2.3.F.3)

S II.2.3.6.4 Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted. (QARD, Rev 18, Supplement II, II.2.3.F.4)

S II.2.4 Conditional Requirements

S II.2.4.1 The controls for samples shall address the following requirements, as applicable: (QARD, Rev 18, Supplement II, II.2.4)

S II.2.4.1.1 If documents contain specific identification or traceability requirements (i.e., identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented. (QARD, Rev 18, Supplement II, II.2.4.A)

S II.2.4.1.2 If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life. (QARD, Rev 18, Supplement II, II.2.4.B)

S II.2.4.1.3 If sample storage is required, then methods shall be established for the control of sample identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable: (QARD, Rev 18, Supplement II, II.2.4.C)

S II.2.4.1.3.1 Maintenance or replacement of markings and identification tags damaged during handling or aging. (QARD, Rev 18, Supplement II, II.2.4.C.1)

S II.2.4.1.3.2 Protection of identification markings subject to excessive deterioration resulting from environmental exposure. (QARD, Rev 18, Supplement II, II.2.4.C.2)

S II.2.4.1.3.3 Updating related documentation. (QARD, Rev 18, Supplement II, II.2.4.C.3)

S II.2.5 Archiving Samples

S II.2.5.1 Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified. (QARD, Rev 18, Supplement II, II.2.5)

S II.2.6 Handling, Storage, and Shipping

S II.2.6.1 Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents. (QARD, Rev 18, Supplement II, II.2.6.A)

S II.2.6.2 If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used. (QARD, Rev 18, Supplement II, II.2.6.B)

S II.2.6.3 Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples, as necessary, to adequately identify, maintain, and preserve the sample. (QARD, Rev 18, Supplement II, II.2.6.C)

S II.2.6.4 Markings and labels shall indicate the presence of special environments or the need for special controls, if necessary. (QARD, Rev 18, Supplement II, II.2.6.D)

S II.2.6.5 If required for particular samples, special equipment (i.e., containers) and special protective environments (i.e., inert gas and moisture and temperature limits) shall be specified and provided. (QARD, Rev 18, Supplement II, II.2.6.E)

S II.2.6.6 Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. (QARD, Rev 18, Supplement II, II.2.6.F)

S II.2.6.6.1 Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained. (QARD, Rev 18, Supplement II, II.2.6.F.1)

S II.2.6.6.2 Operators of special handling and lifting equipment shall be experienced or trained to use the equipment. (QARD, Rev 18, Supplement II, II.2.6.F.2)

S II.2.7 Disposition of Nonconforming Samples

S II.2.7.1 Samples that do not meet requirements specified in work-controlling documents shall be documented, evaluated, identified, and segregated in accordance with Policy Q-15.1, *Control of Nonconforming Items*. (QARD, Rev 18, Supplement II, II.2.7.A)

S II.2.7.2 The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is," "limited use," or "reject". (QARD, Rev 18, Supplement II, II.2.7.B)

Appendix A

Supplement V – Control of the Electronic Management of Information

S V.1 General

S V.1.1 This supplement applies to the processes and controls for the management of information that either exists or is used in an electronic format. This includes electronically formatted information used in design input, developed as design output, developed as an output performance assessment modeling and analysis. (QARD. Rev 18, Supplement V, V.1)

S V.1.2 Development, acquisition, and modification of software, including database applications or software that performs functions of analysis or calculation, shall be controlled in accordance with Policy Q-03.2, *Software Quality*. The acquisition, development, and use of information shall be controlled by the requirements of Policy Q-03.1, *Design Control*. (QARD, Rev 18, Supplement V, V.1)

S V.2 Requirements

S V.2.1 Control of the Electronic Management of Information

S V.2.1.1 Controls shall be established to ensure that: (QARD, Rev 18, Supplement V, V.2.1)

S V.2.1.1.1 Information is suitably protected from damage and destruction during its prescribed lifetime and is readily retrievable. (QARD, Rev 18, Supplement V, V.2.1.A)

S V.2.1.1.2 A description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access. (QARD, Rev 18, Supplement V, V.2.1.B)

S V.2.1.1.3 Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written). (QARD, Rev 18, Supplement V, V.2.1.C)

S V.2.1.1.4 The completeness and accuracy of the information input and any subsequent changes to the information are maintained. (QARD, Rev 18, Supplement V, V.2.1.D)

S V.2.1.1.5 The security and integrity of the information is maintained. (QARD, Rev 18, Supplement V, V.2.1.E)

S V.2.1.1.6 Transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure that no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer tape to disk, writing to a compact disk, etc. (QARD, Rev 18, Supplement V, V.2.1.F)

Appendix B Quality Assurance Manual Acronyms and Abbreviations

AB	Authorization Basis
ASME	American Society of Mechanical Engineers
BNI	Bechtel National, Inc.
CFR	Code of Federal Regulations
CGI	Commercial Grade Item
CGS	Commercial Grade Service
CM	Commercial
DEAR	DOE Acquisition Regulation
DOE	Department of Energy
EPA	Environmental Protection Agency
IHLW	Immobilized High-Level Waste
ISMS	Integrated Safety Management System
NDE	nondestructive examination
OCRWM	Office of Civilian Radioactive Waste Management
ORP	Office of River Protection
PAAA	Price-Anderson Amendments Act of 1988
Q	Quality
QAM	Quality Assurance Manual
QAPjP	Quality Assurance Project Plans
QARD	Quality Assurance Requirements and Description
S/CI	suspect/counterfeit item
WAC	Washington Administrative Code
WGI	Washington Group International
WTP	Hanford Tank Waste Treatment and Immobilization Plant

Appendix C Glossary

acceptance criteria - specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. (NQA-1-2000)

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. (NQA-1-2000, Sub-Part 2.7; DOE O 414.1C, QARD, Rev 18)

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, DOE O 414.1C; 10 CFR 830)

adverse condition - an all-inclusive term used in reference to any of the following:
- Failures, malfunctions, deficiencies, defective items, non-compliance and non-conformances.
- Contractual (of a nuclear or industrial safety or quality nature), procedural, programmatic, or technical conditions adverse to nuclear or process safety, industrial safety and health (IS&H), operations, quality, security, or the environment.

A significant adverse condition is one which, if uncorrected, could have a serious effect on safety or operability. (NQA-1-2000; QARD, Rev 18; Management Requirement)
This term is synonymous with "finding."

assessment - a review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. (DOE O 414.1C)

audit - a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit is not to be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. (NQA-1-2000; QARD, Rev 18)

baseline - a specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process. (NQA-1-2000, Sub-Part 2.7.)

certificate of conformance - a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements. (NQA-1-2000; QARD, Rev 18)

certification - the act of determining, verifying, and attesting in writing to the achievement or compliance with specified requirements. (NQA-1-2000; QARD, Rev 18)

characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable. (NQA-1-2000; QARD, Rev 18)

commercial grade item (CGI) - a structure, system, or component (safety class/safety significant), or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of the NQA-1 standard. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

commercial grade service (CGS) - a service that was not provided in accordance with the requirements of the NQA-1 standard. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

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computer program - combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. (NQA-1-2000; QARD Rev 18)

configuration - the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility. (NQA-1-2000)

configuration item - a collection of hardware or software elements treated as a unit for the purpose of configuration control. (NQA-1-2000; QARD, Rev 18)

configuration management - the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained. (NQA-1-2000)

configuration management (software) - the process of identifying and defining the configuration items in a system (e.g., 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. (NQA-1-2000, Subpart 2.7; QARD, Rev 18; DOE O 414.1C)

control point - a point in the software life cycle at which specified agreements or control (typically a test or review) are applied to the software configuration items being developed, e.g., an approved baseline or release of a specified document or computer program. (NQA-1-2000, Sub-Part 2.7; QARD, Rev 18)

controlled document - documents that specify technical or quality requirements or prescribe activities affecting quality. (QARD, Rev 18, 6.1)

corrective action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. (NQA-1-2000; QARD, Rev 18)

critical characteristics - important design, material, and performance characteristics of a commercial grade item or commercial grade service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II; QARD, Rev 18)

dedication - an acceptance process performed in accordance with this manual to provide reasonable assurance that a commercial grade item or commercial grade service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or services provided under the requirements of the NQA-1 standard. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

dedicating entity - the organization that performs the dedication process (manufacturer of the item, a third-party dedicating entity, BNI, or DOE). (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II; QARD, Rev 18)

defense in depth - the fundamental principle underlying the safety technology of the facility centered on several levels of protection including successive barriers preventing the release of radioactive materials to the workplace or environment. Human aspects of defense in depth are considered to protect the integrity of the barriers, such as quality assurance, administrative controls, safety reviews, operating limits, personnel qualification and training, and safety program. Design provisions, including both those for normal facility systems and those for systems important to safety help to:

- prevent undue challenges to the integrity of the physical barriers;
- prevent failure of a barrier if it is challenged;
- where it exists, prevent consequential damage to multiple barriers in series; and
- mitigate the consequences of accidents.

Defense in depth helps to assure that two basic safety functions (controlling the process flow and confining the radioactive material) are preserved and that radioactive materials do not reach the worker, public, or the environment. (DOE/RL-96/0006 Rev 3)

design authority - the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto. (NQA-1-2000)

design bases (basis) - that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be:

- restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals, or
- requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. (DOE/RL-96/0006 Rev 3, NQA-1-2000; QARD, Rev 18)

design change - any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto. (NQA-1-2000; QARD, Rev 18)

design, final - approved design output documents and approved changes thereto. (NQA-1-2000)

design input - those criteria, parameters, bases, regulatory requirements, or other design requirements upon which design output documents are based. (NQA-1-2000; QARD, Rev 18)

design output - drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs. (NQA-1-2000; QARD, Rev 18)

design process - technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. (NQA-1-2000; QARD, Rev 18)

design review - a critical review to provide assurance that the final design is correct and satisfactory. (NQA-1-2000; QARD, Rev 18)

deviation - a departure from specified requirements. (NQA-1-2000; QARD, Rev 18)

document - any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this manual. (NQA-1-2000)

document control - the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. (NQA-1-2000)

electronic document - a document stored in a form (e.g., magnetic or optical media) that is typically accessible only by a computer. (NQA-1-2000)

error - a condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements. (NQA-1-2000, Sub-Part 2.7)

finding - this term is synonymous with "adverse condition."

graded approach - the process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;

- the life-cycle stage of a facility or item;
- the programmatic mission of a facility;
- the particular characteristics of a facility or item;
- the relative importance to radiological and nonradiological hazards; and
- any other relevant factors. (10 CFR 830, DOE O 414.1C)

guidance - a suggested practice that is not mandatory in programs intended to comply with a standard. The word "should" denotes a guideline; the word "shall" denotes a requirement. (NQA-1-2000)

hazard controls - measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including:

- physical, design, structural, and engineering features;
- safety structures, systems, and components;
- safety management programs;
- technical safety requirements; and
- other controls necessary to provide adequate protection from hazards. (10 CFR 830; DOE O 414.1C)

indoctrination - a method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks. (QARD, Rev 18)

inspection - examination or measurement to verify whether an item or activity conforms to specified requirements. (NQA-1-2000; QARD, Rev 18)

integrated safety management system (program) - a set of activities that are directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment. (DOE/RL-96/0006 Rev 3)

item - an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (NQA-1-2000; QARD, Rev 18; 10 CFR 830; DOE O 414.1C)

measuring and test equipment (M&TE) - devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements. (NQA-1-2000; QARD, Rev 18)

nonconformance - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. (NQA-1-2000; QARD, Rev 18)

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; DOE O 414.1C)

objective evidence - any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity based on observations, measurements, or tests which can be verified. (NQA-1-2000; QARD, Rev 18)

operating environment - a collection of software, firmware, and hardware elements that provide for the execution of computer programs. (NQA-1-2000, Sub-Part 2.7)

owner - the organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction. (NQA-1-2000)

procedure - a document that specifies or describes how an activity is to be performed. (NQA-1-2000)

Appendix C Glossary

process - a series of actions that achieves an end result. (10 CFR 830, DOE O 414.1C; 10 CFR 830)

procurement document - purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. (NQA-1-2000; QARD, Rev 18)

purchaser - the organization (BNI) responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents. (NQA-1-2000; QARD, Rev 18)

qualification, personnel - the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function. (NQA-1-2000; QARD, Rev 18)

qualified automated means - automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits. (NQA-1-2000)

qualified procedure - an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose. (NQA-1-2000)

quality - the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. (10 CFR 830; DOE O 414.1C)

quality assurance - all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. (NQA-1-2000; QARD, Rev 18; DOE O 414.1C)

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; DOE O 414.1C)

quality assurance record - a completed document (or other medium) that furnishes evidence of the quality of items and/or activities affecting quality. (NQA-1-2000; QARD, Rev 18)

receiving - taking delivery of an item at a designated location. (NQA-1-2000)

repair - the process of restoring nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement. (NQA-1-2000; QARD, Rev 18)

rework - the process by which an item is made to conform to original requirements by completion or correction. (NQA-1-2000; QARD, Rev 18)

right of access - the right of a purchaser or designated representative to enter the premises of a supplier for the purposes of inspection, surveillance, or quality assurance audit. (QARD, Rev 18)

root cause - the identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality. (QARD, Rev 18)

safety - an all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment. (DOE O 414.1C)

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 structure, system, or component but helps to ensure the proper accident or hazards analysis of nuclear facilities or a structure, system, or component that performs a safety function. (DOE O 414.1C)

safety basis - the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment. (10 CFR 830)

safety class structures, systems, and components - the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses. (10 CFR 830)

safety evaluation report - the report prepared by DOE to document:

- the sufficiency of the documented safety analysis for a hazard category 1, 2, or 3 DOE nuclear facility;
- the extent to which a contractor has satisfied the requirements of Subpart B of this part; and
- the basis for approval by DOE of the safety basis for the facility, including any conditions for approval. (10 CFR 830)

safety function - a function that is necessary to ensure:

- the integrity of the boundaries retaining the radioactive materials or hazardous chemicals;
- the capability to place and maintain the facility in a safe state; or
- the capability to prevent or mitigate the consequences of facility conditions that could result in radiological or chemical exposures to the general public or workers in excess of appropriate limits. (NQA-1-2000, as tailored in Appendix C of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document*, Volume II)

safety limits - the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials (to workers or the general public). (10 CFR 830, DOE/RL-96/0006 Rev 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. (DOE O 414.1C)

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 and DOE O 414.1C)

safety significant structures, systems, and components - the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses. (10 CFR 830)

safety software - includes safety system software, safety and hazard analysis software and design software, and safety management and administrative controls software. (DOE O 414.1C)

safety structures, systems, and components - both safety class structures, systems, and components and safety significant structures, systems, and components. (10 CFR 830)

safety system software - software for a nuclear facility that performs a safety function as part of a structure, system, or component 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. (DOE O 414.1C)

sample - a physical part of a whole whose properties are studied to gain information about the whole. (QARD, Rev 18)

scientific investigation - a analysis consisting of an explanation, observation, identification,

description, or experimental study either of natural phenomena or of engineered materials that describe the postclosure repository system or its performance. (QARD, Rev 18)

scientific notebook - a record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both. (QARD, Rev 18)

service - the performance of activities, such as design, fabrication, inspection, nondestructive examination, repair, or installation. (NQA-1-2000; QARD Rev 18)

shall - see definition of the term, guidance. (NQA-1-2000)

should - see definition of the term, guidance. (NQA-1-2000)

software - computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. (NQA-1-2000; DOE O 414.1C)

software design implementation - translation of the software design into computer programs. (NQA-1-2000, RQMT 3, 801.3)

software design verification - the process of determining if the product of the software design activity fulfills the software design requirements. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

software development cycle - the activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities:

- software design requirements;
- software design;
- implementation;
- test; and sometimes
- installation. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

software engineering - 1) the application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is, the application of engineering to software; and 2) the study of approaches as in 1. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

software life cycle - the activities that comprise the evolution of software from conception to retirement. The software life cycle typically includes the software development cycle and the activities associated with operation, maintenance, and retirement. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

software tool - a computer program used in the development, testing, analysis, or maintenance of a program or its documentation. Examples include comparators, cross-reference generators, compilers, CASE (Computer Aided Software Engineering) tools, configuration and code management software,

decompilers, disassemblers, editors, flowcharters, monitor test case generators, and timing analyzers. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

special process - a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. (NQA-1-2000; QARD Rev 18)

supplier - any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, fabricator, consultant, and their sub-tier levels. (NQA-1-2000; QARD Rev 18)

support software - software tools and system software. (NQA-1-2000, Subpart 2.7, 600)

suspect/counterfeit items (S/CIs) - an item is suspect when 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):

- defects resulting from inadequate design or production quality control;
- damage during shipping, handling, or storage;
- improper installation;
- deterioration during service;
- degradation during removal;
- failure resulting from aging or misapplication; or
- other controllable causes. (DOE O 414.1C)

system software - software designed to enable the operation and maintenance of a computer system and its associated computer programs. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

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; DOE O 414.1C; DOE/RL-96/0006 Rev 3)

technical specialist - an individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint. (QARD Rev 18)

test case - a set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

test plan (procedure) - a document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

testing - an element of verification for the 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. (NQA-1-2000; QARD Rev 18)

testing (software) - the process of

- operating a system (i.e., software and hardware) or system component under specified conditions;
- observing and recording the results; and
- making an evaluation of some aspect of the system (i.e., software and hardware) or system component; in order to verify that it satisfies specified requirements and to identify errors. (NQA-1-2000, Sub-Part 2.7; QARD Rev 18)

traceability - the ability to trace the history, application, or location of an item, and like items or activities by means of recorded identification. (NQA-1-2000; QARD Rev 18)

use-as-is - a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use. (NQA-1-2000; QARD Rev 18)

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. (DOE O 414.1C)

waiver - documented authorization to depart from specified requirements. (NQA-1-2000)

waste acceptance impacting - an indicator that an item or activity that is critical to meeting one or more specifications in the *Waste Acceptance Systems Requirements Document* (WASRD). These items and activities are subject to the requirements of Office of Civilian Radioactive Waste Management (OCRWM), DOE/RW 0333P (Rev. 18), *Quality Assurance Requirements and Description* (QARD).

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; or data collection and analysis. (DOE O 414.1C)

Appendix D Quality Assurance Criteria and Integrated Safety Management System Crosswalk (10-CFR-830.121 (c)(2))

10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
(a) Criterion 1—Management/ Program	NQA Requirements 1 and 2		
(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.		Line Management Responsibility for Safety Clear Roles and Responsibilities Balanced Priorities Competence Commensurate with Responsibilities	Q-01.1, *Project Organization* Q-02.1, *Quality Assurance Program* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(2) Establish management processes, including planning, scheduling, and providing resources for the work.		Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-01.1, *Project Organization* Q-02.1, *Quality Assurance Program* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(b) Criterion 2—Management/Personnel Training and Qualification	NQA Requirement 2		
(1) Train and qualify personnel to be capable of performing their assigned work.		Competence Commensurate with Responsibilities Worker Involvement	Q-02.4, *Personnel Training and Qualification* Q-02.5, *Qualification and Certification of Auditors* Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*
(2) Provide continuing training to personnel to maintain their job proficiency.		Competence Commensurate with Responsibilities Worker Involvement	Q-02.4, *Personnel Training and Qualification* Q-02.5, *Qualification and Certification of Auditors* Q-02.6, *Qualification and Certification of Inspection and Test, including NDE, Personnel*

Appendix D Quality Assurance Criteria and Integrated Safety Management System Crosswalk (10-CFR-830.121 (c)(2))

10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
			Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*
(c) Criterion 3—Management/Quality Improvement	NQA Requirements 2, 15, and 16		
(1) Establish and implement processes to detect and prevent quality problems.		Provide Feedback and Continuous Improvement Worker Involvement	Q-02.2, *Management Assessment* Q-02.3, *Quality Assurance Surveillance* Q-15.1, *Control of Nonconforming Items* Q-15.2, *Control of Suspect/Counterfeit Items* Q-16.1, *Corrective Action* Q-18.1, *Audits (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*
(2) Identify, control, and correct items, services, and processes that do not meet established requirements.		Provide Feedback and Continuous Improvement Worker Involvement	Q-02.2, *Management Assessment* Q-02.3, *Quality Assurance Surveillance* Q-15.1, *Control of Nonconforming Items* Q-15.2, *Control of Suspect/Counterfeit Items* Q-16.1, *Corrective Action* Q-18.1, *Audits (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*
(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.		Provide Feedback and Continuous Improvement Analyze the Hazards Worker Involvement	Q-02.2, *Management Assessment* Q-02.3, *Quality Assurance Surveillance* Q-15.1, *Control of Nonconforming Items* Q-15.2, *Control of Suspect/Counterfeit Items* Q-16.1, *Corrective Action* Q-18.1, *Audits (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*

Appendix D Quality Assurance Criteria and Integrated Safety Management System Crosswalk (10-CFR-830.121 (c)(2))

10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.		Provide Feedback and Continuous Improvement Analyze the Hazards Worker Involvement	Q-02.2, *Management Assessment* Q-02.3, *Quality Assurance Surveillance* Q-15.1, *Control of Nonconforming Items* Q-15.2, *Control of Suspect/Counterfeit Items* Q-16.1, *Corrective Action* Q-18.1, *Audits (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings.*
(d) Criterion 4—Management/Documents and Records	NQA Requirements 5, 6 and 17		
(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-05.1, *Instructions, Procedures, and Drawings* Q-06.1, *Document Control* Q-17.1, *Quality Assurance Records*
(2) Specify, prepare, review, approve, and maintain records.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement	Q-05.1, *Instructions, Procedures, and Drawings* Q-06.1, *Document Control* Q-17.1, *Quality Assurance Records*

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10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
		Provide Feedback and Continuous Improvement	
(e) Criterion 5—Performance/Work Processes	NQA Requirements 5, 8, 9, 12, 13, and 14 and the Part I, Introduction		
(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-08.1, *Identification and Control of Items* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-13.1, *Handling, Storage, and Shipping* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-15.2, *Control of Suspect/Counterfeit Items*
(2) Identify and control items to ensure their proper use.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-08.1, *Identification and Control of Items* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-13.1, *Handling, Storage, and Shipping* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-15.2, *Control of Suspect/Counterfeit Items*
(3) Maintain items to prevent their damage, loss, or deterioration.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities	Q-08.1, *Identification and Control of Items* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-13.1, *Handling, Storage, and Shipping*

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10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(4) Calibrate and maintain equipment used for process monitoring or data collection.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-08.1, *Identification and Control of Items* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-13.1, *Handling, Storage, and Shipping* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(f) Criterion 6—Performance/Design	NQA Requirement 3		
(1) Design items and processes using sound engineering/scientific principles and appropriate standards.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Worker Involvement	Q-03.1, *Design Control* Q-03.2, *Software Quality* *Appendix E, Supplement to Policy Q-03.2, Software Quality* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(2) Incorporate applicable requirements and design bases in design work and design changes.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Worker Involvement	Q-03.1, *Design Control* Q-03.2, *Software Quality* *Appendix E, Supplement to Policy Q-03.2, Software Quality* Supporting policy:

Appendix D Quality Assurance Criteria and Integrated Safety Management System Crosswalk (10-CFR-830.121 (c)(2))

10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
			Q-05.1, *Instructions, Procedures, and Drawings*
(3) Identify and control design interfaces.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Worker Involvement	Q-03.1, *Design Control* Q-03.2, *Software Quality* *Appendix E, Supplement to Policy Q-03.2, Software Quality* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Worker Involvement	Q-03.1, *Design Control* Q-03.2, *Software Quality* *Appendix E, Supplement to Policy Q-03.2, Software Quality* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(5) Verify or validate work before approval and implementation of the design.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Worker Involvement	Q-03.1, *Design Control* Q-03.2, *Software Quality* *Appendix E, Supplement to Policy Q-03.2, Software Quality* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(g) Criterion 7—Performance/ Procurement	NQA Requirements 4 and 7		
(1) Procure items and services that meet established requirements and perform as specified.		Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-04.1, *Procurement Document Control* Q-07.1, *Control of Purchased Items and Services* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-06.1, *Document Control* Q-15.2, *Control of Suspect/Counterfeit Items*
(2) Evaluate and select prospective suppliers		Clear Roles and Responsibilities	Q-04.1, *Procurement Document Control*

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10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
on the basis of specified criteria.		Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-07.1, *Control of Purchased Items and Services* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-06.1, *Document Control* Q-15.2, *Control of Suspect/Counterfeit Items*
(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.		Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-04.1, *Procurement Document Control* Q-07.1, *Control of Purchased Items and Services* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-06.1, *Document Control* Q-15.2, *Control of Suspect/Counterfeit Items*
(h) Criterion 8—Performance/Inspection and Acceptance Testing	NQA Requirements 8, 10, 11, and 12		
(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-10.1, *Inspection* Q-11.1, *Test Control* Q-14.1, *Inspection, Test and Operating Status* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-15.2, *Control of Suspect/Counterfeit Items*

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10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
			Q-17.1, *Quality Assurance Records*
(2) Calibrate and maintain equipment used for inspections and tests.		Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-10.1, *Inspection* Q-11.1, *Test Control* Q-14.1, *Inspection, Test and Operating Status* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings* Q-09.1, *Control of Special Processes* Q-12.1, *Control of Measuring and Test Equipment* Q-15.2, *Control of Suspect/Counterfeit Items* Q-17.1, *Quality Assurance Records*
(i) Criterion 9—Assessment/Management Assessment	NQA Requirement 2 and 18		
Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.		Line Management Responsibility for Safety Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Worker Involvement Provide Feedback and Continuous Improvement	Q-02.2, *Management Assessment* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(j) Criterion 10—Assessment/Independent Assessment	NQA Requirements 1, 2, 10, 11, 15, 16, and 18		
(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.		Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards	Q-02.3, *Quality Assurance Surveillance* Q-18.1, *Audit (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*

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10 CFR 830	NQA-1-2000 Requirements	ISMS Principles and Functions	WTP Quality Manual
		and Requirements Perform Quality Work within Controls Operations Authorization Provide Feedback and Continuous Improvement	
(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.		Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Provide Feedback and Continuous Improvement	Q-02.3, *Quality Assurance Surveillance* Q-18.1, *Audit (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*
(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.		Clear Roles and Responsibilities Competence Commensurate with Responsibilities Balanced Priorities Define the Scope of Work Analyze the Hazards Develop and Implement Hazard Controls Identification of Safety Standards and Requirements Perform Quality Work within Controls Operations Authorization Provide Feedback and Continuous Improvement	Q-02.3, *Quality Assurance Surveillance* Q-18.1, *Audit (Independent Assessment)* Supporting policy: Q-05.1, *Instructions, Procedures, and Drawings*

Appendix E Supplement to Policy Q-03.2, Software Quality

E3.2.1 Purpose and Applicability

E3.2.1.1 This appendix provides additional requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of this appendix shall be implemented through the procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities. (NQA-1-2000, Subpart 2.7, 100; QARD, Rev 18, Supplement I, 1.1.A, 1.1.B)

Appendix F to this Quality Assurance Manual provides requirements related to software quality other than those provided in main policies and Appendices A and E. Appendix F encompasses the requirements previously included in 24590-WTP-QAM-QA-01-001 and applies to work activities identified in 24590-WTP-PL-IT-08-0001, *IS&T Project Plan for Implementation of 24590-WTP-QAM-QA-06-001 rev 2a*, Rev 0. This plan was developed to communicate the project plan for implementation of the software quality requirements of the new 24590-WTP-QAM-QA-06-001, *Quality Assurance Manual*. The scope of this plan includes the Software Plan, Guide, Procedures, and Forms as identified in the Project Schedule (Appendix A to the plan). The plan defines five efforts:

- To perform a safety software pre-survey to determine the types and sources of safety software
- To modify the existing procedures, guides and forms to include the new QAM requirement reference and to switch to the software designations Levels D, E, or F
- To extensively modify and develop plans, procedures, guides, and forms in order to implement safety software designation Levels A, B, and C
- Modify automated systems that support procedure driven process
- Develop Training for WTP Staff who have procedural responsibility

The requirements of 24590-WTP-QAM-QA-01-001, Policies 03.1 and 03.2, and 24590-WTP-QAM-QA-06-001, will coexist for the duration of 24590-WTP-PL-IT-08-0001. The procedures subject to the plan will remain compliant with the software quality requirements of 24590-WTP-QAM-QA-01-001, Policy 3.2, Software Quality, until reissued, in accordance with the plan schedule, as compliant with the applicable policies of 24590-WTP-QAM-QA-06-001.

E3.2.2 Requirement

E3.2.2.1 Software Project Management and Quality Planning

E3.2.2.1.1 Engineering design authority shall be involved in the selection of safety software standards and the identification of safety software requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement. (DOE O 414.1C, Attachment 2, 5(a))

E3.2.2.1.2 Using the grading levels established and approved below in Section E3.2.2.2, "Software Graded Approach", select and implement applicable SQA work activities from the following list to ensure that software performs its intended functions: (DOE O 414.1C, Attachment 2, 5(d))

E3.2.2.1.2.1 Project Management and Quality Planning (DOE O 414.1C, Attachment 2, 5(d)(1))

E3.2.2.1.2.2 Risk Management (DOE O 414.1C, Attachment 2, 5(d)(2))

E3.2.2.1.2.3 Configuration Management (DOE O 414.1C, Attachment 2, 5(d)(3))

E3.2.2.1.2.4 Procurement and Supplier Management (DOE O 414.1C, Attachment 2, 5(d)(4))

E3.2.2.1.2.5 Requirements Identification and Management (DOE O 414.1C, Attachment 2, 5(d)(5))

E3.2.2.1.2.6 Design and Implementation (DOE O 414.1C, Attachment 2, 5(d)(6))

E3.2.2.1.2.7 Software Safety (DOE O 414.1C, Attachment 2, 5(d)(7))

E3.2.2.1.2.8 Verification and Validation (DOE O 414.1C, Attachment 2, 5(d)(8))

E3.2.2.1.2.9 Problem Reporting and Corrective Action (DOE O 414.1C, Attachment 2, 5(d)(9))

E3.2.2.1.2.10 Training Personnel in the Design, Development, Use and Evaluation of Safety Software (DOE O 414.1C, Attachment 2, 5(d)(10))

E3.2.2.2 Software Graded Approach (see Tables 3.2-1 and 3.2-2)

E3.2.2.2.1 Software grading shall determine the extent of application of the software engineering activities commensurate with the risk associated with the failure of the software (e.g. potential impacts on safety and/or operation, complexity of computer program design, degree of standardization, level of customization, state of the art, and similarity to previously proven computer programs shall be considered). (Management Requirement)

E3.2.2.2.2 Grading is based in part on software type, which include: (1) custom developed, (2) configurable, (3) acquired, (4) utility calculation, and (5) commercial design and analysis. (DOE O 414.1C, Attachment 2, 5(c); Management Requirement)

E3.2.2.2.3 In addition grading includes the identification of safety software, as defined in Appendix C, *Glossary*, and its level of risk based on the following definitions: (Management Requirement)

E3.2.2.2.3.1 Level A Safety Software applications that meet one or more of the following:

E3.2.2.2.3.1.1 Software failure that could compromise a limiting condition for operation. (Management Requirement)

E3.2.2.2.3.1.2 Software failure that could cause a reduction in the safety margin for a safety structure, system or component that is cited in DOE approved documented safety analysis. (Management Requirement)

E3.2.2.2.3.1.3 Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either a DOE approved documented safety analysis or an approved hazard analysis per DOE P 450.1 and the DEAR ISMS clause. (Management Requirement)

E3.2.2.2.3.1.4 Software failure that could result in non-conservative safety analysis, design, or misclassification of facilities, structures, systems or components. (Management Requirement)

E3.2.2.2.3.2 Level B Safety Software applications that meet one or more of the following:

E3.2.2.2.3.2.1 Safety management databases used to aid in decision making whose failure could impact safety structure, system, or component operation. (Management Requirement)

E3.2.2.2.3.2.2 Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or the public. (Management Requirement)

E3.2.2.2.3.2.3 Software failure that could compromise the defense in depth capability for the nuclear facility. (Management Requirement)

E3.2.2.2.3.3 Level C Safety Software applications that meet one or more of the following:

E3.2.2.2.3.3.1 Software failure that could cause a potential violation of regulatory permitting requirements. (Management Requirement)

E3.2.2.2.3.3.2 Software failure that could affect environment, safety, health monitoring or alarming systems. (Management Requirement)

E3.2.2.2.3.3.3 Software failure that could affect the safe operation of a structure, system or component. (Management Requirement)

Table 3.2-1 Safety Software Graded Approach

(DOE O 414.1C, Attachment 2, 5(d))

	Level A					Level B					Level C				
	Safety Custom or Design/ Develop	Safety Configurable	Safety Acquired	Safety Utility Calcs.	Safety Commercial Design & Analysis Services	Safety Custom or Design/ Develop	Safety Configurable	Safety Acquired	Safety Utility Calcs.	Safety Commercial Design & Analysis Services	Safety Custom or Design/ Develop	Safety Configurable	Safety Acquired	Safety Utility Calcs.	Safety Commercial Design & Analysis Services
Software Project Management and Quality Planning, Software Safety and Risk Management	Full	Full	Grade	Grade	N/A	Full	Full	Grade	Grade	N/A	Grade	Grade	Grade	Grade	N/A
Software Configuration Management	Full	Grade	Grade	Grade	Grade	Full	Grade	Grade	Grade	Grade	Grade	Grade	Grade	Grade	Grade
Software Procurement	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full
Software Requirements	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full
Software Design Control	Full	Grade	N/A	Grade	N/A	Full	Grade	N/A	Grade	N/A	Full	Grade	N/A	Grade	N/A
Software Test Control	Full	Full	Full	Grade	N/A	Grade	Grade	Grade	Grade	N/A	Grade	Grade	Grade	Grade	N/A
Software Corrective Action	Full	Full	Full	Grade	Full	Full	Full	Full	Grade	Full	Full	Grade	Grade	Grade	Grade
Records	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full	Full

Table 3.2-2 Non-Safety Software Graded Approach

(DOE O 414.1C, Attachment 2, 5(d))

	Non-Safety Custom or Design/Develop	Non-Safety Configurable	Non-Safety Acquired	Non-Safety Utility Calcs.	Non-Safety Commercial Design & Analysis Services
Software Project Management and Quality Planning	Grade	Grade	Grade	Grade	N/A
Software Configuration Management	Grade	Grade	Grade	Grade	Grade
Software Procurement	Grade	Grade	Grade	Grade	Grade
Software Requirements	Grade	Grade	Grade	Grade	Grade
Software Design	Grade	Grade	N/A	Grade	N/A
Software Test	Grade	Grade	Grade	Grade	N/A
Software Corrective Action	Grade	Grade	Grade	Grade	N/A
Records	Grade	Grade	Grade	Grade	Grade

E3.2.2.2.4 Software Safety and Risk Management

E3.2.2.2.4.1 Training of personnel in the design, development, use, and evaluation of safety software shall be in accordance with Policy Q-02.4, *Personnel Training and Qualification.* (DOE O 414.1C, Attachment 2, 5(d)(10))

E3.2.2.2.4.2 The appropriate quality practices, standards and conventions shall be applied to safety software ensure the software performs its intended function and to mitigate the risk of failure of safety systems to acceptable and manageable levels. (Management Requirement)

E3.2.2.2.4.3 Software processes shall include the identification, documentation, and maintenance of a safety software inventory. (DOE O 414.1C, Attachment 2, 5)

E3.2.2.3 Software Engineering

E3.2.2.3.1 The scope of software engineering activities include the following elements, as appropriate: (NQA-1-2000, Subpart 2.7, 101; QARD, Rev 18, Supplement I, 1.1.B)

E3.2.2.3.1.1 Software acquisition method(s) for controlling the acquisition process for software and software services. (NQA-1-2000, Subpart 2.7, 101(a); QARD, Rev 18, Supplement I, 1.1.B.1)

E3.2.2.3.1.2 Software engineering method(s) used to manage the software life-cycle activities. (NQA-1-2000, Subpart 2.7, 101(b); QARD, Rev 18, Supplement I, 1.1.B.2, 1.1.D, 1.1.E, 1.2.1.A.1, 1.2.1.A.2, 1.2.1.B.1, 1.2.1.B.2, 1.2.2.B.5, 1.2.3.C.2, 1.2.6.A, 1.2.6.B)

E3.2.2.3.1.3 Application of standards, conventions, and other work practices that support the software life cycle. (NQA-1-2000, Subpart 2.7, 101(c); QARD, Rev 18, Supplement I, 1.1.B.3, 1.2.1.A, 1.2.1.A.2)

E3.2.2.3.1.4 Controls for support software used to develop, operate, and maintain computer programs. (NQA-1-2000, Subpart 2.7, 101(d); QARD, Rev 18, Supplement I, 1.1.B.4)

E3.2.2.4 Documentation

E3.2.2.4.1 The appropriate software engineering elements, described above, shall define the baseline documents that are to be maintained as records, in accordance with Policy Q-17.1, *Quality Assurance Records.* (NQA-1-2000, Subpart 2.7, 201; QARD, Rev 18, Supplement I, 1.1.B, 1.2.4.E.1)

E3.2.2.4.2 Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents. (NQA-1-2000, Subpart 2.7, 201)

E3.2.2.5 Review

E3.2.2.5.1 The appropriate software engineering elements, as described in Section E3.2.2.3, "Software Engineering" of this policy, shall define the control points and associated reviews. (NQA-1-2000, Subpart 2.7, 202; QARD, Rev 18, Supplement I, I.2.1.A.3)

E3.2.2.5.2 Reviews of software shall assure compliance with the approved software design requirements. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.3 Although multiple review requirements are specified in this policy, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.4 The following two reviews are required: (NQA-1-2000, Subpart 2.7, 202; QARD, Rev 18, Supplement I, I.2.2.B.6)

E3.2.2.5.4.1 One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification. (NQA-1-2000, Subpart 2.7, 202(a); QARD, Rev 18, Supplement I, I.2.2.B.4)

E3.2.2.5.4.2 The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review. (NQA-1-2000, Subpart 2.7, 202(b))

E3.2.2.5.5 Reviews shall identify the participants and their specific review responsibilities. (NQA-1-2000, Subpart 2.7, 202; QARD, Rev 18, Supplement I, I.2.1.B.5)

E3.2.2.5.6 Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. (NQA-1-2000, Subpart 2.7, 202; QARD, Rev 18, Supplement I, I.2.1.B.6)

E3.2.2.5.7 When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.8 Tests performed in support of a review can be used to complement acceptance testing. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.9 The tests and test results shall be included in the acceptance testing documentation. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.10 Such tests shall be subjected to the same criteria as the acceptance tests. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.5.11 These tests do not substitute for performing the comprehensive, end of development, acceptance test. (NQA-1-2000, Subpart 2.7, 202)

E3.2.2.6 Software Configuration Management

E3.2.2.6.1 In addition to the requirements of Policy Q-03.2, *Software Quality,* software configuration management activities shall include the following: (NQA-1-2000, Subpart 2.7, 203)

E3.2.2.6.1.1 The appropriate software engineering elements, described in Section E3.2.2.3, "Software Engineering" shall identify when configuration baselines are to be established. (NQA-1-2000, Subpart 2.7, 203(a))

E3.2.2.6.1.2 Configuration items to be controlled shall include, as appropriate: (NQA-1-2000, Subpart 2.7, 203(a))

E3.2.2.6.1.2.1 Documentation (e.g., software design requirements, instructions for computer program use, test plans, and results). (NQA-1-2000, Subpart 2.7, 203(a)(1))

E3.2.2.6.1.2.2 Computer program(s) (e.g., source, object, back-up files). (NQA-1-2000, Subpart 2.7, 203(a)(2))

E3.2.2.6.1.2.3 Support software. (NQA-1-2000, Subpart 2.7, 203(a)(3))

E3.2.2.6.2 The software configuration change control process shall include: (NQA-1-2000, Subpart 2.7, 203(b))

E3.2.2.6.2.1 Initiation, evaluation, and disposition of a change request. (NQA-1-2000, Subpart 2.7, 203(b)(1))

E3.2.2.6.2.2 Control and approval of changes prior to implementation. (NQA-1-2000, Subpart 2.7, 203(b)(2))

E3.2.2.6.2.3 Requirements for retesting and acceptance of the test results. (NQA-1-2000, Subpart 2.7, 203(b)(3))

E3.2.2.7 Problem Reporting and Corrective Action

E3.2.2.7.1 Method(s) for documenting, evaluating, and correcting software problems shall: (NQA-1-2000, Subpart 2.7, 204(a); QARD, Rev 18, Supplement I, I.2.2.B.7, I.2.5.A, I.2.5.C)

E3.2.2.7.1.1 Describe the evaluation process for determining whether a reported problem is an error or other type of problem (i.e., user mistake). (NQA-1-2000, Subpart 2.7, 204(a)(1); QARD, Rev 18, Supplement I, I.2.5.C.2)

E3.2.2.7.1.2 Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation. (NQA-1-2000, Subpart 2.7, 204(a)(2); QARD, Rev 18, Supplement I, I.2.5.C.1)

E3.2.2.7.2 When the problem is determined to be an error, the method shall provide, as appropriate, for: (NQA-1-2000, Subpart 2.7, 204(b); QARD, Rev 18, Supplement I, I.2.5.C.3)

E3.2.2.7.2.1 How the error relates to appropriate software engineering elements. (NQA-1-2000, Subpart 2.7, 204(b)(1); QARD, Rev 18, Supplement I, I.2.5.C.3(a))

E3.2.2.7.2.2 How the error impacts past and present use of the computer program. (NQA-1-2000, Subpart 2.7, 204(b)(2); QARD, Rev 18, Supplement I, I.2.5.C.3(b))

E3.2.2.7.2.3 How the corrective action impacts previous development activities. (NQA-1-2000, Subpart 2.7, 204(b)(3); QARD, Rev 18, Supplement I, I.2.5.C.3(c))

E3.2.2.7.2.4 How the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions. (NQA-1-2000, Subpart 2.7, 204(b)(4); QARD, Rev 18, Supplement I, I.2.5.C.5)

E3.2.2.7.3 The problem reporting and corrective action process shall be documented and controlled in accordance with Policy Q-16.1, *Corrective Action.* (NQA-1-2000, Subpart 2.7, 204; QARD, Rev 18, Supplement I, I.2.5.D)

E3.2.2.7.4 Computer software nonconformances shall be documented and controlled in accordance with Policy Q-15.1, *Control of Nonconforming items.* (QARD, Rev 18, 15.1.B)

E3.2.2.8 Software Acquisition

E3.2.2.8.1 Policies Q-04.1, *Procurement Document Control* and Q-07.1, *Control of Items and Services,* shall be applied to the procurement of software and software services. (NQA-1-2000, Subpart 2.7, 301, QARD, Rev 18, I.2.1.A.2)

E3.2.2.8.2 The purchaser shall be responsible for the appropriate requirements of this manual upon acceptance of the software or related item (e.g., programmable device). (NQA-1-2000, Subpart 2.7, 301, I.2.6.A.2)

E3.2.2.9 Otherwise Acquired Software

E3.2.2.9.1 Software that has not been previously approved under a program consistent with this manual for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software) shall be evaluated in accordance with the requirements of this policy. (NQA-1-2000, Subpart 2.7, 302; QARD, Rev 18, I.2.7, I.2.1.A.2.b)

E3.2.2.9.1.1 The software shall be identified and controlled prior to evaluation. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.2 The evaluation, specified by this section, shall be performed and documented to determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.3 This determination shall be documented and shall identify as a minimum: (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.3.1 Capabilities and limitations for intended use. (NQA-1-2000, Subpart 2.7, 302(a))

E3.2.2.9.1.3.2 Test plans and test cases required to demonstrate the capabilities within the limitations. (NQA-1-2000, Subpart 2.7, 302(b))

E3.2.2.9.1.3.3 Instructions for use within the limits of the capabilities. (NQA-1-2000, Subpart 2.7, 302(c))

E3.2.2.9.1.4 Exceptions from the documentation requirements of this policy and the justification for acceptance shall be documented. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.5 The results of the above evaluation and the performance of the actions necessary to accept the software shall be reviewed and approved. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.6 The resulting documentation and associated computer program(s) shall establish the current baseline. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.9.1.7 Revisions to previously baselined software received from organizations not required to follow this policy shall be evaluated in accordance with this section. (NQA-1-2000, Subpart 2.7, 302)

E3.2.2.10 Software Engineering Method

E3.2.2.10.1 Software engineering method(s) shall be documented. (NQA-1-2000, Subpart 2.7, 400; QARD, Rev 18, Supplement I, I.2.3.A.3)

E3.2.2.10.2 The selected software engineering method shall ensure that software life cycle activities are planned and performed in a traceable and orderly manner. (NQA-1-2000, Subpart 2.7, 400; QARD, Rev 18, Supplement I, I.2.3.A.3)

E3.2.2.10.3 The appropriate requirements of Policies Q-03.1, *Design Control* and Q-03.2 *Software Quality*, shall be met. (NQA-1-2000, Subpart 2.7, 400)

E3.2.2.10.4 Software Design Requirements

E3.2.2.10.4.1 Software design requirements shall address technical and software engineering requirements, as addressed in Section E3.2.2.3, "Software Engineering" of this policy. (NQA-1-2000, Subpart 2.7, 101, 401)

E3.2.2.10.4.2 Software design requirements shall be traceable throughout the software life cycle. (NQA-1-2000, Subpart 2.7, 401)

E3.2.2.10.5 Software Design

E3.2.2.10.5.1 An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program's operating environment. (NQA-1-2000, Subpart 2.7, 402)

E3.2.2.10.5.2 Measures to mitigate the consequences of problems shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program. (NQA-1-2000, Subpart 2.7, 402)

E3.2.2.10.5.3 Software Design Verification

E3.2.2.10.5.3.1 Software design verification shall evaluate the technical adequacy of the design approach and assure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. (NQA-1-2000, Subpart 2.7, 402.1)

E3.2.2.10.5.3.2 Software design verification shall include review of test results. (NQA-1-2000, Subpart 2.7, 402.1; QARD, Rev 18, Supplement I, I.2.1.B.3)

E3.2.2.10.5.3.3 The software design verification shall be completed prior to approval of the computer program for use. (NQA-1-2000, Subpart 2.7, 402.1; QARD, Rev 18, Supplement I, I.2.1.B.4)

E3.2.2.10.5.3.4 The requirements for the software design verification activity shall be documented in the software engineering method. (NQA-1-2000, Subpart 2.7, 402.1)

E3.2.2.10.6 Implementation

E3.2.2.10.6.1 The implementation process shall result in software products such as computer program listings and instructions for computer program use. A review shall be performed in accordance with Section E3.2.2.5, "Review" of this policy. (NQA-1-2000, Subpart 2.7, 403)

E3.2.2.10.7 Acceptance Testing

E3.2.2.10.7.1 The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.2 Acceptance testing shall demonstrate, as appropriate, that the computer program: (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.2.1 Properly handles abnormal conditions and events as well as credible failures. (NQA-1-2000, Subpart 2.7, 404(a))

E3.2.2.10.7.2.2 Does not perform unintended adverse functions. (NQA-1-2000, Subpart 2.7, 404(b))

E3.2.2.10.7.2.3 Does not degrade the system either by itself, or in combination with other functions or configuration items. (NQA-1-2000, Subpart 2.7, 404(c))

E3.2.2.10.7.3 Acceptance testing shall be performed prior to approval of the computer program for use. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.4 Configuration items shall be under configuration change control (in accordance with this policy) prior to starting acceptance testing. (NQA-1-2000, Subpart 2.7, 404; QARD, Rev 18, Supplement I, I.2.3.D.1)

E3.2.2.10.7.5 Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.6 Testing shall include a comprehensive acceptance test performed in the operating environment prior to use. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.7 The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program in accordance with Policy Q-11.1, *Test Control*. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.8 Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.7.9 The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements. (NQA-1-2000, Subpart 2.7, 404)

E3.2.2.10.8 Operation

E3.2.2.10.8.1 After the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. (NQA-1-2000, Subpart 2.7, 405)

E3.2.2.10.8.2 These include, as appropriate: (NQA-1-2000, Subpart 2.7, 405)

E3.2.2.10.8.2.1 Application documentation (e.g., application log). (NQA-1-2000, Subpart 2.7, 405(a))

E3.2.2.10.8.2.2 Access control specifications. (NQA-1-2000, Subpart 2.7, 405(b))

E3.2.2.10.8.2.3 Problem reporting and corrective action. (NQA-1-2000, Subpart 2.7, 405(c))

E3.2.2.10.8.2.4 In-use tests. (NQA-1-2000, Subpart 2.7, 405(d))

E3.2.2.10.8.2.5 The configuration change control process. (NQA-1-2000, Subpart 2.7, 405(e))

E3.2.2.10.9 Maintenance

E3.2.2.10.9.1 The appropriate software engineering elements, as described in Section E3.2.2.3, "Software Engineering" of this policy, shall identify how changes to the software are controlled. (NQA-1-2000, Subpart 2.7, 406)

E3.2.2.10.9.2 Typically, changes are in response to: (NQA-1-2000, Subpart 2.7, 406)

E3.2.2.10.9.2.1 Enhancement requests from the user community. (NQA-1-2000, Subpart 2.7, 406(a))

E3.2.2.10.9.2.2 Revisions to software based on software design requirements. (NQA-1-2000, Subpart 2.7, 406(b))

E3.2.2.10.9.2.3 Changes to the operating environment. (NQA-1-2000, Subpart 2.7, 406(c))

E3.2.2.10.9.2.4 Reported software problems that must be corrected. (NQA-1-2000, Subpart 2.7, 406(d))

E3.2.2.10.10 Retirement

E3.2.2.10.10.1 During retirement, support for the software product is terminated, and the routine use of the software shall be prevented. (NQA-1-2000, Subpart 2.7, 407)

E3.2.2.11 Standards, Conventions, and Other Work Practices

E3.2.2.11.1 As appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life cycle activities (e.g., software design and implementation activities). Standards, conventions, and other required work practices shall be documented. (NQA-1-2000, Subpart 2.7, 500)

E3.2.2.12 Support Software

E3.2.2.12.1 Support software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools. (NQA-1-2000, Subpart 2.7, 600)

E3.2.2.12.2 Software Tools

E3.2.2.12.2.1 Software tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. (NQA-1-2000, Subpart 2.7, 601; QARD, Rev 18, Supplement I, I.2.4.C)

E3.2.2.12.2.2 Software tools that do not affect the performance of the software need not be placed under configuration control. (NQA-1-2000, Subpart 2.7, 601)

E3.2.2.12.2.3 In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. (NQA-1-2000, Subpart 2.7, 601)

E3.2.2.12.2.4 Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required. (NQA-1-2000, Subpart 2.7, 601)

E3.2.2.12.3 System Software

E3.2.2.12.3.1 System software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include: lower level software layers, assemblers, interpreters, diagnostics, and utilities. (NQA-1-2000, Subpart 2.7, 602)

E3.2.2.12.3.2 System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. (NQA-1-2000, Subpart 2.7, 602)

E3.2.2.12.3.3 System software shall be placed under configuration change control. (NQA-1-2000, Subpart 2.7, 602)

E3.2.2.12.3.4 Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required. (NQA-1-2000, Subpart 2.7, 602)

Appendix F Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2

1 Purpose and Applicability

1.2 This policy establishes requirements for the acquisition, development, modification, control, and use of quality-affecting software. Acquired software that is integral to the operations, maintenance, or calibration of measuring and test equipment, and has not been developed or modified for the project is controlled by Policy Q-12.1 - *Control of Measuring and Test Equipment,* and Appendix A Policy Q-12.1 - *Control of Measuring and Test Equipment*, and is exempt from the requirements of this policy. This policy defines requirements and responsibilities for controlling the quality of computer software.

1.3 This policy applies to organizations involved in quality-affecting software formulation and control. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this policy. This policy applies to organizations that develop, procure, modify, maintain, operate, use, or retire software that is directly used in the design, analysis, and operation of structures, systems, and components (SSCs).

1.4 Requirements for electronic management of data are addressed in Supplement V - *Control of the Electronic Management of Information.*

2 Implementation Strategy

2.1 Computer software used for the control or support of work processes is to be controlled. Access to the computer software will be controlled.

2.2 Software quality assurance procedures will provide measures to ensure that computer programs used to develop or verify designs or establish safety envelopes (design analyses, models, or algorithms) are adequate for intended use. These measures include previous use, validation, or simulation.

2.3 The Deputy Project Manager, Business Services, is responsible for developing and maintaining procedures that identify software control requirements concurred with by the Quality and Performance Assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Computer software used to produce or analyze data, which is used directly in the design, analysis, and operation of SSCs, shall comply with the requirements of this policy, which is in accordance with ASME NQA-2a-1990, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications.* The application of specific requirements

shall be prescribed in software quality assurance plan(s) and/or in written policies and procedures.

3.1.2 Software development shall proceed in a traceable, planned, and orderly manner.

3.1.3 The number of software life cycle phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software.

3.1.4 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.1.5 Acquired software or software previously developed not using this policy must be either: acquired through a procurement activity with appropriate quality controls; or be controlled and qualified in accordance with subsection 3.13 of this policy. In either case, software planning in accordance with subsection 3.3 and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3.1.6 When software is retired or the support for a software product is terminated, the software shall not be used.

3.2 Software Verification and Validation

3.2.1 Software verification and validation activities shall:

3.2.1.A Ensure that the software adequately and correctly performs intended functions.

3.2.1.B Ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

3.2.1.C Be planned and performed for each system configuration, which may impact the software.

3.2.2 Software verification shall be performed during the software development to ensure that the products of a given life cycle phase fulfill the requirements of the previous phase or phases.

3.2.3 The results of the verification and validation activities shall be documented with the identification of the verifier and responsibilities indicated.

3.2.4 Software verification methods shall include any one or a combination of design reviews, alternate calculations, and test results performed during computer program development.

3.2.5 The extent of verification and the methods chosen are a function of the following:

3.2.5.A The complexity of the software.

3.2.5.B The degree of standardization.

3.2.5.C Similarity with previously proved software.

Appendix F Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2

3.2.5.D Importance to safety.

3.2.6 Software verification and validation shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization with higher management approval and documented justification.

3.3 Software Planning

3.3.1 A software quality assurance plan shall be developed for each new software project at the start of the software life cycle, or for procured software when it enters the purchaser's organization.

3.3.1.A Note: The software quality assurance plan may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program.

3.3.2 The software quality assurance plan shall identify:

3.3.2.A A description of the overall nature and purpose of the software.

3.3.2.B The software products to which it applies.

3.3.2.C The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.

3.3.2.D The required documentation.

3.3.2.E The standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.

3.3.2.F The required software reviews.

3.3.2.G The methods for error reporting and corrective action.

3.4 Requirements Phase

3.4.1 Software design requirements shall be identified and documented and their selection reviewed and approved.

3.4.2 Software requirement documentation shall outline the requirements that the proposed software must satisfy.

3.4.3 The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

3.4.4 The requirements shall address the following, as applicable:

3.4.4.A Functionality—the functions the software is to perform.

3.4.4.B Performance—the time-related issues of software operation (i.e., speed, recovery time, response time).

3.4.4.C Design constraints imposed on implementation phase activities—any elements that will restrict design options.

3.4.4.D Attributes—non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability.

3.4.4.E External interfaces—interactions with people, hardware, and other software.

3.4.5 These requirements shall define the response of the software to anticipate classes of input data, and shall provide the detail and information necessary to either design the software or make an acquisition decision.

3.4.6 Software requirements shall be traceable throughout the remaining stages of the software development cycle.

3.4.7 The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the identified requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and useable code.

3.5 Design Phase

3.5.1 The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.

3.5.2 Software design and implementation documentation shall include:

3.5.2.A A description of the major components of the software design as they relate to the software requirements.

3.5.2.B A description of the allowable or prescribed ranges for inputs and outputs.

3.5.2.C As applicable, numerical methods, mathematical models, control flow, physical models, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

3.5.2.D A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.

3.5.3 Design phase software verification and validation activities shall consist of the following:

3.5.3.A Generation of test plans based on the requirements and design.

3.5.3.B Generation of design-based test cases.

3.5.3.C Review of the software design to ensure that the requirements are addressed.

3.5.4 A software design review shall be held at the completion of the software design documentation. The review shall meet the requirements of Policy Q-03.1 – *Design Control* - subsection 3.1.2.6.8 – *Design Reviews*. This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of software design, and shall be traceable to the requirements.

3.6 Implementation Phase

3.6.1 The software design shall be translated into computer program(s) and the implemented software shall be analyzed to identify and correct errors.

3.6.2 Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to coding standards and conventions.

3.6.3 Software validation activities shall be performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use.

3.7 Testing Phase

3.7.1 Testing to an approved plan or process shall be the primary method of software validation to ensure adherence to the requirements and to ensure that the software produces correct results for the test cases.

3.7.2 Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

3.7.3 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. Test procedures or plans shall specify the following as applicable:

3.7.3.A Required tests and test sequence.

3.7.3.B Required ranges of input parameters.

3.7.3.C Identification of the stages at which testing is required.

3.7.3.D Criteria for establishing test cases.

3.7.3.E Requirements for testing logic branches.

3.7.3.F Requirements for hardware integration.

3.7.3.G Anticipated output values.

3.7.3.H Acceptance criteria.

3.7.3.I Reports, records, standard formatting, and convention.

3.7.4 Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

3.7.5 For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.

3.7.6 The computer test procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, experiments and tests, standard problems with known solutions, or empirical data and information from technical literature.

3.7.7 Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the software in each phase and the validation of software at the end of the development cycle. The documentation shall:

3.7.7.A Specify the hardware and software configurations pertinent to the software validation.

3.7.7.B Be organized in a manner that allows traceability to both software requirements and design.

3.7.7.C Contain the results of the execution of the verification and validation activities.

3.7.7.D Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

3.7.8 Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.

3.7.9 Software validation of modifications to released software shall be subjected to regression testing to detect errors introduced during the modification of the software to verify that the modifications have not caused unintended adverse affects, or to verify that a modified software still meets specified requirements.

3.7.10 Upon completion of the testing phase, the development cycle documentation shall be reviewed and approved to assure completion and acceptability.

3.7.11 Depending on the complexity of the computer program being tested, testing may range from a single test and a series of tests performed at various stages of computer program

development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test.

3.7.12 Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

3.8 Operations and Maintenance Phase

3.8.1 Upon acceptable validation of the software, in accordance with subsection 3.7 of this policy, the software shall be baselined and placed under configuration management controls in accordance with subsection 3.10 of this policy.

3.8.2 Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance).

3.8.3 Software modifications shall be approved, documented, verified and validated, and controlled.

3.8.4 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

3.8.5 In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.

3.8.6 Require periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs where computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

3.8.7 In-use tests shall identify:

3.8.7.A Computer program tested.

3.8.7.B Computer hardware used.

3.8.7.C Test equipment and calibration, if applicable.

3.8.7.D Date of the test.

3.8.7.E Test or data records.

3.8.7.F Acceptability.

3.8.8 In-use tests shall be developed, performed and documented, and verified to provide confirmation of acceptance performance of software that is performing continuous data acquisitions of process control functions.

Appendix F Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2

3.9 Installation and Checkout Phase

3.9.1 Software installation and checkout activities shall be performed and documented when the software is installed on a computer, or when there are changes in the operating system, to ensure that the software properly satisfies the requirements for its intended use.

3.9.2 Installation and checkout phase software verification and validation activities shall consist of:

3.9.2.A The execution of tests for installation and integration design.

3.9.2.B The documentation of the approval of the software for operational use.

3.10 Software Configuration Management

3.10.1 A configuration baseline shall be defined at the completion of each major phase of the software development and include appropriate control points within each major phase. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

3.10.2 A labeling system for configuration items shall be implemented includes:

3.10.2.A A definition of the baseline elements of each software baseline.

3.10.2.B Uniquely identifies each configuration item.

3.10.2.C Identifies changes to configuration items by revision.

3.10.2.D Provides the ability to uniquely identify each configuration of the revised software available for use.

3.10.3 Changes to software shall be formally controlled and documented.

3.10.3.A The software change documentation shall include:

3.10.3.A.1. A description of the change.

3.10.3.A.2. The rationale for the change.

3.10.3.A.3. The identification of the affected software baselines.

3.10.3.A.4. A release and control process for baseline elements.

3.10.3.B The changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.

3.10.3.C Only authorized changes shall be made to software baselines.

3.10.3.D Appropriate verification and validation activities shall be performed for the change.

3.10.3.E The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.

3.10.3.F Appropriate acceptance testing shall be performed for the change.

3.10.4 The information that is needed to manage a configuration shall be documented and transmitted to all organizations affected by the change. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, the status of in-process changes, the history of the changes including descriptions, and information to support the functions of configuration identification, and configuration control.

3.11 Defect Reporting and Resolution

3.11.1 The defect reporting and resolution system shall be integrated with the software configuration management system.

3.11.2 Software defect reporting and resolution systems shall include the following controls:

3.11.2.A Problems are identified, evaluated, documented, and, if required, corrected.

3.11.2.B Problems are assessed for impact on past and present applications of the software by the responsible organization.

3.11.2.C Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

3.11.2.D Notification along with preventive actions and corrective actions are provided to the user organizations.

3.11.3 If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Policy Q-16.1 - *Corrective Action*.

3.11.4 A software defect reporting and resolution system shall be implemented for software errors and failures to assure that problems are promptly reported to impacted organizations and to assure formal processing of problem resolutions.

3.12 Procurement

3.12.1 Individuals or organizations developing and supplying software shall be required to have policies and procedures that meet the applicable requirements of this policy as specified in procurement documents.

3.12.2 The documentation that is required by this policy shall be delivered or made available by the supplier to the purchaser.

Appendix F Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2

3.12.3 The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this policy as specified in procurement documents. The user organization shall determine the adequacy of this plan.

3.12.4 Software errors and failures shall be reported between the supplier and purchaser in accordance with subsection 3.11 – *Defect Reporting and Resolution.*

3.12.5 Upon receipt of the software from the supplier, the purchaser assumes responsibility of the applicable requirements of this policy.

3.13 Software Developed Not Using This policy

3.13.1 Unqualified software in which the history of the software is not known, but the software is required to be used in quality activities shall meet the following requirements:

3.13.1.A Software that was previously developed not using this policy shall be placed under configuration controls prior to use.

3.13.1.B The user organization shall perform, document and provide for an independent review and evaluation to:

3.13.1.B.1. Determine its adequacy to support software operation and maintenance.

3.13.1.B.2. Identify the activities to be performed and documents required in order for the software to be placed under configuration management as a minimum, these activities include:

3.13.1.B.2.1. User application requirements.

3.13.1.B.2.2. Test plans and test cases required to validate the software for acceptability.

3.13.1.B.2.3. User documentation required in accordance with subsection 3.15 of this policy.

3.13.1.B.2.4. Upon independent review and approval of the above activities, the software shall be placed under configuration control in accordance with subsection 3.10 of this policy.

3.14 Access Control

3.14.1 To the extent appropriate, controls shall be established to permit authorized access and prevent unauthorized access to a computer system.

3.15 User Documentation

3.15.1 User documentation, as a minimum, shall include:

3.15.1.A User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software.

3.15.1.B Input and output specifications.

3.15.1.C Input and output formats.

3.15.1.D A description of systems limitations.

3.15.1.E A description of anticipated errors and how the user can respond.

3.15.1.F Information for obtaining user and maintenance support.

4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.2 Implementation Phase

4.2.1 The design shall be translated into source code and resulting executables necessary to perform the functions required.

4.2.2 The source code and resulting executables shall adhere to the design specifications.

4.2.3 User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

4.2.3.A Instructions that contain an introduction, description of the user's interaction with the software, and a description of any required training necessary to use the software.

4.2.3.B Input and output specifications.

4.2.3.C Data files, input and output data, defaults, and file formats.

4.2.3.D A description of the allowable and tolerable ranges for inputs and outputs.

4.2.3.E Anticipated errors and how the user can respond.

4.2.3.F The hardware and software environments.

4.2.3.G Available sample problems.

4.2.3.H Installation procedures.

Appendix F Software Quality Requirements from 24590-WTP-QAM-QA-01-001, Rev 7b, Policy Q-03.2

4.2.4 Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculation, without recourse to the original, shall have limited requirements applied as follows:

4.2.4.A Identification, including version of the software routine or macro.

4.2.4.B Documentation that includes inputs, computer program-generated correct results for a specified range of input parameters, computer program-generated evidence of the programmed algorithms or equations (e.g., computer program listings and spreadsheet cell contents), and verification results.

4.2.4.C Identification, including version of the commercially available software used to develop the routine and macro.

4.2.5 Software shall be placed under configuration management control as each baseline element is approved. Software shall not be used in quality-affecting activities unless it is obtained and limited to received copies from software configuration management.

4.3 Control of the Use of Software

4.3.1 Quality-affecting software shall be controlled and documented, and the use of released software items such that comparable results can be obtained, with any difficulties explained, through independent replication of the process.

4.3.2 Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

4.3.3 If the use of software items falls outside the range of validation as baselined, changes shall be made to the appropriate baseline elements prior to use.

4.3.4 Documentation for the receipt of software obtained from software configuration management in accordance with this policy shall be provided and maintained for all software in operation or use.