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AFS-13-0257

November 18, 2013

ATTN: Document Control Desk
Director, Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: For U.S. NRC Approval - Proposed Revision 03 to the AREVA Federal Services Quality Assurance Program Description / U.S. NRC QA Program Approval No. 71-0938

To Whom It May Concern:

With this letter, AREVA Federal Services, LLC (AFS) submits for U.S. Nuclear Regulatory Commission (NRC) approval proposed Revision 03 to the AFS Quality Assurance Program Description (QAPD) as required by 10 CFR Part 71.

AFS has reviewed the applicable requirements contained in 10 CFR Part 71 and the guidance provided in NRC Regulatory Guide 7.10 (Revision 2) and concluded that the changes made to the program with this proposed Revision 03 do not constitute a reduction in program commitment.

A summary of the changes made by this revision along with a copy of Revision 03 to the QAPD are included as enclosures.

Please note that prior revisions of this QAPD were approved by the NRC under QA Program Approval Number 0938 / Docket Number 71-0938 for use in accordance with the requirements of 10 CFR Part 71.

Please contact Chris Lloyd, Manager – Environment, Safety, Health & Quality (ESH&Q) if you require additional information regarding this submittal.

Sincerely,

Tara J. Neider
President & CEO

NMSS01
Q004

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Enclosures:

1. Summary of Changes Incorporated by Revision 03 (2 pages)
2. Revision 03, AREVA Federal Services, LLC Quality Assurance Program Description / AFS Document Number AFS-QA-PMD001 (55 pages)

cc: (w/enclosures)

U.S. Nuclear Regulatory Commission
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Summary of Changes Incorporated
Proposed Revision 03 – AFS Quality Assurance Program Description
(Page 1 of 2)

1. Added introduction statement with a brief description of the scope of the program and the AFS locations to which it applies.
2. Added "Statement of Quality Policy and Authority" to identify the regulations, standards and orders to which to program conforms. The statement also identifies overall responsibility for the program and states the company's commitment to providing services and products with the highest level of quality consistent with regulatory and other requirements.
3. Section 1 – Editorial changes and restructuring of information throughout without change of intent.
4. Section 1 – Completely revised the organization responsibilities statements in paragraph 1-202 and replaced the Figure 1-1 to simplify organization statements and describe only those management positions that have responsibilities under the program.
5. Section 1 – Added paragraph 1-203 to provide organizational flexibility in the use of titles both in the QAPD and associated implementing procedures.
6. Section 2 – Editorial changes and restructuring of information throughout without change of intent.
7. Section 2 – In paragraph 2-100, added discussion on the use of RG 7.10 and NUREG/CR 6407 for applying the program in a graded fashion to activities subject to 10 CFR Part 71 and Part 72 activities
8. Section 2 – Relocated list of Codes, Standards, and Regulations contained in paragraph 2-103 to the "Statement of Quality Policy and Authority". Updated the list for currency purposes.
9. Section 2 – Revised discussion and standards / codes used for the basis of qualifying NDE personnel for clarity and correctness purposes.
10. Section 3 – Minor editorial changes and restructuring of information without change in intent.
11. Section 4 – Editorial change with no change in intent.
12. Section 5 – Added new paragraph stating the compliance with written instruction is required.
13. Section 7 – Restructured the information in paragraphs 7-201, 202 and 203 to reduce duplicated information and improve readability. Deleted statement about "ongoing supplier" evaluation. Deleted paragraph 7-204 and relocated some information to paragraph 7-201.

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Enclosure – AFS Letter No. AFS-13-0257

Summary of Changes Incorporated
Proposed Revision 03 – AFS Quality Assurance Program Description

14. Section 7 – Minor editorial changes and restructuring of information without change in intent.
15. Section 7 – Added paragraph 7-704-2 to describe the conditions for utilizing NVLAP/A2LA accreditation as an acceptable means for satisfying requirements for a commercial grade survey in support of dedicating a commercial calibration suppliers services. Requirements added are based in industry guidance.
16. Section 9 – Editorial change with no change in intent.
17. Section 10 – Revised statement of requirements for the contents of inspection records to conform to 10 CFR Part 71 requirements.
18. Section 11 – Editorial change with no change in intent.
19. Section 12 – Editorial change with no change in intent.
20. Section 15 – Revised statement in first paragraph on evaluating nonconforming condition for reportability for clarity purposes.
21. Section 16 – Added paragraph on evaluating conditions identified in corrective action documents for reportability. This is not stated in current revision.
22. Section 17 – Minor editorial changes and restructuring of information without change in intent.
23. Section 17 – Paragraph 17-401 rewritten to identify that determination of lifetime records is based on Nonmandatory Appendix 17A-1 to ASME NQA-1-2008/2009a, applicable regulation and customer requirements.
24. Section 17 – Paragraph 17-700 rewritten to provide clarification of retention times for lifetime records subject to the requirements of 10 CFR Part 71 and 72.
25. Section 18 – Deleted discussion of surveillance as this information is not relevant to requirements for internal audits provided in DOE and NRC regulation and ASME NQA-1-2008/2009a.
26. Section 18 – Added paragraph 18-201 to provide for the use of alternative to audit in satisfying audit commitments. Conditions of use for an alternative method are also specified. This change is based on guidance provided in Nonmandatory Appendix 18A-1 to ASME NQA-1-2008/2009a.

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AREVA Federal Services LLC
DOCUMENT APPROVAL RECORD

Document Number: AFS-QA-PMD-001 **Revision:** 03

Document Title: QUALITY ASSURANCE PROGRAM DESCRIPTION

Approval	Name	Signature	Date
Manager, ESH&Q	Chris Lloyd		11/15/13
Manager, Operations	Joe Stringer		11/15/13
President & CEO	Tara J. Neider		11/15/13

Editorial Change: ☐ **Technical Change:** ☒

Description of Changes:

See Revision History for description of changes

Document Type: Business Sensitive ☐ Quality Assurance ☒ Other ☐

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INTRODUCTION

AREVA Federal Services, LLC (AFS) has developed this Quality Assurance Program Description (QAPD) to define the quality assurance requirements that apply to activities affecting quality associated with design, licensing, procurement, fabrication, construction, decommissioning, handling, shipping, assembly, inspection, modification, testing, repair and operations of equipment and facilities subject to the requirements of United State Department of Energy (DOE) regulations provided in 10 CFR, Part 830 and United States Nuclear Regulatory Commission (NRC) regulations provided in 10 CFR, Part 71.

This QAPD also satisfies the provisions of 10 CFR, Part 50, 10 CFR, Part 72 and other parts of Title 10 to the Code of Federal Regulations that are associated with nuclear materials and facilities.

QAPD requirements are also invoked to the extent applicable upon suppliers to which AFS subcontracts quality affecting work that is subject to the requirements of this QAPD.

The QAPD applies to the following AFS locations and other service locations when required by customer contract provisions:

7135 Minstrel Way
Columbia, MD 21045

7207 IBM Drive
Charlotte, NC 28262

2101 Horn Rapids Road
Richland, WA 99354

505 South 336th Street
Federal Way, WA 98003

3315 Old Forest Road
Lynchburg, VA 24501

830 Colony Parkway
Aiken, SC 29803

1070 Riverwalk Drive
Idaho Falls, ID 83402

STATEMENT OF QUALITY POLICY AND AUTHORITY

AFS is engaged in the business of supplying design and engineering services, delivery of equipment procured from subcontracted organizations including packaging utilized for the transport of radioactive materials; facility cleanup and closure; facility construction and commissioning, testing and operations to governmental agencies and others for use in nuclear applications. This business carries with it the responsibility for protecting the environment and the health and safety of the public and workers from the deleterious effects of radiation and radioactive materials. Therefore, it is the Policy of AFS that all services and products must be delivered with the highest levels of quality consistent with the expectations and requirements of our customers, stakeholders, and the governmental agencies which regulate our activities.

In order to carry out this policy, AFS has established this Quality Assurance Program Description (QAPD) and associated implementing policies, procedures and instructions; which comply with the following Regulations, Standards and Orders:

10 CFR Part 830, Subpart A	10 CFR Part 72, Subpart G	10 CFR 21
10 CFR Part 820	10 CFR Part 50, Appendix B	ASME NQA-1 2008/2009a
DOE Order (O) 414.1D (or later approved revision)	10 CFR Part 70	NRC Regulatory Guide 1.28, Revision 4 (June 2010)
10 CFR Part 71, Subpart H	10 CFR Part 63, Subpart G	

While the ultimate responsibility for compliance with the QAPD rests with the President & CEO of AFS, every employee is expected to assume personnel responsibility for performing their assigned work activities in accordance with the applicable requirements of the QAPD and the associated implementing policies, procedures and instructions in effect.

The Manager, Operations is assigned responsibility for implementing the requirements of the QAPD in a fashion consistent with this policy.

The Manager, Environment, Safety, Health & Quality (ESH&Q) is assigned responsibility for developing, maintaining and verifying implementation of the QAPD in a fashion consistent with this policy.

Tara J. Neider
President & CEO

SECTION 1
ORGANIZATION

1-100 BASIC REQUIREMENT

This QAPD and associated implementing policies, procedures and instructions are collectively referred to as the AFS Quality Assurance Program (QAP). Within this program, responsibilities are defined, including the organizational structure, responsibilities, levels of authority, and lines of communication for quality-affecting activities.

QAP requirements apply to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Examples of nuclear facilities include facilities for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, and other related facilities. Activities include siting, designing, procuring, fabricating, constructing, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, transportation packaging for radioactive materials and decommissioning. For subcontracted activities, QAP application, or portions thereof, is invoked by written contracts, policies, procedures, specifications, or other appropriate documents.

1-200 STRUCTURE AND RESPONSIBILITY

1-201 General: AFS has created its organizational structure and assignments of responsibility to ensure that:

- Senior management establishes overall expectations for effective implementation of the quality assurance program and associated process that are designed to detect and prevent quality problems and is responsible for obtaining the desired end result
- Quality is achieved and maintained by those assigned responsibility for performing work
- Quality achievement is verified by those not directly responsible for performing the work
- Those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include the following:
  - Identifying quality problems
  - Initiating, recommending, or providing solutions to quality problems through designated channels
  - Verifying implementation of solutions

- Assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

1-202 Organization: AFS is organized as shown in *Figure 1-1*. Business-only organizations and functions that are not governed by the requirements prescribed by this QAPD and are not described, below.

- President & CEO: Has full authority over all functions of the company and is responsible for overall company policy and providing executive direction and guidance to senior management staff. The President & CEO has assigned responsibility for implementing the requirements of this QAPD to the Manager, Operations and the responsibility for developing, maintaining and verifying implementation of this QAPD to the Manager, ESH&Q.
- Manager, Operations: Reports directly to the President & CEO and has overall responsibility for the implementation of the QAPD. This responsibility includes setting priorities, objectives and policies to ensure that activities subject to the requirements of the QAPD are performed in accordance with the QAPD and associated implementing policies, procedures and instructions. Managers assigned responsibility for Construction and Commissioning, Engineering, Contracts and Procurement and the Facility Security Officer report directly to the Manager, Operations.
- Manager, ESH&Q: Reports directly to the President & CEO and has responsibility for developing, maintaining and verifying implementation of the QAPD. The responsibilities assigned to this position include; administering the corrective action program, document control, records management, ensuring that ESH&Q staff are properly qualified, conducting audits and other activities such as surveillance and inspection to verify that activities are being conducted in accordance with the QAPD requirements. The Manager, ESH&Q is also responsible for periodically reporting to the President & CEO on the status and effectiveness of QAPD implementation.
- Managers, Business Lines: Report directly to the President and CEO and are responsible for Project Management functions subject to the requirements of the QAPD.

1-203 Delegation of Work: The individual(s) assigned responsibilities by this QAPD and associated implementing procedures may delegate any or all of the work to others but retain overall responsibility for ensuring compliance with the requirements of this QAPD and associated implementing procedures.

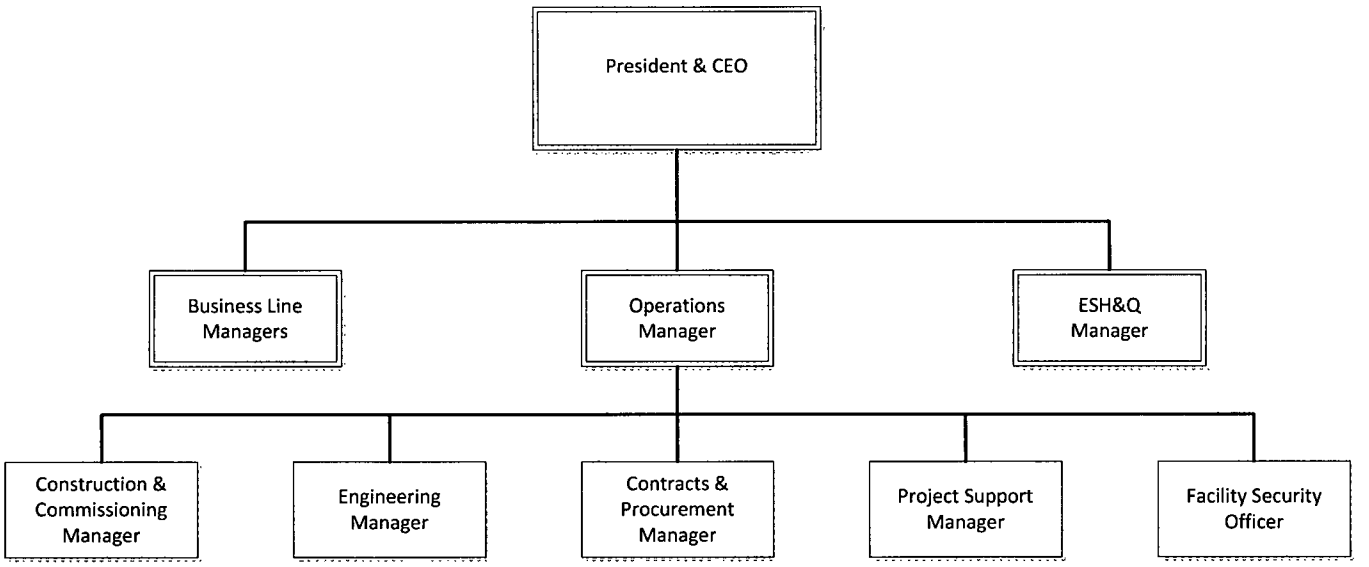
1-204 Position Titles: When used in this QAPD, the position title of "Manager" is used to describe a management position responsible for a function. Other terms such as "Senior Manager", "Director" or "Vice President" may be used in implementing policies, procedures and instructions to identify these positions.

1-300 INTERFACE CONTROL

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. The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

Figure 1-1

AREVA Federal Services Organization



SECTION 2
QUALITY ASSURANCE PROGRAM

2-100 BASIC REQUIREMENT

AFS implements a planned and documented QAP. The program consists of this QAPD and associated policies, procedures and instructions utilized to ensure proper implementation. The program identifies the activities and items to which it applies and provides controls in a graded fashion over activities affecting quality to an extent consistent with their importance to safety. The level of control provided takes into account the complexity of an activity, the potential consequences and probability of a failure, as well as regulatory and customer requirements.

When the program is applied to activities subject to 10 CFR Part 71 or 10 CFR Part 72, the guidance provided in NRC Regulatory Guide 7.10 and NRC NUREG/CR-6407 is used when applying the QAP in a graded fashion.

The QAP includes activities that monitor performance against approved acceptance criteria to verify quality-affecting activities are performed satisfactorily. The program prescribes requirements to plan and perform quality-affecting activities, including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program prescribes requirements that can include special controls, processes, test equipment, tools, and skills necessary to attain the required quality of activities and items and for verification of that quality. AFS has established and implemented processes to detect and correct quality problems. The requirements of this QAPD also serve as the basis for any unique project specific QA Plans, procedures and instructions that may be required.

2-101 Indoctrination, Training, and Qualification: The program prescribes indoctrination, training, and qualification requirements for personnel who perform or manage quality-affecting activities to ensure they achieve and maintain proficiency suitable to those activities.

2-102 Management Assessments: AFS management regularly assesses the adequacy and effectiveness of quality assurance program implementation and reports assessment results to the President & CEO.

2-103 Codes, Standards, and Regulations: The AFS QAP applies to structures, systems, components and related services that have been classified as having a safety function based the applicable codes, standards and regulations listed in the "STATEMENT OF QUALITY POLICY AND AUTHORITY" provided in this QAPD and customer requirements.

2-200 INDOCTRINATION AND TRAINING

AFS indoctrination and training is commensurate with the scope, complexity, and importance of the activities and the education, experience, and proficiency of the assigned individual.

2-201 Indoctrination: Personnel performing or managing quality-affecting activities receive indoctrination training specific to their job responsibilities and authority. AFS indoctrination training includes general criteria, technical objectives, applicable codes and standards, regulatory commitments, company procedures, and QAP requirements.

2-202 Training: AFS determines the need to train personnel performing or managing activities affecting quality. If needed, training is provided to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training is used when direct hands-on application or experience is needed to achieve and maintain proficiency.

2-300 QUALIFICATION REQUIREMENTS

Each organization (i.e., AFS department, project, etc.) identifies activities that require qualification of its personnel. Policies, procedures and instructions have been established to assure that only qualified personnel are permitted to perform specified activities. Qualification requirements for personnel performing nondestructive examinations, inspections, tests and audits are provided below:

2-301 Nondestructive Examination (NDE) Personnel: Approved procedures or instructions are used to implement qualification requirements for personnel conducting NDE activities. These activities include but are not limited to; radiography (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), visual (VT), etc. AFS uses guidance provided in Recommended Practice No. SNT-TC-1A and other recognized national standards such as the ASME Code and American Welding Society (AWS) to establish qualification requirements for NDE personnel. Design information, customer requirements and other relevant information is used to identify the specific editions of codes and standards that form the basis for the qualification of NDE personnel.

2-302 Inspection and Test Personnel: The initial capabilities of AFS inspection and test candidates are determined by evaluating the education, experience, and training of the candidate and by utilizing an evaluation of either test results or a demonstration of the candidate's capabilities. Inspection and test personnel job performance is reevaluated at periodic intervals by reviewing evidence of continued satisfactory performance or redetermination of capability. If the reevaluation determines the capabilities of an individual are not in accordance with the qualification requirements specified for the job, then the individual is removed from that activity until such time as the required capability has been demonstrated. Personnel that have not performed inspection or testing activities in a qualified area for a period of one (1) year will be reevaluated.

2-303 Lead Auditors: Lead Auditors are required to meet the following requirements for qualification.

2-303.1 Communication Skills: A demonstrated capability to communicate effectively, both in writing and orally. AFS attests to these skills in writing.

2-303.2 Training: Training (classroom and on-the-job) to assure competence in:

- Knowledge and understanding of the AFS QAPD and applicable nuclear-related codes, standards, regulations, and regulatory guides
- General structure of quality assurance programs as a whole and the applicable elements included in this QAPD
- Audit planning
- Audit techniques that include reviewing, examining, questioning, evaluating, and reporting; methods of identifying items that require corrective action, following up on completed corrective actions; and closing out audit findings

2-303.3 Audit Participation: Participation in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one (1) audit of which shall be a nuclear quality assurance audit within the year prior to qualification.

Participation in independent assessments, including team assessments such as operations readiness reviews and regulatory inspections/surveys, may be used to satisfy up to four (4) of the five (5) required audits, provided that their use is reviewed and approved for the qualification and the activities demonstrate the following:

- Independence from the functional areas being assessed
- Planning that establishes the scope of the activities and associated evaluation criteria
- Performance by technically qualified and experienced personnel
- Results that are documented and reported to management
- Appropriate corrective action initiated and tracked to resolution

2-303.4 Examination: Sit for and pass an examination that evaluates comprehension of, and ability to use, the skills identified above. The examination may be oral, written, practical, or any combination thereof.

2-303.5 Maintenance of Proficiency: Maintain proficiency through one or more of the following methods: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s). AFS management annually assesses the qualification of each Lead Auditor and may extend the qualification, require retraining, or require requalification.

2-303.6 Requalification: Lead Auditors who fail to maintain proficiency for a period of two (2) years or more are required to be requalified. Requalification includes retraining, reexamination, and participation as an Auditor in at least one nuclear quality assurance audit.

2-304 Auditors: AFS auditors are participants in an audit. Auditors have completed appropriate training or orientation to develop their competence for performing audits. Competence is developed by one or more of the following methods:

- Orientation to provide a working knowledge and understanding of this QAPD and procedures that implement audits and report results
- Training in audit performance that includes fundamentals, objectives, characteristics, organization, performance, results of quality auditing, methods of examining, questioning, evaluating, and documenting specific audit items, and methods of closing out audit findings
- On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. That training includes planning, performing, reporting, and follow-up action involved in conducting audits.

2-305 Technical Specialists: AFS establishes qualifications and requirements for technical specialists who participate in audits of quality assurance programs.

2-400 CERTIFICATION OF QUALIFICATION

AFS certifies the qualification of NDE, inspection, test, and Lead Auditor personnel in writing and includes the following information:

- Employer's name
- Identification of person being certified
- Activities certified to perform
- Basis of qualification including: education, experience, indoctrination, and training; test results, where applicable, and; capability demonstration results
- Results of periodic evaluations
- Results of physical examinations, when required
- Signature of the AFS designated representative who is responsible for such certifications
- Date of certification or recertification and certification expiration
- 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

AFS may delegate qualification examination activities to an independent certifying agency, but retains responsibility for conformance of the examination and its administration. Examination integrity is maintained by AFS or its certifying agency through the confidentiality of files and, if applicable, the

proctoring of examinations. Copies of objective evidence regarding the type(s) and content of the examination(s) shall be retained by AFS in accordance with the requirements of this QAPD.

2-500 STOP WORK AUTHORITY

All AFS employees have the authority and the responsibility to stop work when unsatisfactory work or unsafe conditions are observed. The following conditions will be immediately reported to AFS management for evaluation of the condition and initiation of appropriate corrective actions:

- When continuation of activities could result in significant deficiencies that would negatively affect nuclear safety,
- When work being conducted is such that the quality of work or the product of that work is unacceptable,
- When the quality of the work is indeterminate, or
- When working conditions are such that continuing work could result in an immediate hazard to the public, the environment, or working personnel.

Stopped work is evaluated for restart relative to, and commensurate with, the complexity and significance of the conditions preceding the stoppage of work. All stopped work shall be documented to record the initiating condition(s), the evaluation of those conditions, corrective actions taken prior to resumption of work, and actions taken to prevent recurrence.

2-600 RECORDS

Records of personnel indoctrination, training, qualification and when required, certification are maintained in accordance with approved procedures.

SECTION 3
DESIGN CONTROL

3-100 BASIC REQUIREMENT

AFS defines, controls, and verifies designs. AFS specifies and translates design inputs into design documents. Design interfaces are identified and controlled. Design adequacy is verified by individuals other than those who designed the item or computer program. Design changes, including field changes, are governed by control measures commensurate with those applied to the original design.

3-200 DESIGN INPUT

AFS documents, identifies, reviews, and approves applicable design inputs and their selection. Design inputs are specified to the level of detail necessary to permit design activities to be performed correctly and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3-300 DESIGN PROCESS

The AFS organization(s) responsible for a design prescribe and document design activities to the level of detail necessary to permit the design process to be performed correctly, and to permit independent verification that the design meets requirements.

- Design documents support system, structure, and component (SSC) design, construction, and operation.
- Appropriate quality standards are identified and documented, and their selection reviewed and approved.
- Design methods, materials, parts, equipment, and processes essential to the function of items are selected and reviewed for suitability of application.
- Applicable information derived from experience, as set forth in reports or other documentation, is made available to design personnel.
- Final designs:
  - Relate to the design input by documentation of sufficient detail to permit design verification
  - Specify required inspections and tests, and include or reference appropriate acceptance criteria; and
  - Identify assemblies and/or components that are a part of the item being designed. When such an assembly or component is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those critical characteristics are documented. Critical characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function. 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.

3-400 DESIGN ANALYSES

AFS design analyses are 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.

3-401 Use of Computer Programs: To the extent required, acceptability of computer programs is pre-verified or the results are verified with the design analysis for each application. Pre-verified computer programs are controlled in accordance with the requirements of this QAPD.

- The computer program is verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed
- The encoded mathematical model is shown to produce a valid solution to the physical problem associated with the particular application

3-402 Documentation of Design Analysis: Design analysis documentation includes the following:

- Objective(s) of the analyses
- Design inputs and their sources
- Results of literature searches or other applicable background data
- Assumptions and indication of those assumptions that must be verified as the design proceeds
- Identification of any computer calculation(s), including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem
- Review and approval

3-500 DESIGN VERIFICATION

AFS design verification documents identify the responsible design organization and the specific design verification method(s) used.

The results of design verification are documented with the identification of the verifier clearly indicated. 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. The originator's supervisor may perform verification, provided:

- 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
- The supervisor is the only individual in the organization competent to perform the verification
- Cursory supervisory reviews do not satisfy the intent of this requirement

- 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. In those cases, the unverified portion of the design is identified and controlled. In all cases, design verification is completed prior to relying upon the component, system, structure, or computer program to perform its function.
- If the design is modified to resolve verification findings, the modified design is verified prior to release for use.
- The extent of design verification is 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 approved designs. Where the design has been subjected to a verification process in accordance with this QAPD, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, is verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features are considered. The original design and associated verification documentation is referenced in records of subsequent application of the design.

3-501 Methods: Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

3-501.1 Design Reviews: Design reviews are performed to provide assurance that the final design is correct and satisfactory by verifying the items below, as applicable:

- The design inputs were correctly selected
- Assumptions necessary to perform the design activity were adequately described and reasonable. The assumptions were identified for subsequent re-verification when the detailed design activities are completed.
- Appropriate design methods and computer programs were used
- The design inputs were correctly incorporated into the design
- The design output is reasonable compared to design inputs
- The necessary design inputs for interfacing organizations are specified in design documents or in supporting procedures or instructions

- Suitable materials, parts, processes, and inspection and testing criteria have been specified

3-501.2 Alternate Calculations: Alternate calculations use alternative methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used, are also reviewed.

3-501.3 Qualification Tests: Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other means. When tests are being performed on models or mockups, scaling laws are established and verified. The results of model test work are subject to error analysis, where applicable, prior to use in final designs.

3-600 CHANGE CONTROL

AFS justifies changes to design inputs, final designs, field changes, and temporary and permanent modifications. Those changes are subjected to design control measures equal to the control measures given to the original design.

- Evaluation includes configurations that occur during operation, maintenance, test, surveillance, and inspection activities. The design organization approving the change demonstrates competence in the specific design area of interest and has an adequate understanding of the requirements and intent of the original design.
- When a design change is approved other than by revision to the affected design documents, measures are established to incorporate the change into these documents, where such incorporation is appropriate.
- Where a significant design change is necessary because of an incorrect design, the design process and verification procedure are reviewed and modified as necessary.

3-601 Configuration Management: Procedures implementing configuration management requirements are established and documented at the earliest practical time. These procedures include the responsibilities and authority of the organizations whose functions affect the configuration, including activities such as operations, design, maintenance, construction, licensing, and procurement.

3-601.1 Configuration management requirements include measures to ensure changes that may affect the approved configuration are recognized and processed.

3-601.2 The configuration is established and approved at the earliest practical time prior to initial use of the SSC and maintained for the life of the SSC.

3-601.3 The configuration includes, 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.

3-601.4 Interface controls include the integration of activities of organizations that can affect the approved configuration.

3-601.5 Documentation identifies the design bases and the approved configuration for the approved modes of operation.

3-601.6 Measures are established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases.

3-601.7 The implementation sequence for approved configuration changes are reviewed to determine that the configuration conforms to the design bases.

3-601.8 Approval by the design authority is required prior to implementation of a change to the design bases.

3-601.9 The configuration of the SSC is documented in drawings, specifications, procedures, and other documents which reflect the operational status of the SSC. The process utilized to control the current revision and issuance of these documents takes into account the use of the documents and the need for revision.

3-700 INTERFACE CONTROL

AFS interface control assigns responsibility among participating design organizations for review, approval, release, distribution, and revision of documents. When design information is transmitted across interfaces, AFS identifies the status of the design information or document provided, and identifies incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal is confirmed by a controlled document.

3-800 SOFTWARE DESIGN CONTROL

The requirements of this section apply to computer software design control and are used instead of Sections 3-200, Design Input; 3-300, Design Process; 3-500, Design Verification; and 3-600, Change Control.

- Section 3-900 provides requirements for the acquisition, development, operation, maintenance, and retirement of software to be utilized in nuclear facility applications.

3-801 Software Design Process: The AFS software design process is documented, approved by the responsible design organization, and controlled in accordance with the following requirements:

3-801.1 Identification of Software Design Requirements: Software design requirements are identified and documented and their selection reviewed and approved. Software requirements identify the operating system, function,

interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

3-801.2 Software Design: Software design is documented and defines the computational sequence(s) necessary to meet software requirements. The documentation includes, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. 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.

3-801.3 Implementation of the Software Design: Software design is translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.

3-801.4 Software Design Verification: Software design verification is 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. The originator's supervisor may perform verification, provided:

- 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
- The supervisor is the only individual in the organization competent to perform the verification
- Cursory supervisory reviews do not satisfy the intent of this requirement

The results of verification are documented with the identification of the verifier indicated. Software verification methods include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, degree of standardization, similarity with previously approved software, and importance to safety

3-801.5 Computer Program Testing: Computer program testing is performed in accordance with Section 11.

3-802 Software Configuration Management: Software configuration management includes, but is not limited to, configuration identification, change control, and status control. Configuration items are maintained under configuration management until the software is retired.

3-802.1 Configuration Identification: A software baseline is established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline are added to the baseline. A baseline defines the most recently approved software configuration. A labeling system for configuration items is implemented that uniquely identifies each configuration item, identifies changes to configuration items by revision, and

provides the ability to uniquely identify each configuration of the revised software available for use.

3-802.2 Configuration Change Control: Changes to software are formally documented. The documentation includes a description of the change, the rationale for the change, and the identification of affected software baselines. The change is 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. Only authorized changes are made to software baselines. Appropriate verification activities are performed for the change. The change is appropriately reflected in documentation and traceability of the change to the software design requirement is maintained. Appropriate acceptance testing is performed for the change.

3-802.3 Configuration Status Control: The status of configuration items resulting from software designs are maintained current. Configuration item changes are controlled until they are incorporated into the approved product baseline. The controls include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls also provide for notification of this information to affected organizations.

3-900 COMPUTER SOFTWARE FOR NUCLEAR FACILITY APPLICATIONS

3-901 General: AFS controls the acquisition, development, operation, maintenance, and retirement of software to be utilized in nuclear facility applications. Control is implemented, as appropriate, through policies, procedures, plans, specifications, or work practices, etc. which provide the framework for software engineering activities. This section supplements the requirements of Section 3-800 and is used in conjunction with other applicable QAPD requirements when, and to the extent, appropriate.

3-901.1 Software Engineering: AFS includes the following elements in software engineering activities, as appropriate to the activity:

- Software acquisition method(s) for controlling the acquisition process for software and software services
- Software engineering method(s) used to manage the software life-cycle activities
- Application of standards, conventions, and other work practices that support the software life cycle
- Controls for support software used to develop, operate, and maintain computer programs

3-902 Software Engineering Elements: The following requirements are included in the software engineering elements described in Section 3-901.1.

3-902.1 Documentation: When multiple or duplicate documents are required, in addition to baseline documents maintained as quality records, those documents can be provided either as separate or as combined documents.

3-902.2 Review AFS utilizes software reviews to ensure compliance with approved software design requirements. When multiple review requirements

are specified, AFS may perform and document reviews separately or combined, as appropriate, to the defined software engineering method.

3-902.3 Software Configuration Management: AFS utilizes configuration management elements for software to be utilized in nuclear facility applications:

- Configuration items to be controlled include, as appropriate:
  - Documentation (e.g., software design requirements, instructions for computer program use, test plans, and results)
  - Computer program(s) (e.g., source, object, backup files)
  - Support software
- The software configuration change control process includes:
  - Initiation, evaluation, and disposition of a change request
  - Control and approval of changes prior to implementation
  - Requirements for retesting and acceptance of the test results

3-902.4 Problem Reporting and Corrective Action: AFS documents, evaluates, and corrects software problems in accordance with the AFS Corrective Action Program. When software problems are determined to be an error, the error evaluation considers the following, as appropriate to the problem:

- How the error relates to appropriate software engineering elements
- How the error impacts past and present use of the computer program
- How the corrective action impacts previous development activities
- How users are notified of the identified error, its impact; and how to avoid the error, pending implementation of corrective actions

3-903 Software Acquisition: Software acquisition includes software or software services procured in accordance with the AFS QA program, or which is otherwise acquired for use in quality affecting activities.

3-903.1 Procured Software and Software Services: AFS utilizes Section 4 and Section 7 for the procurement of software and software services. The purchaser is responsible for implementing the appropriate requirements of this section upon acceptance of the software or related item (e.g., programmable device). AFS procurement documents identify requirements for the supplier's reporting of software errors and, as appropriate, AFS's reporting of software errors to the supplier.

3-903.2 Otherwise Acquired Software: Software that has not been previously approved under a program consistent with the AFS QA Program for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software), is evaluated in accordance with the requirements of this section. The software is identified and controlled prior to evaluation.

- AFS performs and documents the evaluation to determine adequacy; to support operation and maintenance; and to identify the activities to be performed and the documentation that is needed.
- AFS documents exceptions from documentation requirements and the justification for acceptance.
- AFS reviews evaluation results and the performance of the actions necessary to accept the software. The resulting documentation and associated computer program(s) establish the current baseline. Revisions to previously baselined software received from organizations not required to follow this section are evaluated in accordance with this section.

3-904 Software Engineering Method: AFS documents its software engineering method(s). The software engineering method selected ensures that software life cycle activities are planned and performed in a traceable and orderly manner in accordance with the requirements of this QAPD.

3-904.1 Software Design Requirements: AFS utilizes software design requirements to address technical and software engineering requirements, including security features, and identify applicable reference drawings, specifications, codes, standards regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements are specified, commensurate with risk from unauthorized access or use. Software design requirements are traceable throughout the software life cycle.

3-904.2 Software Design and Software Design Verification: An integral part of software design is the design of a computer program that is part of an overall system. AFS software design considers the computer program operating environment and takes measures to mitigate the consequences of problems as an integral part of the design. Potential problems to consider include external and internal abnormal conditions and events that can affect the computer program. Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.

3-904.3 Implementation: The implementation process will result in software products such as computer program listings and instructions for computer program use. AFS performs reviews in accordance with Section 3-902.2.

3-904.4 Acceptance Testing: Acceptance testing demonstrates that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing demonstrates, as appropriate, that the computer program

- Properly handles abnormal conditions and events as well as credible failures
- Does not perform adverse unintended functions
- Does not degrade the system either by itself, or in combination with other functions or configuration items

AFS performs acceptance testing prior to approving the computer program for use. Configuration change control is used to control configured items prior to the start of acceptance testing. Acceptance testing is planned and performed for all software design requirements and can range from a single test of all software design requirements to a series of tests performed during computer program development. Testing includes a comprehensive acceptance test performed in the operating environment prior to use.

Test plans, test cases, and test results are documented, reviewed, and approved in accordance with Section 11, Test Control, prior to using the computer program. Observations of unexpected or unintended results are documented and dispositioned prior to test results approval.

Changes to a computer program are subjected to selective retesting to detect unintended adverse effects introduced during the change, to 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.

3-904.5 Operation: After software is approved for use and installed in the operating environment, AFS controls the use of the software in accordance with approved procedures and instructions.

3-904.6 Maintenance: The appropriate software engineering elements, as described in Section 3-901.1, identify how changes to the software are controlled.

3-904.7 Retirement: During retirement, AFS terminates support for the software product, and the routine use of the software is prevented.

3-905 Standards, Conventions, And Other Work Practices: As appropriate, either the software engineering method or the software acquisition method 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 are documented.

3-906 Support Software: Support software includes software tools and system software. As appropriate, either the software engineering method or software acquisition method establishes the need for software tools.

3-906.1 Software Tools: AFS software tools are evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software are not required to be placed under configuration control. In cases involving modifications of software products

using the software tools, the configuration of the support software associated with that modification is managed. Changes to the software tool are evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

3-906.2 System Software: 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. 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. System software is placed under configuration change control. Changes to system software are evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

3-1000 RECORDS

AFS design records include not only final design documents, such as drawings and specifications and revisions to such documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support final designs. Design records are maintained in accordance with approved procedures.

SECTION 4
PROCUREMENT DOCUMENT CONTROL

4-100 BASIC REQUIREMENT

AFS includes or references applicable design bases and other requirements necessary to assure adequate quality of purchased items and services in procurement documents. To the extent necessary, AFS procurement documents require suppliers to have a QA program consistent with the applicable requirements of this QAPD.

4-200 CONTENT OF PROCUREMENT DOCUMENTS

As necessary, AFS includes the following provisions in procurement documents issued at all tiers of procurement.

4-201 Scope of Work: A statement of the scope of the work to be performed by the supplier.

4-202 Technical Requirements: Technical requirements 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. Procurement documents identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

4-203 Quality Assurance Program Requirements: QA requirements consistent with importance and/or complexity of the item or service being procured. Procurement documents require the supplier to incorporate appropriate quality requirements in sub-tier procurement documents.

4-204 Right of Access: Requirements to assure access to supplier and sub-tier supplier facilities and records for surveillance, inspection, or audit by AFS, its designated representative, and others authorized by AFS.

4-205 Documentation Requirements: Documentation required to be submitted for information, review, or approval by AFS. The time of submittal is also established in procurement documents. When AFS requires the supplier to maintain specific records, the retention times and disposition requirements are prescribed in procurement documents.

4-206 Nonconformances: Requirements for the supplier's reporting of nonconformances to AFS for review and approval.

4-207 Spare and Replacement Parts: Requirements for identifying spare and replacement parts or assemblies and the related data required for ordering those parts or assemblies.

4-300 PROCUREMENT DOCUMENT REVIEW

AFS reviews procurement documents prior to award to assure that documents transmitted to prospective supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. AFS incorporates

technical or quality assurance program changes made as a result of bid evaluations or negotiations into procurement documents prior to issuing them to the supplier. AFS reviews procurement documents using personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4-400 PROCUREMENT DOCUMENT CHANGES

AFS subjects procurement document changes affecting technical requirements or QA program requirements to the same degree of control and review as was utilized in the preparation of the original procurement documents.

SECTION 5
INSTRUCTIONS, PROCEDURES AND DRAWINGS

5-100 BASIC REQUIREMENT

AFS activities and services affecting quality are prescribed by, and are 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. AFS describes activities and services affecting quality to a level of detail commensurate with the complexity of the activities and services and the need to assure consistent and acceptable results. The need for detail in written procedures or instructions, and the level of detail, is determined by the complexity of the task; the significance of the item, activity, or service; the work environment; and worker proficiency and capability (based upon worker education, training, and/or experience).

Compliance with requirements stated in approved instructions, procedures and drawings is required for all personnel performing work subject to the requirements of the QAP.

SECTION 6
DOCUMENT CONTROL

6-100 BASIC REQUIREMENT

AFS controls the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings to assure that correct documents are being utilized. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.

6-200 DOCUMENT CONTROL

AFS applies the following controls to initial documents and changes to existing documents:

- Identification of controlled documents
- Specified distribution of controlled documents for use at the appropriate location
- Identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents
- Review of controlled documents for adequacy, completeness, and approval prior to distribution
- Methods to ensure the correct documents are being used

6-300 DOCUMENT CHANGES

6-301 Major Changes: Changes to documents, other than those defined as minor changes are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

6-302 Minor Changes: Minor changes to documents, such as inconsequential editorial corrections, do not require that revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such review and approval and the persons who can authorize such decisions are clearly delineated.

SECTION 7
CONTROL OF PURCHASED ITEMS AND SERVICES

7-100 BASIC REQUIREMENT

AFS controls the procurement of items and services to assure conformance with specified requirements. Such controls shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion.

7-200 SUPPLIER EVALUATION AND SELECTION

Prior to awarding a contract, AFS evaluates a supplier's capability to provide items or services in accordance with the requirements specified in procurement documents. Supplier evaluation and selection, and the results of those activities, are documented and include one or more of the following:

- Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history must reflect current capability
- Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated
- Supplier's technical and quality capability as determined by a direct evaluation of his facilities, personnel, and the implementation of the supplier's quality assurance program

7-201 When required, supplier audits are performed on a triennial basis and supplemented by an annual evaluation of the supplier performance. These evaluations are documented and take into consideration the following where applicable:

- The review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions
- Results of previous source verifications, audits, and receiving inspections
- Operating experience of identical or similar products furnished by the same supplier
- The results of audits and inspections from other sources (e.g., DOE, NRC Inspection Reports) if available

7-202 For activities conducted on a periodic basis (e.g., audits and evaluations), AFS may apply a grace period of up to 90 days to the scheduled interval as long as the periodicity of the activity remains based on the original schedule.

7-203 AFS may arrange for and utilize an audit of a supplier on behalf of itself through other qualified parties. When utilizing a shared audit, AFS remains responsible for the adequacy of such audit.

7-300 BID EVALUATION

When AFS solicits bids from potential suppliers, the bid evaluation includes a determination of a supplier's capability to conform to the technical and quality assurance requirements. Prior to awarding a contract, AFS resolves, or obtains commitments to resolve, unacceptable technical and quality assurance conditions identified through the bid evaluation.

7-400 CONTROL OF SUPPLIER GENERATED DOCUMENTS

AFS implements controls to assure that the submittal and evaluation of supplier-generated documents and changes are accomplished in accordance with procurement document requirements. Those controls provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

7-500 ACCEPTANCE OF ITEM OR SERVICE

7-501 General: Prior to offering an item or service to its client for acceptance, AFS verifies that the item or service being furnished complies with the procurement requirements. The extent of verification activities are related to the importance, complexity, and quantity of the item or service(s) procured and the supplier's quality performance. Where required by codes, regulations, or contract requirements, documentary evidence that items conform to procurement requirements are transmitted prior to installation or use.

7-502 Methods of Acceptance: AFS uses various methods to accept an item or service from a supplier, which include supplier-provided Certificates of Conformance, source verifications, receiving inspections, post-installation tests, or a combination of these methods.

7-503 Certificates of Conformance: When AFS uses a Certificate of Conformance to accept an item or service from a supplier, the following requirements must be met:

- The certificate identifies the purchased material or equipment, such as by the purchase order number
- The certificate identifies the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate identifies any procurement requirements that have not been met, including an explanation and the means for resolving the nonconformances

- The certificate is signed or otherwise authenticated by a person who is responsible for the supplier's QA function, and whose function and position are described in the supplier's QA program
- The certification system, including the procedures to be followed in filling out a certificate and the procedures for review and approval of the certificates, are described in the supplier's QA program
- Means are 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 is conducted by the AFS at intervals commensurate with the supplier's past quality performance.

7-504 Source Verification: When AFS uses source verification, it is performed at intervals consistent with the importance and complexity of the item or service, and includes monitoring, witnessing, or observing selected activities. Source verification is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon AFS acceptance of source verification, documented evidence of acceptance is furnished to the receiver of the item, to the AFS purchaser, and to the supplier.

7-505 Receiving Inspection: When AFS uses receiving inspections, purchased items are 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. Receiving inspections verify such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspections are coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

7-506 Post-Installation Testing: When AFS uses post-installation testing, test requirements, and acceptance documentation are mutually established by AFS and the supplier.

7-507 Acceptance of Services: In cases involving procurement of services, such as third party inspection; engineering and consulting; auditing; and installation, repair, overhaul, or maintenance work, AFS accepts the service by any or all of the following means: technical verification of data produced; surveillance and/or audit of the activity; or review of objective evidence for conformance to the procurement document requirements.

7-600 CONTROL OF SUPPLIER NONCONFORMANCES

AFS controls the disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements by:

- Evaluating nonconforming items
- Requiring submittal of nonconformance notices to AFS by the supplier. Those submittals must include supplier-recommended disposition (e.g., use-

as-is or repair) and technical justification. Nonconformances to AFS procurement requirements or AFS-approved documents, which consist of one or more of the following, must be submitted to AFS for approval of the recommended disposition:

- Technical or material requirement is violated
- Requirement in supplier documents that has been approved by the purchaser, is violated
- Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework
- 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

- Evaluating supplier recommendations for disposition of nonconformances
- Verifying implementation of the disposition
- Maintaining records of supplier-submitted nonconformances.

7-700 COMMERCIAL GRADE ITEMS

AFS adheres to the following requirements when procuring and accepting commercial grade items and services for nuclear applications subject to DOE or NRC regulations.

7-701 Supplier Evaluation and Selection: When necessary, AFS utilizes Section 7-200, the results of the technical evaluation and associated critical characteristics to evaluate and select commercial grade suppliers.

7-702 Utilization: AFS includes the following when utilizing commercial grade items or services:

- A technical evaluation to determine that the item or service performs a safety function
- Confirmation that the item or service meets the definition of commercial grade
- Identification of the critical characteristics, including acceptance criteria
- Selection, performance, and documentation of the dedication method(s) for determining compliance with acceptance criteria

When one or more critical characteristics for acceptance cannot be verified by the dedication methods, AFS cannot dedicate and provide the commercial grade item or service for use in a nuclear application.

7-703 Critical Characteristics: AFS addresses the following when selecting critical characteristics for acceptance:

- Identifiable and measurable attributes or variables appropriate for the safety function

- 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

7-704 Dedication: AFS provides reasonable assurance that the commercial grade item or service meets the identified critical characteristics acceptance criteria through the use of inspections, tests, or analyses performed after delivery.

Prior to accepting a commercial grade item or service, AFS determines the following, as applicable:

- Damage was not sustained during shipment
- The item or service has satisfied the specified identified critical characteristics acceptance criteria
- Specified documentation was received and is acceptable

7-704.1 Commercial Grade Survey: AFS performs commercial grade surveys at the supplier's facility in accordance with a checklist or plan.

AFS does not employ commercial grade surveys as a supplemental basis for accepting commercial grade items or services from suppliers with undocumented quality programs and from suppliers with programs that do not effectively implement specified process and control requirements.

After a supplier's processes and controls have been determined to be adequate, AFS invokes or references the verified processes and controls as a part of the purchase order or control requirements for the commercial grade item or service and requires the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls.

AFS establishes survey frequencies to reconfirm the previous supplier survey information for application to additional purchases.

7-704.2 Alternate Means of Qualifying Commercial Calibration Services: AFS may utilize Commercial Calibration Service Providers that have received accreditation by National Voluntary Laboratory Accreditation (NVLAP), American Association for Laboratory Accreditation (A2LA) and other International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) accreditation bodies (AB) to ANSI/ISO/IEC 17025. When used, this alternative takes the place of the need to perform a Commercial Grade Survey of the commercial calibration service provider. Requirements for and limitation for the use of this alternative are defined in approved procedures.

7-704.3 Source Verification: AFS applies source verification only to those commercial grade item(s) or service(s) being verified at the supplier's facility or other applicable location. Source verifications are performed in accordance with Section 7-504. Source verifications utilize a checklist or plan with documented evidence of the source verification.

7-704.4 Acceptable Supplier/Item/Service Performance Records: AFS includes the following in acceptable supplier/item/service performance records:

- Identification of the supplier/item/service being evaluated
- Identification of previously established critical characteristics specific to the supplier/item/service
- Identification of industry data examined to evaluate the supplier/item/service
- Identification of basis for determining that industry data substantiates acceptability of the supplier/item/service
- Documentation of the adequacy and acceptance of the supplier/item/service performance record

AFS does not employ an acceptable supplier/item/service performance record unless:

- The established historical record is based on industry-wide performance data that is 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)
- The manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity

When AFS continues to apply an acceptable supplier/item/service performance record, it will utilize a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

7-705 Supplier Deficiency Correction: Deficiencies in a supplier's processes and controls identified through the dedication process will be corrected by the supplier and will verified by AFS to be acceptable and complete, if AFS uses the specified dedication process to verify a critical characteristic.

7-800 RECORDS: Records of purchased items and services are maintained in accordance with approved procedures. These records include but are not limited to:

- Supplier evaluation and selection
- Acceptance of items or services
- Supplier nonconformance to procurement document requirements, including their evaluation and disposition
- Utilization and acceptance of commercial grade items

SECTION 8

IDENTIFICATION AND CONTROL OF ITEMS

8-100 BASIC REQUIREMENT

AFS assures that only correct and accepted items are used or installed. AFS maintains identification on the items or in documents traceable to the items, or in a manner that assures identification is established and maintained.

8-200 IDENTIFICATION METHODS

8-201 Item Identification: Items of production (batch, lot, component, part) are identified from the initial receipt and fabrication up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document.

8-202 Physical Identification: Physical identification is used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means are employed. Identification markings are applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings are transferred to each part of an identified item when sub-divided and are not obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

8-300 SPECIFIC REQUIREMENTS

8-301 Identification and Traceability of Items: When codes, standards, or specifications include specific identification or traceability requirements (such as 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), AFS provides such identification and traceability control.

8-302 Limited Life Items: Items having limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired.

8-303 Maintaining Identification of Stored Items: Provisions are made for the control of item identification consistent with the planned duration and conditions of storage, such as:

- Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging
- Protection of identifications on items subject to excessive deterioration due to environmental exposure
- Provisions for updating existing plant records.

SECTION 9

CONTROL OF SPECIAL PROCESSES

9-100 BASIC REQUIREMENT

AFS utilizes qualified personnel and qualified procedures in accordance with specified requirements to perform special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination.

9-200 PROCESS CONTROL

9-201 Special Processes: Special processes are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions include or reference procedure, personnel, and equipment qualification requirements. Conditions necessary for accomplishment of the process are included. Those conditions include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.

9-202 Acceptance Criteria: The requirements of applicable codes and standards, including acceptance criteria for the process, are specified or referenced in procedures or instructions.

9-203 Special Requirements: For special processes not covered by existing codes and standards, or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment are specified or referenced in procedures or instructions.

9-300 RESPONSIBILITY

AFS requires the organization performing the special process to adhere to the approved procedures and processes.

9-400 RECORDS

Records of personnel, process and equipment qualification for special processes are maintained in accordance with approved procedures.

SECTION 10
INSPECTION

10-100 BASIC REQUIREMENT

AFS plans and executes inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service. Characteristics subject to inspection and inspection methods are specified. AFS documents the results of inspections. Inspections for acceptance are performed by qualified persons other than those who performed or directly supervised the work being inspected.

10-200 INSPECTION REQUIREMENTS

AFS ensures inspection requirements and acceptance criteria specify requirements that are included in applicable design documents or other pertinent technical documents that have been approved by the responsible design organization.

10-300 INSPECTION HOLD POINTS

AFS indicates specific hold points in appropriate documents when mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative. AFS records the consent to waive specified hold points prior to work continuing beyond the designated hold point.

10-400 INSPECTION PLANNING

10-401 Planning: Characteristics to be inspected, methods of inspection, and acceptance criteria are identified during the inspection planning process.

10-402 Sampling: Sampling procedures, when used, are based upon valid statistical methods with engineering approval.

10-500 IN-PROCESS INSPECTION

As necessary, AFS performs inspection of items under construction or otherwise in process to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel are provided. Process monitoring is performed by qualified personnel or qualified automated means. Both inspection and process monitoring are provided when control is inadequate without both.

10-600 FINAL INSPECTIONS

10-601 Resolution of Nonconformances: Final inspections include a records review of the results and resolution of nonconformances identified by prior inspections.

10-602 Inspection Requirements: Completed items are inspected for completeness, markings, calibration, adjustments, protection from damage, or

other characteristics as required to verify the quality and conformances of the item to specified requirements.

10-603 Modifications, Repairs, or Replacements: Any modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or retest, as appropriate, to verify acceptability.

10-604 Acceptance The acceptance of the item is approved by authorized personnel.

10-700 INSPECTIONS DURING OPERATIONS

10-701 Inservice Inspections When appropriate, AFS plans and performs periodic inspections (e.g., in-service inspections) or surveillances of systems, structures, or components to assure the continued performance of their required functions.

10-800 RECORDS

Approved procedures require that inspection records include the following minimum information:

- Item inspected
- Date of inspection
- Inspector or data recorder
- Type of observation
- Results
- Acceptability
- Action taken in connection with and noted deficiency.

SECTION 11
TEST CONTROL

11-100 BASIC REQUIREMENT

AFS plans and executes 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. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with test requirements and acceptance criteria are evaluated.

11-200 TEST REQUIREMENTS

AFS test requirements and acceptance criteria are provided or approved by the responsible design organization.

11-201 Required Tests: Required tests (other than for computer programs), including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests, and computer program tests such as software design verification, factory acceptance tests, site acceptance tests, and in-use tests are controlled. Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests, are controlled. Required tests are 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. The tests performed obtain the necessary data with sufficient accuracy for evaluation and acceptance.

11-202 Test Requirements: Test requirements and acceptance criteria are based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements

11-203 Temporary Changes: If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test

11-204 Computer Program Test Requirements and Acceptance Criteria: The organization responsible for the use of the computer program provides test requirements and acceptance criteria which include the following, as applicable:

- Software design verification testing which demonstrates the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.
- Computer program acceptance testing which consists 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.

- In-use computer programs testing which demonstrates required performance over the range of operation of the controlled function or process.

11-300 TEST PROCEDURES (OTHER THAN FOR COMPUTER PROGRAMS)

AFS test procedures include or reference the test configuration and test objectives.

- Test procedures 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. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.
- As an alternative to the requirements specified above, appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used if they include, or are supplemented with, appropriate criteria from the requirements of the immediately previous section, to assure adequate procedures for the test.

11-400 COMPUTER PROGRAM TEST PROCEDURES

When testing computer programs, and as appropriate, computer hardware and operating systems, the following requirements are applied, rather than those of Section 11-300:

- AFS computer program test procedures provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures provide for assuring that the computer program produces correct results. For those computer programs used for operational control, computer program test procedures provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures 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.
- In-use test procedures are developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures are performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests are prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

11-500 TEST RESULTS

AFS documents test results and evaluates those results using a responsible authority to ensure test requirements have been satisfied. Test results for design qualification tests and software design verification are evaluated by the responsible design organization.

11-600 RECORDS

Test records necessary to demonstrate the ability of an item or computer program to satisfactorily perform its intended function are maintained in accordance with approved procedures.

SECTION 12
CONTROL OF MEASURING AND TEST EQUIPMENT

12-100 BASIC REQUIREMENT

AFS ensures all tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.

12-200 SELECTION

AFS selects measuring and test equipment based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

12-300 CALIBRATION AND CONTROL

12-301 Calibration: Measuring and test equipment is calibrated at prescribed time periods or usage intervals and whenever the accuracy of the equipment is suspect. Calibration is against, and traceable to, certified equipment having known valid relationships to nationally recognized standards or to international standards known to be equivalent to, and verified against, nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented.

12-302 Reference Standards: Reference standards will have a minimum accuracy four times greater than that of the measuring and test equipment being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where a 4:1 ratio cannot be maintained, the basis for selection of the standard in question will be technically justified and documented.

12-303 Control: Calibration procedures identify or reference required accuracy and define methods and frequency of checking accuracy. Methods and frequency of checking accuracy are defined in procedures. The calibration method and interval of calibration is based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. Out-of-calibration measuring and test equipment, and those found to be overdue for calibration, is tagged or segregated or both, or is removed from service, and is not used until satisfactory recalibration. Measuring or test equipment consistently found to be out of calibration is repaired or replaced.

12-303.1 Application: Measuring and test equipment is traceable to its application and use.

12-303.2 Corrective Action: When measuring and test equipment is lost, damaged, or found to be out of calibration, AFS evaluates the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested. This evaluation is from the last acceptable calibration of the M&TE. The evaluation and resulting actions are commensurate with the significance of the condition.

12-303.3 Handling and Storage: Measuring and test equipment is properly handled and stored to maintain accuracy.

12-303.4 Environmental Controls: Measuring and test equipment is used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

12-303.5 Pre-calibration Checks: Measuring and test equipment and reference standards submitted for calibration are checked and the results recorded before any required adjustments or repairs are made.

12-303.6 Status Indication: Measuring and test equipment is suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

12-304 Commercial Devices: Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

12-400 RECORDS

Records that identify calibration status and the capability of the measuring and test equipment to perform its intended function are maintained in accordance with approved procedures.

SECTION 13
HANDLING, STORAGE, AND SHIPPING

13-100 BASIC REQUIREMENT

AFS controls handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. AFS conducts those activities 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.

13-200 SPECIAL REQUIREMENTS

AFS specifies and provides 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) when required and verifies their existence.

13-300 PROCEDURES

AFS uses specific procedures for handling, storage, packaging, shipping, and preservation when required for critical, sensitive, perishable, or high value items.

13-400 TOOLS AND EQUIPMENT

AFS utilizes and controls special handling tools and equipment where necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested periodically or prior to use as necessary to ensure performance.

13-500 OPERATORS

AFS operators of special handling and lifting equipment are experienced or trained in use of the equipment.

13-600 MARKING OR LABELING

AFS utilizes marking or labeling as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

SECTION 14
INSPECTION, TEST, AND OPERATING STATUS

14-100 BASIC REQUIREMENT

AFS identifies the status of inspection and test activities either on items or in documents traceable to items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed required inspections and tests are not inadvertently installed, used, or operated. AFS maintains status through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps is specified. When applicable to a nuclear facility, status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

SECTION 15
CONTROL OF NONCONFORMING ITEMS

15-100 BASIC REQUIREMENT

AFS controls items that do not conform to specified requirements to prevent inadvertent installation or use. Those controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

Nonconforming conditions are evaluated for reportability needs as required by applicable DOE or NRC regulations (e.g., 10 CFR Part 820, 10 CFR Part 21) and project specific requirements. This evaluation and any subsequent reporting are controlled in accordance with approved procedures.

15-200 IDENTIFICATION

AFS identifies nonconforming items by legible marking, tagging, or other methods not detrimental on the item, container, or package containing the item.

15-300 SEGREGATION

AFS segregates nonconforming items, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of a nonconforming item

15-400 DISPOSITION

15-401 Control: Nonconforming items are evaluated and recommended dispositions are proposed. Further processing, delivery, installation, or use of a nonconforming item is controlled pending the evaluation and an approved disposition by authorized personnel.

15-402 Responsibility and Authority: The responsibility and authority for the evaluation and disposition of nonconforming items are defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items is designated in writing.

15-403 Personnel: Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

15-404 Disposition: Disposition of a nonconforming item as use-as-is, reject, repair, or rework, is made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is is documented. Nonconformance to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those applied to the original design. Required as-built records reflect the use-as-is or repair condition.

15-405 Reexamination: Reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items are reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

SECTION 16
CORRECTIVE ACTION

16-100 BASIC REQUIREMENT

AFS promptly identifies conditions adverse to quality and corrects adverse conditions as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action(s) taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management. Completion of corrective actions is verified.

Corrective action documents are evaluated for reportability needs as required by applicable DOE or NRC regulations (e.g., 10 CFR Part 820, 10 CFR Part 21) and project specific requirements. This evaluation and any subsequent reporting are controlled in accordance with approved procedures.

SECTION 17
QUALITY ASSURANCE RECORDS

17-100 BASIC REQUIREMENT

AFS controls records consistent with its schedule for accomplishing work activities to furnish documentary evidence that items or activities meet specified quality requirements. QA records are identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities are documented and include controls for the storage of records in electronic media.

17-200 GENERATION OF RECORDS

AFS QA records are legible. Quality records are traceable to associated items and activities and accurately reflect the work accomplished or information required. Records to be generated, supplied, or maintained are specified in applicable documents, such as design specifications, procurement documents and approved procedures and instructions.

17-300 AUTHENTICATION OF RECORDS

AFS considers documents to be valid quality records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents are reviewed and approved by the responsible individual from the originating or authorized organization. Electronic documents are authenticated with comparable information as described above or by one of the following means, as appropriate:

- With identification on the media
- With authentication information contained within or linked to the document itself

17-400 CLASSIFICATION

AFS QA records are classified as lifetime or nonpermanent in accordance with the following criteria:

17-401 Lifetime Records: AFS utilizes the guidance provided in Appendix 17A-1 (Nonmandatory) to ASME NQA-1, requirements provided in applicable regulation as well as requirements specified in customer documents to identify and classify lifetime records.

17-402 Nonpermanent Records: Nonpermanent records are those 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 records. Nonpermanent record retention periods are defined in implementing procedures.

17-500 RECEIPT CONTROL OF RECORDS

AFS designates a person or organization responsible for receiving the records. The designee is responsible for organizing and implementing a system of

receipt control of records for permanent and temporary storage. Receipt controls provide a method of identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.

17-600 STORAGE

17-601 General: Records shall be stored at a predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from:

- Natural disasters such as winds, floods, or fires
- Environmental conditions such as high and low temperatures and humidity
- Infestation of insects, mold, or rodents
- Dust or airborne particles

Activities detrimental to the records shall be prohibited in the storage area. Access to the processing, storage, and retrieval of records shall be limited to authorized personnel. Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

17-602 Facility Types: There are two equally satisfactory methods of providing storage, single or dual.

17-602.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

17-602.2 Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements of Section 17-602.1, but shall meet the requirements of Section 601.

17-603 Temporary Storage: When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless dual storage requirements of Section 602.2 are met.

17-700 RETENTION

AFS specifies and documents record retention requirements such that QA records are maintained in accordance with prescribed retention periods.

For lifetime records subject to the requirements of 10 CFR Part 71, AFS retains such records for 3 years after the life of the packaging to which they apply. For superseded lifetime records, AFS retains such records for 3 years after the record was superseded.

For lifetime records subject to the requirements of 10 CFR Part 72, AFS retains such records until the NRC Certificate of Compliance (CoC) is terminated by the NRC.

17-800 MAINTENANCE OF RECORDS

AFS protects QA records from damage or loss. QA records are retrievable within planned retrieval times based upon the record type or content. Methods for record changes are documented. Provisions are made to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

AFS ensures that QA records remain retrievable after hardware, software, or technology changes and has established provisions to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

- Duplication or transfer is appropriately authorized
- Record content, legibility, and retrievability are maintained

SECTION 18
AUDITS

18-100 BASIC REQUIREMENT

AFS performs audits to verify compliance to QA program requirements, to verify performance criteria are met, and to determine the effectiveness of the program implementation. Audits are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented, reported to, and reviewed by responsible management. Follow-up action is taken where indicated.

18-200 SCHEDULING

AFS schedules audits in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits are supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

The applicable elements of the AFS QA program should be audited at least once each year or at least once during the life of an activity, whichever is shorter. In determining the audit scope, the activity(s) being audited should be evaluated to determine the applicable elements. The evaluation may include reviewing the results of previous QA program audits and the results of audits from other sources, and can consider the nature and frequency of identified deficiencies and any significant changes in personnel, the organization, or the QA program.

18-201 Audit Equivalents: Dependent on the program elements to be audited, AFS may utilize equivalent activities such as independent assessments and technical surveillances to satisfy part or all of an audit requirement provided that the audit equivalent meets the following conditions:

- The requirements for a quality assurance audit are met (audit personnel qualification and independence)
- They are reviewed and approved for use as such by the organization responsible for the audit function
- Audit equivalents used to satisfy audits of the QA organization are reviewed and approved by the AFS President & CEO

18-300 PREPARATION

18-301 Audit Plan: The auditing organization develops an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

18-302 Personnel: Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18-303 Selection of Audit Team: An audit team is identified prior to the beginning of each audit. This team contains one or more auditors, one being designated the Lead Auditor who organizes and directs the audit.

18-400 PERFORMANCE

AFS audit elements are evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine if those elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization.

18-500 REPORTING

AFS audit reports are signed or otherwise endorsed by the Lead Auditor and is issued to the audited organization. The audit report:

- Describes the audit scope
- Identifies Auditors and persons contacted
- Summarizes audit results, including a statement on the effectiveness of the elements audited
- Describes each reported adverse audit finding

18-600 RESPONSE

Management of AFS audited organizations or activities 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 action taken or planned. Audit responses are evaluated by or for the auditing organization.

18-700 FOLLOW-UP ACTION

AFS takes audit follow-up action(s) to verify that corrective actions are accomplished as scheduled.

REVISION HISTORY

QAPD Revision Number	Section(s) Revised	Description of Revision(s)
00	All	Original Issue
01	1-100	Added second paragraph, describing application to activities.
	1-201	Added QA responsibility requirements to fourth bullet and four new sub-bullets
	1-202	Updated to reflect current AFS Organization
	Figure 1-1	Updated to reflect current AFS Organization
	2-202	Added training requirements
	2-302	Added NDE personnel requirements
	2-303.3	Added independent assessments as alternate activities to audits requirement
	2-600	Added "implementation" as a qualifier for records requirements
	3-300	Fourth bullet – changed "characteristics" to "critical characteristics" throughout
	3-800	Added a condition for using the section and reference to new Section 3-900
	3-801.4	Added requirements which allow the use of a supervisor's verification
	3-900	New section added: Computer Software for Nuclear Facility Applications
	7-201	Added supplier evaluation requirements
	7-202	Added supplier evaluation scheduling requirements
	7-203	Added shared supplier evaluation requirements
	7-204	Added supplier annual evaluation requirements
	7-700	Commercial Grade Items section completely revised
	10-402	Added "with engineering approval" to requirement
	11-300	Added supplemental conditions to second bullet
	12-302	New section added: Reference Standards
	12-303	Added frequency, performance, overdue calibration, and removal requirements
	12-303.1	New section added: Application
	12-303.2	Added requirements for lost or damaged equipment and previous results
	12-303.4	New section added: Environmental Controls
	12-303.5	New section added: Pre-calibration Checks
	12-303.6	"Equipment" changed to "Measuring and test equipment"
	17-100	Added "schedule for accomplishing work activities" to requirement
	17-402	Added nonpermanent record retention period and maintenance requirements
	18-100	Added "verify compliance to QA program requirements"
	18-200	Added specificity to scheduling requirements
02	1-202	Updated to reflect the current AFS organization
	Figure 1-1	Updated to reflect the current AFS organization
	2-100	Amended to include "processes ... to detect and correct quality problems"
	2-103	Removed reference to document AFS-QA-POL-001
	2-103	Eliminated revision level from DOE O 414.1
	2-201	Amended to include "... technical objectives ..."
	2-305	Added to include Technical Specialist qualifications
	3-200	Added "... applicable ..."

	3-300	Added requirements to identify, document, review and approve quality stds.
	3-500	Added provisions for supervisor's verification
	3-904	Added "... in accordance with this QAPD."
	3-904.1	Added security requirements
	3-904.2	Added design verification requirements
	3-904.4	Added requirements for acceptance testing
	7-201	Removed requirement which allowed supplier audits to not be performed
	7-201	Added requirement specifying supplier audit and evaluation frequencies
	7-202	Added requirements for supplier audit schedule grace period
	7-203	Removed references and requirements relating to "... other purchasers ..."
	7-204	Removed paragraph "Results from other sources ..."
	7-400	Added "... and changes ..."
	7-501	Added requirements for a graded approach
	7-502	Added "... supplier-provided ..."
	7-504	Added "... receiver of the item, to the AFS purchaser, and to the ..."
	7-507	Added "... any or all of the following means: ..."
	7-600	Removed "... or rework ..."
	7-800	Added section to describe "Records" relating to purchased items and services
	10-500	Added requirements for process monitoring
	10-700	Added to include requirements for in-service inspections
	11-201	Added requirements specific to testing computer programs
	11-204	Added requirements specific to testing computer programs
	11-400	Added reference to Section 11-300
	12-301	Added "intervals" and international standards
	12-303.2	Changed evaluation requirements
	12-303.6	Added traceability requirements
	12-401	Added title "General"
	12-402	Added requirements for reports and certificates
	14-100	Added requirements applicable to a nuclear facility
	15-405	Added reworked items
	17-200	Added requirements for generation of records
	17-300	Added requirements for authentication of records
	17-500	Changed requirements for control of records
	17-600	Completely rewrote requirements for storage of records
	17-700	Added requirements for retention of records
	17-800	Completely rewrote requirements for maintenance of records
	18-804	Clarified requirements for surveillance reports
	18-901	Added audit records requirements
	18-902	Added surveillance records requirements
03	NA	Added "Introduction" and "Statement of Quality Policy and Authority". This information is new or was previously located elsewhere in the QAPD or in implementing procedures.
	1-100	Editorial changes to improve readability. Added statement for applicability of the QAP to subcontracted activities.
	1-201	Editorial changes with no change in intent

	1-202	Completely revised based on new organization structure
	1-203	Editorial changes with no change in intent
	1-204	Added to identify use of generic titles
	Figure 1-1	Completely revised based on new organization structure
	2-100	Editorial changes and added reference to RG 7.10 and NUREG CR/6407 for applying the program in a graded fashion to activities subject to Part 71/72
	2-103	Completely revised to point to Statement of Quality Policy and Authority for the listing of codes, standards, and regulations
	2-200	Editorial changes with no change in intent
	2-201	Editorial changes with no change in intent
	2-300	Revised to improve readability with no change in intent
	2-301	Revised to improve readability and more accurately define the basis for qualification of NDE personnel
	2-302 to 2-500	Editorial changes to improve readability with no change in intent
	2-600	Revised completely to remove the level of specificity
	Section 3	Editorial changes with no change in intent
	5-100	Added new last paragraph to state that compliance with the requirements of approved instructions is required.
	7-201	Revised in its entirety for clarity and readability. Moved information formally contained in paragraph 7-204 into 7-201 and deleted paragraph 7-204
	7-202 and 7-203	Revised to improve readability with no change in intent
	7-700	Revised to generically state compliance with DOE and NRC requirements versus identifying specific regulations
	7-701 and 7-702	Editorial changes with no change in intent
	7-704.2	Added new paragraph to address alternate means of qualifying commercial calibration services based on current NRC information
	7-800	Editorial changes to improve readability with no change in intent
	9-400	Editorial changes to improve readability with no change in intent
	10-800	Editorial changes to improve readability with no change in intent
	11-500	Deleted paragraph as the information was previously stated
	12-400	Deleted paragraph as the information was previously stated
	15-100	Revised reportability considerations for clarity purposes
	16-100	Added reportability considerations as not previously stated
	17-100	Deleted last sentence as this is non-relevant information and added new sentence to address electronic records
	17-200	Editorial changes with no change in intent
	17-400	Editorial changes with no change in intent
	17-401	Revised in its entirety to identify documents and other consideration needed to classify a record as lifetime
	17-700	Revised to clarify retention times for records subject to Part 71/72
	Section 18	Editorial comments throughout with no change in intent. Deleted requirements for surveillance activities as specific requirements for this activity are not provided in NQA-1. Added new paragraph 18-201 to provide for use of alternatives to satisfy audit requirements as discussed in NQA-1 nonmandatory appendices.