



AFS-10-0324

November 11, 2010

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Attention: Document Control Desk  
Mr. E. William Brach  
U.S. Nuclear Regulatory Commission  
Mail Stop EBB-3D-02M  
Washington D.C. 20555

Subject: Amendment Request for QA Program Approval Number 0938

Mr. Brach:

This letter submits a request by AREVA Federal Services LLC (AFS) that the U.S. Nuclear Regulatory Commission (NRC) amend Quality Assurance Program Approval Number 0938, Revision 1 (Docket Number 71-0938).

AFS has revised its quality assurance program. *Quality Assurance Program Description*, AFS-QA-PMD-001, Revision 01, reflects changes to the AFS organizational structure and incorporates the requirements of ASME NQA-1-2004 and NQA-1-2008 with 2009 Addenda applicable to safety-related, quality-affecting, and important-to-safety activities performed by AFS.

A copy of *Quality Assurance Program Description*, AFS-QA-PMD-001, Revision 01, is included with this request. If for any reason you would like to discuss this request, please contact me at 704-805-2636, email at [jerome.ebner@areva.com](mailto:jerome.ebner@areva.com). Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'J.M. Ebner'.

Jerome M. Ebner  
Director, Environmental, Safety, Health, and Quality  
AREVA Federal Services LLC

JME/je

Attachment: AFS-QA-PMD-001, Revision 01 (*forty-nine pages*)

2004

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AREVA Federal Services LLC  
DOCUMENT APPROVAL RECORD

Document Number: AFS-QA-PMD-001

Revision: Rev. 01

Document Title: QUALITY ASSURANCE PROGRAM DESCRIPTION

Approval	Name	Signature	Date
Originator	Jerome M. Ebner		09/02/2010
Senior Vice President, Operations	Dirk S. Leach		9/2/10
President	William D. Gallo		10/29/10

Editorial Change:

Technical Change:

Description of Changes:

- Table of Contents and Sections 1, 2, 3, 7, 10, 11, 12, 17, and 18 revised.
- Added Revision History to provide description of changes.

Document Type: Business Sensitive  Quality Assurance  Other

AFS-AD-FRM-001 Rev 00 (Issued April 2, 2008)  
Refer to AFS-AD-PRC-001, Preparation and Review of Policies, Procedures, and Instructions

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Records Management

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## SECTION 1 ORGANIZATION

### 1-100 BASIC REQUIREMENT

AFS QA Program responsibilities are defined, including the organizational structure, functional responsibilities, levels of authority, and lines of communication for quality-affecting activities.

QA program requirements apply to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Examples of nuclear facilities are 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, and decommissioning. QA program 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 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.

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**1-202 Organization:** AFS is organized as shown in *Figure 1-1*. Business-only activities, which are not depicted, are not governed by the requirements prescribed in this QAPD.

- CEO – Responsible for management of AFS, establishment of overall company policy, and identification of long-term company goals and resources.
- Deputy, Operations – Reports to the CEO; responsible for project operations.
- Deputy, Program Development – Reports to the CEO; responsible for program development.
- Vice President, EM Programs – Reports to the Office of the President; responsible for Environmental Management programs.
- Vice President, Strategic Programs – Reports to the Office of the President; responsible for strategic and business development activities for DOE programs other than EM.
- Vice President, SRR – Reports to the Office of the President; responsible for the SRR contract and the Enhanced Chemical Cleaning (ECC) project.
- Vice President, MOX – Reports to the Office of the President; responsible for the Savannah River Site Mixed Oxide Fuel Fabrication Facility (MOX) project.
- Vice President, EM Support – Reports to the Office of the President; responsible for the Savannah River Site Liquid Waste Operations project.
- Vice President, UDS/ITER – Reports to the Office of the President; responsible for the DUF6 (depleted uranium hexafluoride) project at Paducah, KY and Portsmouth, OH and for the ITER (International Thermonuclear Experimental Reactor) project.
- Vice President, Richland/Idaho Projects – Reports to the Office of the President; responsible for projects managed from the Richland, WA and Idaho Falls, ID offices.
- Director, Environmental, Safety, Health, and Quality – Reports to the CEO; responsible for maintaining the QA Program and for providing required quality overview of AFS projects.

**1-203 Delegation of Work:** The individual(s) or organization(s) responsible for establishing and executing a program under this QAPD may delegate any or all the work to others but shall retain such responsibilities.

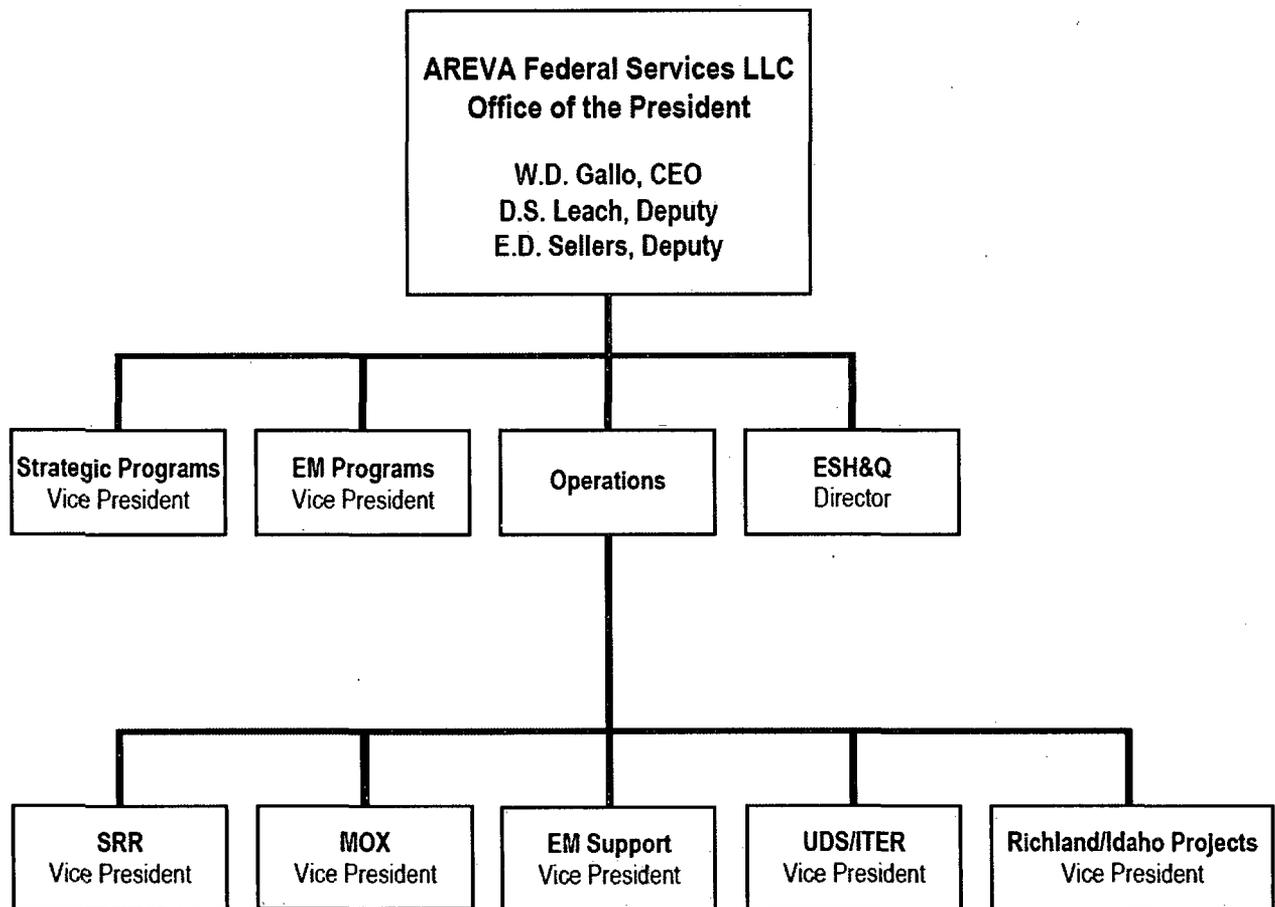
### 1-300 INTERFACE CONTROL

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.

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Figure 1-1

AREVA Federal Services Organization



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**SECTION 2**  
**QUALITY ASSURANCE PROGRAM**

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**2-100 BASIC REQUIREMENT**

AFS implements a planned and documented QA Program that is maintained in accordance with this QAPD. The program identifies the activities and items to which it applies and provides control over activities affecting quality in a graded approach that is consistent with their importance. The AFS QA Program 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. The requirements of this QAPD also serve as the basis for any unique project or site-specific AFS QA Plans 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 the results of those assessments.

**2-103 Codes, Standards, and Regulations:** *AREVA Federal Services Quality Policy*, Document Number AFS-QA-POL-001, was issued by the President, AREVA Federal Services and is the foundation of the AFS QA Program. The AFS QA Program applies to activities that are important-to-safety (or nuclear safety-related) and to activities that require compliance with any or all of the codes, standards, and regulations listed below:

- 10 CFR 21
- 10 CFR 50, Appendix B
- 10 CFR 63, Subpart G
- 10 CFR 70
- 10 CFR 71, Subpart H
- 10 CFR 72, Subpart G
- 10 CFR 820
- 10 CFR 830.120
- DOE O 414.1C
- ASME NQA-1

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## 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 person.

**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, applicable codes and standards, regulatory commitments, company procedures, and quality assurance program 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 and the associated personnel qualification requirements. Each organization establishes procedures that assure only qualified personnel are permitted to perform specified activities. Qualification requirements for personnel performing nondestructive examinations, inspections, tests to verify quality, and QA audits are as follows.

**2-301 Nondestructive Examination (NDE) Personnel:** AFS implements specific requirements to qualify personnel who perform radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT). AFS uses American Society of Nondestructive Testing (ASNT) Recommended Practices or Standards to provide qualification requirements for NDE personnel. Applicable codes and standards or design criteria controlling the qualification of NDE personnel are utilized to establish the applicable ASNT qualification requirement and edition, or to specify an equivalent alternative requirement.

**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 not to exceed three (3) years. Reevaluation is performed by reviewing evidence of continued satisfactory performance or redetermination of capability. If the organization determines the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person will be removed from that activity until such time as the required capability has been

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demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of one year will be reevaluated.

**2-303 Lead Auditors:** AFS Lead Auditors organize and manage audits, report audit findings, and evaluate corrective actions. In order to be designated a Lead Auditor an individual must meet the following requirements.

**2-303.1 Communication Skills:** AFS Lead Auditors are capable of communicating effectively, both in writing and orally. AFS attests to these skills in writing.

**2-303.2 Training:** Prospective Lead Auditors receive training to assure auditing competence including:

- 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.
- On-the-job training to include applicable elements of the AFS audit program.
- Planning audits of quality-affecting activities.
- Utilization of auditing 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:** Prospective AFS Lead Auditors participate in a minimum of five quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.

Participation in independent assessments, including team assessment activities such as operations readiness reviews and regulatory inspections/surveys, may be used to satisfy up to four of the five required quality assurance audits for prospective Lead Auditors, provided that their use is reviewed and approved for the qualification and provided that the activities can 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:** Prospective AFS Lead Auditors are required to pass an examination that evaluates their comprehension of, and their ability to use, the skills identified above. The examination may be oral, written, practical, or any combination thereof.

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**2-303.5 Maintenance of Proficiency:** AFS Lead Auditors maintain their 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 AFS 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 their proficiency for a period of two (2) years or more must complete requalification activities. 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.

## **2-400 CERTIFICATION OF QUALIFICATION**

AFS certifies the qualification of 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.

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- 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 the employer in accordance with the requirements of this QAPD.

## 2-500 STOP WORK AUTHORITY

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 for the implementation of indoctrination and training are in the form of attendance sheets, training logs, or personnel training records. Qualification records for Auditors, Lead Auditors, and inspection and test personnel, including requalification records, are established and maintained by AFS in accordance with the requirements of this QAPD.

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### SECTION 3 DESIGN CONTROL

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#### 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 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.
- 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

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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.
- Design verification is performed prior to releasing the design for procurement, manufacture, construction, or use by another design

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organization except where this timing cannot be met, such as when insufficient data exists. 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 reverifications 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.

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**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.

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**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**

When design information is transmitted across interfaces, AFS identifies the status of the design information or of the document provided and identifies *incomplete items that require further evaluation, review, or approval*. Where it is necessary to transmit initial design information orally or by other informal means, the transmittal is confirmed promptly 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,

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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

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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.

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**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.

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- 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.

**3-904.1 Software Design Requirements:** AFS utilizes software design requirements to address technical and software engineering requirements. 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.

**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).

- **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

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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 DOCUMENTATION AND RECORDS**

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

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## 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, and subsequent changes, prior to award to assure that documents transmitted to prospective supplier(s) include

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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.

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**SECTION 5**  
**INSTRUCTIONS, PROCEDURES AND DRAWINGS**

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**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).

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## SECTION 6 DOCUMENT CONTROL

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### 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.

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**SECTION 7**  
**CONTROL OF PURCHASED ITEMS AND SERVICES**

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**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** After awarding a contract to a supplier, AFS may determine, based on annual evaluations of the supplier, that external audits are not necessary for procuring items that are relatively simple and standard in design, manufacturing, and testing and which are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

**7-202** AFS will either audit its suppliers' QA programs on a triennial basis or arrange for such an audit to be performed. The triennial period begins when an audit is performed. AFS may perform an audit when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases placed during the triennial period. If a subsequent contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, AFS will conduct an audit of the modified requirements, which will start a new triennial period. If the supplier is implementing the same QA program for other customers as that proposed for use on AFS's contract, a preaward survey may serve as the first triennial audit. Therefore, when a preaward survey is used as the first triennial audit, it will satisfy the same audit elements and criteria as those used on other triennial audits.

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**7-203** AFS may either perform an audit of a supplier or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of the audit should satisfy the needs of all the purchasers, and all the purchasers for whom the audit was conducted should receive the audit report. When utilizing these types of shared audits, AFS will remain individually responsible for the adequacy of the audit.

**7-204** AFS will perform or arrange for annual evaluations of suppliers. AFS will document these evaluations and take the following considerations into account, 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.

Results of audits from other sources (e.g., Nuclear Procurement Issues Committee audit reports or NRC inspection reports) should ensure that the suppliers are effectively implementing their approved QA programs.

#### **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 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. 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 Certificates of Conformance, source verifications, receiving inspections, post-installation tests, or a combination of these methods.

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**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 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.

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**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 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, repair, or rework) 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 application in nuclear power plants licensed pursuant to 10CFR50 or 10CFR52 in order to implement the requirements for dedication activities for acceptance required by 10CFR21.

**7-701 Supplier Evaluation and Selection:** When deemed to be necessary or appropriate, AFS utilizes Section 7-200 to evaluate and select a commercial grade supplier.

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**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 does not utilize the requirements of this section to procure and accept the commercial grade item or service.

**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

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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 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.

**7-704.3 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 be verified by AFS to be acceptable and complete, if AFS uses the specified dedication process to verify a critical characteristic.

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**SECTION 8**  
**IDENTIFICATION AND CONTROL OF ITEMS**

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**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.

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**SECTION 9  
CONTROL OF SPECIAL PROCESSES**

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**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**

AFS maintains records as appropriate for currently qualified personnel, processes, and equipment of each special process.

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## SECTION 10 INSPECTION

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### 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. 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.

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

**10-700 RECORDS**

As a minimum, AFS establishes, maintains, and identifies the following in appropriate inspection records:

- Item inspected
- Date of inspection
- Inspector
- Type of observation
- Results or acceptability
- Reference to information on action taken in connection with nonconformances.

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**SECTION 11**  
**TEST CONTROL**

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**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.

- Required tests, 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. 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.
- Test requirements and acceptance criteria are based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.
- 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.

**11-300 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

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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, AFS applies the following requirements:

- 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 TEST RECORDS**

AFS establishes and maintains test records to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.

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## 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 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. 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, an evaluation commensurate with the significance of the condition is made and documented including the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. This evaluation is from at least the last acceptable calibration of the measuring and test equipment.

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**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 Precalibration 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 or otherwise identified to indicate calibration status.

**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**

AFS establishes and maintains records to indicate calibration status and the capability of measuring and test equipment to perform their intended function satisfactorily.

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**SECTION 13**  
**HANDLING, STORAGE, AND SHIPPING**

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**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.

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**SECTION 14**  
**INSPECTION, TEST, AND OPERATING STATUS**

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**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.

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## 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. Conditions that may be reportable either as deficiencies affecting the ability of important-to-safety structures, systems and components to perform their intended safety function or as "substantial safety hazards" in accordance with either 10 CFR 21 or 10 CFR 820 are evaluated and reported in accordance with applicable 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. Nonconformances to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those

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applied to the original design. Required as-built records reflect the use-as-is or repair condition.

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

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**SECTION 16**  
**CORRECTIVE ACTION**

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**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.

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**SECTION 17**  
**QUALITY ASSURANCE RECORDS**

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**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 those activities are documented. The term *records*, used throughout this section of the QAPD, are to be interpreted as meaning *Quality Assurance Records*.

**17-200 GENERATION OF RECORDS**

AFS QA records must be legible. Quality records must be traceable to associated items and activities and accurately reflect the work accomplished or information required

**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.

**17-400 CLASSIFICATION**

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

**17-401 Lifetime Records:** Lifetime records are required to be maintained by or for a licensee for the life of the particular item while it is installed in a licensee facility or stored for future use. Lifetime records are those that meet one or more of the following criteria:

- Those which would be of significant value in demonstrating capability for safe operation.
- Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
- Those which would be of significant value in determining the cause of an accident or malfunction of an item.
- Those which provide required baseline data for in-service inspections.

**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 will be documented and nonpermanent records will be maintained for their retention period.

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### **17-500 RECEIPT CONTROL AND RETENTION OF RECORDS**

AFS retains quality records in accordance with the above classifications. Retention periods for nonpermanent records are established in writing. Each organization responsible for the receipt of records 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.

For records related to important to safety packaging systems and components, AFS retains sufficient records to describe the activities affecting quality for three years beyond the date when last engaged in the activity(ies) for which the AFS QA Program or QA Plan was developed. If any portion of the written procedures or instructions is superseded, AFS retains the superseded material for three years after it has been superseded.

### **17-600 STORAGE**

AFS stores quality records in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from natural disasters such as winds, floods, or fires, environmental conditions such as high and low temperatures and humidity, and infestation of insects, mold, and rodents. Dual facilities, containers, or combination thereof shall be provided for records storage if a single facility, container, or combination thereof is not capable of providing adequate protection

### **17-700 DISPOSITION**

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

### **17-800 MAINTENANCE OF RECORDS**

AFS protects QA records from damage or loss. QA records are retrievable. Methods for record changes are documented. Provisions are made for specially processed records (such as radiographs, photographs, negatives, microform, and magnetic and optical media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

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## SECTION 18 AUDITS AND SURVEILLANCES

### 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 applicable QA program. 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(ies) 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.

### 18-300 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.

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### 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.

### 18-800 RECORDS

AFS audit records include audit plans, audit checklists, audit reports, audit response correspondence, corrective action completion records, and audit closeout letters, when applicable.

### 18-900 SURVEILLANCES

**18-901 Purpose:** AFS uses internal surveillances to review the status of an item or activity and to verify applicable requirements are satisfactorily implemented. A surveillance is a "snap shot" of a particular activity.

**18-902 Personnel:** Surveillances are performed by individuals who are independent from the specific activity, yet knowledgeable in the topic. Surveillance personnel are trained to the extent necessary to verify conformance of the activity to the appropriate criteria.

**18-903 Scheduling:** Surveillances can be planned, conducted at random intervals, or conducted upon request. Surveillances are tracked, documented, and reported to management of the affected organization.

**18-904 Reporting:** Surveillance reports are signed or otherwise endorsed by the performer and issued to the audited organization. The contents of a surveillance report include:

- Report number
- Date of surveillance

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- Description of activities
- Name of the person who performed the surveillance
- Results of surveillance
- Findings, observations, and comments, as applicable
- Immediate actions taken to correct identified problems.



**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: Precalibration 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	