



August 20, 2007

Attention: Document Control Desk
Mr. E. William Brach
Director, Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
11555 Rockville Pike
Rockville, MD 20852

Subject: AREVA Federal Services LLC Quality Assurance Program Description

Dear Mr. Brach:

We are hereby submitting Revision 00 of the AREVA Federal Services LLC Quality Assurance Program Description, AFS-QA-PMD-001, for NRC review and approval under the provisions of 10 CFR 71, Subpart H.

AREVA Federal Services LLC (AFS) was formed to provide an integrated and central authority for contracted services performed by AREVA and its affiliate companies in the United States for the U.S. Department of Energy (DOE) and other government agencies.

AFS is owned by AREVA Inc., AREVA NC Inc. and AREVA NP Inc., and began operation on January 1, 2007. AFS is responsible for all services contracted by the DOE or other government agencies from AREVA Group companies for continuing contracts and new contracts awarded after January 1, 2007.

For 2007, AFS will remain as an unpopulated LLC since all employees of the constituent AREVA Group organizational entities will not become AFS employees until 2008. Those AREVA Group employees being utilized by AFS will remain as employees of their current organizational entities, while being seconded to AFS to support their assigned projects and work activities. These projects and work activities shall continue be performed under the QA Programs of the AREVA Group entities until the AFS QA Program has been issued, approved by the NRC for those contracts requiring NRC licensed products, or until such time as it has been determined by AFS management to transition to the AFS QA Program.

NRC approval of the AFS QAPD is needed to support transition activities such that when AFS is fully populated on January 1, 2008, we can continue to provide contracted services requiring products licensed under an NRC approved Part 71 QA Program.

AREVA Federal Services LLC

One Bethesda Center - 4800 Hampden Lane, Suite 1100 - Bethesda, MD 20814
Tel.: 1 (301) 841 1600 - Fax: 1 (301) 841 1611 - www.aveva.com

Q004
NMS01

The enclosed QAPD applies to safety-related, quality-affecting or important-to-safety activities performed by AFS, which is headquartered at the following location:

AREVA Federal Services LLC
4800 Hampden Lane, Suite 1100
Bethesda, MD 20814

As additional information, upon approval of the enclosed QAPD by the NRC, AFS will initiate the necessary actions to transfer Part 71 package licenses currently held by Packaging Technology, Inc. which will be merged into AFS on January 1, 2008.

Any questions regarding this submittal may be addressed to me at 7135 Minstrel Way, Suite 300, Columbia, MD 21045, or by contacting me at 410-910-6870. Thank you for your attention to this matter.

Very truly yours,



Steven C. White
Director, Environmental Safety, Health and Quality
AREVA Federal Services LLC

c (w attachment):

Mr. Robert Lewis
11555 Rockville Pike
Mail Stop 013-D13
Rockville, MD 20852

c (w/o attachment):

W. Gallo
G. Field

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**AREVA Federal Services LLC
DOCUMENT APPROVAL RECORD**

Document Number: AFS-QA-PMD-001 **Revision:** 00

Document Title: QUALITY ASSURANCE PROGRAM DESCRIPTION

<u>Approval</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
President	William D. Gallo		8/14/07
Vice President, Office of Civilian Radioactive Waste Management Programs	Thomas A. Coleman		8/14/07
Vice President, Nuclear Energy & Science Programs	Dorothy R. Davidson		8/14/07
Vice President, Project Operations	J. Gregory Field		8/14/07
Vice President, National Nuclear Safety Administration Programs	Ian J. Hunter		8/14/07
Vice President, Deputy	Thomas R. Stevens		8/14/7
Vice President, Environmental Management Programs	Joe B. Stringer <i>for</i>		8/14/7
Director, Environmental Safety, Health And Quality	Steven C. White		8/14/07

Editorial Change:

Technical Change:

Description of Change:

New issue.

Document Type: Business Sensitive Quality Assurance Other



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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.

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 verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function

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.

President – Responsible for management of AFS, establishment of overall company policy, and identification of long-term company goals and resources.

Vice President, Deputy – Reports to the President, responsible for executive support functions.


Vice President, Project Operations – Reports to the President, responsible for AFS project operations.

Vice President, Environmental Management Programs – Reports to the President, responsible for EM Programs.

Vice President, Nuclear Energy and Science Programs – Reports to the President, responsible for NES Programs.

Vice President, National Nuclear Safety Administration Programs – Reports to the President, responsible for NNSA Programs.

Vice President, Office of Civilian Radioactive Waste Management Programs – Reports to the President, responsible for RW Programs.

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Director, Environmental Safety, Health, and Quality – Reports to the President, responsible for maintaining the QA Program and 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.


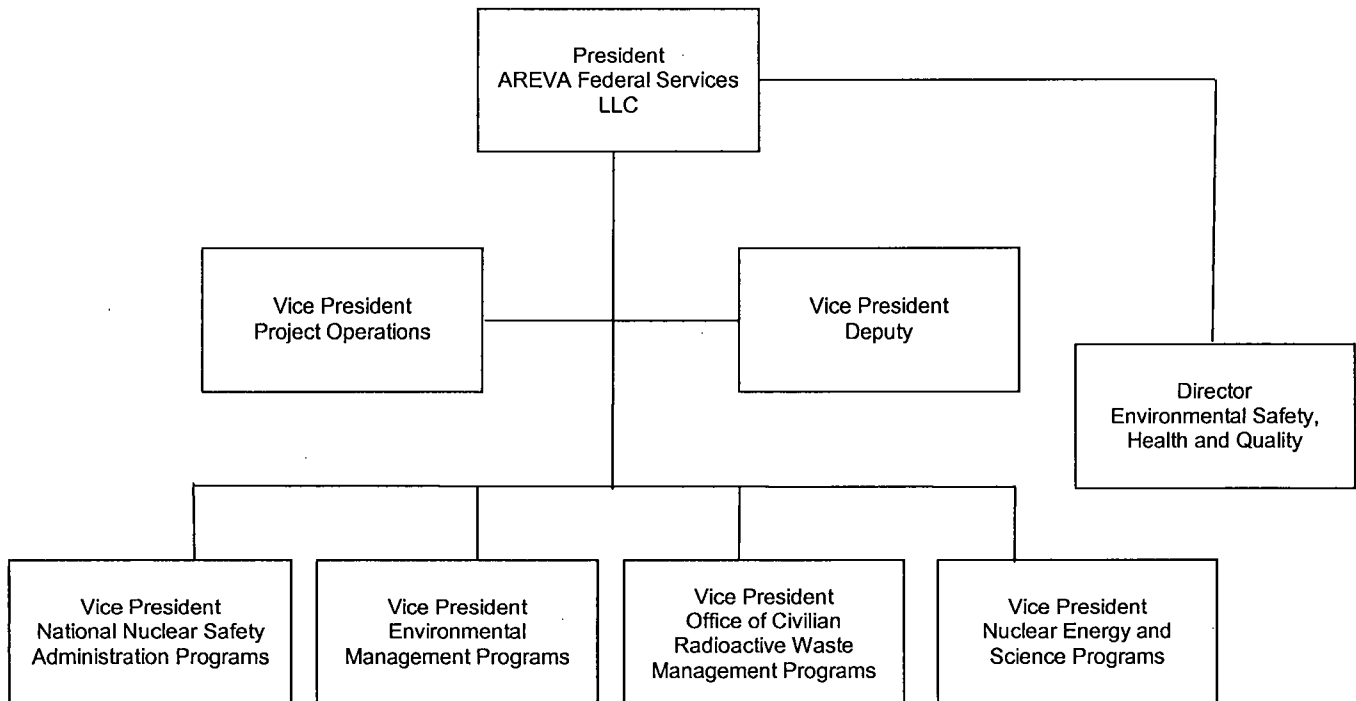

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Figure 1-1

AREVA Federal Services Organization



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SECTION 2
QUALITY ASSURANCE PROGRAM

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

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- DOE O 414.1C
- ASME NQA-1

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: The AFS training program ensures personnel who perform or manage quality-affecting activities achieve initial proficiency, maintain proficiency, and adapt to changes in processes, technology, and job responsibilities.

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). NDE personnel are qualified to the requirements of The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, December 1988 Edition, and its applicable supplements.

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.

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.

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.

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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
- 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.

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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

AFS indoctrination and training records may be 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

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 characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics are documented. 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

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than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3-400 DESIGN ANALYSES

AFS design analyses are sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

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

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


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

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

3-500 DESIGN VERIFICATION

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

- The results of design verification are documented with the identification of the verifier clearly indicated. Design verification is performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization.
- 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

These requirements apply to the control of computer software design where computer software is the deliverable. This section is used instead of QAPD Sections: 3-200: Design Input, 3-300: Design Process, 3-500: Design Verification, and 3-600: Change Control.

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

3-801.1 Identification of Software Design Requirements: Software design requirements are identified and documented and their selection reviewed and approved. Software requirements identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

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

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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 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 the Section 11 of this QAPD.

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

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

3-802.2 Configuration Change Control: Changes to software are formally documented. The documentation includes a description of the change, the rationale for the change, and the identification of affected software baselines. The change is formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes are made to software baselines. Appropriate verification activities are performed for the change. The change is appropriately reflected in documentation and traceability of the change to the software design requirement is maintained. Appropriate acceptance testing is performed for the change.


3-802.3 Configuration Status Control: The status of configuration items resulting from software designs are maintained current. Configuration item

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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 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.


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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 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

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

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 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

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

7-300 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.

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

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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.

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

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requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier. Receiving inspections verify such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspections are coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.


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

7-507 Acceptance of Services: In cases involving procurement of services, such as third party inspection; engineering and consulting; auditing; and installation, repair, overhaul, or maintenance work, AFS accepts the service by 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.

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7-700 COMMERCIAL GRADE ITEMS

Where a design specifies or allows the use of commercial grade items, AFS utilizes the following requirements as an acceptable alternative for procuring and accepting items:

- Identification of commercial grade items in approved design output documents. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.
- Performance of source evaluation and selection, where determined necessary by AFS based on complexity and importance to safety.
- Identification of commercial grade items in the purchase order by the manufacturer's published product description (for example, catalog number).
- Utilization of one or a combination of the following methods to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:
 - ◆ Special test(s) or inspection(s) or both
 - ◆ Commercial grade survey of the supplier
 - ◆ Source verification
 - ◆ Acceptable supplier/item performance records.
- Determination prior to acceptance of a commercial grade item that:
 - ◆ Damage was not sustained during shipment
 - ◆ The item has satisfied the specified acceptance criteria
 - ◆ Specified documentation, as applicable to the item, was received and is acceptable.

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SECTION 8 IDENTIFICATION AND CONTROL OF ITEMS

8-100 BASIC REQUIREMENT

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

8-200 IDENTIFICATION METHODS

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

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


8-300 SPECIFIC REQUIREMENTS

8-301 Identification and Traceability of Items: When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), AFS provides such identification and traceability control.

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

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

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

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SECTION 9
CONTROL OF SPECIAL PROCESSES

9-100 BASIC REQUIREMENT

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

9-200 PROCESS CONTROL

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

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


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

9-300 RESPONSIBILITY

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

9-400 RECORDS

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

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**SECTION 10
INSPECTION**

10-100 BASIC REQUIREMENT

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

10-200 INSPECTION REQUIREMENTS

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

10-300 INSPECTION HOLD POINTS

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

10-400 INSPECTION PLANNING

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


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

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.

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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 conformance of the item to specified requirements.

10-603 Modifications, Repairs, or Replacements: Any modifications, repairs, or replacements of items performed subsequent to final inspection require 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

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,

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equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used

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 are calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect. Calibration is against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented.


12-302 Control: Calibration procedures identify or reference required accuracy. Methods and frequency of checking accuracy are defined in procedures. The calibration method and interval of calibration for measuring and test equipment is defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting capability. Out-of-calibration devices are tagged or segregated, or both, and will not be used until satisfactory recalibration. Measuring or test equipment consistently found to be out of calibration are repaired or replaced.

12-302.1 Corrective Action: When measuring and test equipment are 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.

12-302.2 Handling and Storage: Measuring and test equipment are properly handled and stored to maintain accuracy.


12-302.3 Status Indication: Equipment are suitably marked or otherwise identified to indicate calibration status.

12-303 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.

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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

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

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-

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is or repair are subject to design control measures commensurate with those applied to the original design. Required as-built records reflect the use-as-is or repair condition.


15-405 Reexamination: 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

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

17-100 BASIC REQUIREMENT

AFS provides QA records which 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, is 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.

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

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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 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.

18-300 PREPARATION

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

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

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


18-400 PERFORMANCE

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

18-500 REPORTING

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

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

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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
- 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.