REQUIREMENT 1
Organization

100 GENERAL

Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.

200 STRUCTURE AND RESPONSIBILITY

201 General

The organizational structure and responsibility assignments shall be such that

(a) senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result

(b) quality is achieved and maintained by those assigned responsibility for performing work

(c) quality achievement is verified by those not directly responsible for performing the work

(d) 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:

(1) identifying quality problems

(2) initiating, recommending, or providing solutions to quality problems through designated channels

(3) verifying implementation of solutions

(4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

202 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility thereof.

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.

REQUIREMENT 2
Quality Assurance Program

100 GENERAL

(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.

(b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

(c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.

200 INDOCTRINATION AND TRAINING

Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

201 Indoctrination

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.

202 Training

The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

300 QUALIFICATION REQUIREMENTS

The responsible organization shall designate those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities.

Specific qualification requirements for personnel performing nondestructive examination, inspection, and tests to verify quality, and auditing are specified in paras. 301 through 304 of this Requirement.

301 Nondestructive Examination (NDE)

This paragraph specifies requirements for the qualification of 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) to verify conformance to the specified requirements. The American Society of Nondestructive Testing (ASNT) Recommended Practices or Standards provide acceptable qualification requirements for NDE personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement.

302 Inspection and Test

The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 yr. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200 of this Requirement. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of 1 yr shall be reevaluated.

303 Lead Auditor

The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. An individual shall meet the requirements of paras. 303.1 through 303.4 of this Requirement prior to being designated a Lead Auditor. Lead Auditors shall maintain proficiency in accordance with the requirements of para. 303.5 of this Requirement or requalify in accordance with the requirements of para. 303.6 of this Requirement, as applicable.

303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including

(a) knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable

(b) general structure of quality assurance programs as a whole and applicable elements as defined in this Standard

(c) auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings

(d) planning audits of activities affecting quality

(e) on-the-job training to include applicable elements of the audit program

303.3 Audit Participation. Prospective Lead Auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed 3 yr prior to the date of qualification, one 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, provided that the activities can demonstrate the following:

(a) independence from the functional areas being assessed

(b) planning that establishes the scope of the activities and associated evaluation criteria

(c) performance by technically qualified and experienced personnel

(d) results that are documented and reported to management

(e) appropriate corrective action initiated and tracked to resolution

Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.

303.4 Examination. Prospective Lead Auditors shall pass an examination that evaluates the comprehension of and ability to apply the body of knowledge identified in paras. 303.2(a) through 303.2(d) of this Requirement. The examination may be oral, written, practical, or any combination thereof.

303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following:

(a) regular and active participation in the audit process

(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing

(c) participation in training program(s)

Based on annual assessment, management may extend the qualification, require retraining, or require requalification.

303.6 Requalification. Lead Auditors who fail to maintain their proficiency for a period of 2 yr or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.

304 Auditors

Auditors are participants in an audit. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results.

(b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

305 Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.

400 RECORDS OF QUALIFICATION

The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information:

(a) employer's name

(b) identification of person being certified

(c) activities certified to perform

(d) signature of employer's designated representative

In addition to the requirements above, specific requirements for each qualification/certification that are to be certified in writing are specified in paras. 401 and 402 of this Requirement.

The employer may delegate qualification examination activities to an independent certifying agency but shall retain responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of section 500 of this Requirement.

401 Inspection and Test Personnel

Additional requirements to those listed in para. 400 of this Requirement shall include the following:

(a) education

(b) work experience

(c) training

(d) demonstration of capabilities

(e) date of certification/recertification

(f) any special physical requirements needed in the performance of each activity, including the need for initial and subsequent physical examination

(g) certification expiration

402 Lead Auditor Personnel

Additional requirements to those listed in para. 400 of this Requirement shall include the following:

(a) education

(b) work experience

(c) training

(d) audit participation

(e) examination results

(f) date of certification/recertification

(g) annual assessment of proficiency maintenance

500 RECORDS

Records of indoctrination and training shall include one or more of the following:

(a) attendance sheets

(b) training logs

(c) personnel training records

The employer shall establish and maintain records for indoctrination and training, Auditor and Lead Auditor qualification and requalification, and inspection and test personnel qualification and requalification.

REQUIREMENT 3
Design Control

100 GENERAL

The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

200 DESIGN INPUT

Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

300 DESIGN PROCESS

(a) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

(b) The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

(c) The final design shall

(1) be relatable to the design input by documentation in sufficient detail to permit design verification.

(2) specify required inspections and tests and include or reference appropriate acceptance criteria.

(3) identify assemblies and/or components that are part of the item being designed.

400 DESIGN ANALYSES

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

401 Use of Computer Programs

Each computer program used for design analysis shall be accepted for use and controlled by applying the applicable requirements of Parts I and II prior to use, or the computer program's results shall be independently verified with the design analysis for each application.

The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:

(a) The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.

(b) The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

402 Documentation of Design Analyses

Documentation of design analyses shall include the following:

(a) the objective of the analyses

(b) design inputs and their sources

(c) results of literature searches or other applicable background data

(d) assumptions and indication of those assumptions that must be verified as the design proceeds

(e) identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem

(f) review and approval

500 DESIGN VERIFICATION

(a) The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided

(1) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or

(2) the supervisor is the only individual in the organization competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of this Standard.

(b) Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance with this Part (Part I), 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, shall be verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

501 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following:

(a) design reviews

(b) alternate calculations

(c) qualification testing

501.1 Design Reviews. Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable, paras. 501.1(a) through 501.1(g) of this Requirement.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Were appropriate design methods and computer programs used?

(d) Were the design inputs correctly incorporated into the design?

(e) Is the design output reasonable compared to design inputs?

(f) Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?

(g) Have suitable materials, parts, processes, and inspection and testing criteria been specified?

501.2 Alternate Calculations. Alternate calculations shall use alternate 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 shall also be reviewed.

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

600 CHANGE CONTROL

(a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. When the organization originally responsible

for review and approval of the orginal design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization. The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

(b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

(c) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

601 Configuration Management of Operating Facilities

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.

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

601.2 The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility, and maintained for the life of the facility.

601.3 The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

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

601.5 Documentation shall identify the design bases and the approved configuration for the approved modes of operation.

601.6 Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.

601.7 The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.

601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.

601.9 The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.

700 INTERFACE CONTROL

Interface controls shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

800 SOFTWARE DESIGN CONTROL

The requirements of Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, apply to computer software design control and shall be used instead of section 200, Design Input; section 300, Design Process; section 500, Design Verification; and section 600, Change Control.

900 DOCUMENTATION AND RECORDS

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

REQUIREMENT 4
Procurement Document Control

100 GENERAL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

200 CONTENT OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

201 Scope of Work

Procurement documents shall include a statement of the scope of the work to be performed by the Supplier.

202 Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

203 Quality Assurance Program Requirements

Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with importance and/or complexity of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

204 Right of Access

The procurement documents shall provide for access to the Supplier's and subtier Supplier's facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others authorized by the Purchaser.

205 Documentation Requirements

The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

206 Nonconformances

The procurement documents shall specify the Purchaser's requirements for the Supplier's reporting of nonconformances.

207 Spare and Replacement Parts

The procurement documents shall specify the Supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

300 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents, and changes thereto, shall be made and documented 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.

Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the Supplier.

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

400 PROCUREMENT DOCUMENT CHANGES

Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

REQUIREMENT 5
Instructions, Procedures, and Drawings

100 GENERAL

Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

REQUIREMENT 6
Document Control

(21)

100 GENERAL

The preparation, issuance, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy by a cognizant individual other than the originator, and approved for release by authorized personnel.

200 DOCUMENT CONTROL

The following controls shall be applied to documents and changes thereto:

(a) the unique identification of the controlled documents, including a revision control identifier

(b) the specified distribution of controlled documents for use at the appropriate location

(c) the identification of the individual roles responsible for the preparation, review, approval, and distribution of controlled documents

(d) the review of controlled documents for adequacy and completeness prior to approval, distribution, or processing

(e) a method to ensure the correct document and revision is being used

300 DOCUMENT CHANGES

301 Major Changes

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

302 Minor Changes

Minor changes to documents that do no change its applicability, meaning, intent, or technical content (such as editorial corrections) shall not require that the revised documents receive the same review and approval as the original documents. The types of changes to be considered “Minor” shall be specified.

REQUIREMENT 7
Control of Purchased Items and Services

100 GENERAL

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control 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.

200 SUPPLIER EVALUATION AND SELECTION

Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:

(a) Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated and may include current third-party certificates that recognize the Supplier's quality assurance program (QAP) or other technical certifications.

(c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's QAP.

300 BID EVALUATION

If bids are solicited, the bid evaluation shall include a determination of the Supplier's capability to conform to the technical and quality assurance requirements. Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.

400 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

500 ACCEPTANCE OF ITEM OR SERVICE

501 General

Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

502 Methods of Acceptance

Purchaser methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination of these methods.

503 Certificate of Conformance

When a Certificate of Conformance is used, the minimum criteria of (a) through (f) shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify 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 shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

504 Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

505 Receiving Inspection

When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall verify by objective evidence such features as

(a) configuration
(b) identification
(c) dimensional, physical, and other characteristics
(d) freedom from shipping damage
(e) cleanliness

Receiving inspection shall be coordinated with a review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

506 Postinstallation Testing

When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.

507 Acceptance of Services Only

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

(a) technical verification of data produced
(b) surveillance and/or audit of the activity
(c) review of objective evidence for conformance to the procurement document requirements

600 CONTROL OF SUPPLIER NONCONFORMANCES

Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements shall include (a) through (e).

(a) evaluation of nonconforming items.

(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:

(1) technical or material requirement is violated
(2) requirement in Supplier documents, which has been approved by the Purchaser, is violated
(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework
(4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired

(c) Purchaser disposition of Supplier recommendation.

(d) verification of the implementation of the disposition.

(e) maintenance of records of Supplier-submitted nonconformances.

700 COMMERCIAL GRADE ITEMS AND SERVICES

When dedication is used for accepting commercial grade items or services, the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply.

800 RECORDS

Records shall be established and maintained to indicate the performance of the following functions:

(a) supplier evaluation and selection
(b) acceptance of items or services
(c) supplier nonconformances to procurement document requirements, including their evaluation and disposition

REQUIREMENT 8
Identification and Control of Items

100 GENERAL

Controls shall be established to assure that only correct and accepted items are used or installed.

Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.

200 IDENTIFICATION METHODS

201 Item Identification

Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

202 Physical Identification

Physical identification shall be used to the maximum extent possible. Physical identification methods include, but are not limited to, written markings, etching, affixing stickers with bar or quick response (QR) codes, stamping, and tags. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

300 SPECIFIC REQUIREMENTS

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), the program shall provide such identification and traceability control.

302 Limited Life Items

Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

303 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as

(a) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging

(b) protection of identifications on items subject to excessive deterioration due to environmental exposure

(c) provisions for updating existing plant records

REQUIREMENT 9
Control of Special Processes

100 GENERAL

Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

200 PROCESS CONTROL

201 Special Processes

Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements. Conditions necessary for accomplishment of the process shall be included. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.

202 Acceptance Criteria

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.

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 shall be specified or referenced in procedures or instructions.

300 RESPONSIBILITY

It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.

400 RECORDS

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

REQUIREMENT 10
Inspection

100 GENERAL

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

200 INSPECTION REQUIREMENTS

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

300 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

400 INSPECTION PLANNING

401 Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.

402 Sampling

Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.

500 IN-PROCESS INSPECTION

Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. When process monitoring is used to verify quality, it shall be performed by qualified personnel independent from the personnel performing the process controls or qualified automated means. Both inspection and process monitoring shall be provided when quality verification is inadequate without both.

600 FINAL INSPECTIONS

601 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.

602 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

603 Modifications, Repairs, or Replacements

Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

604 Acceptance

The acceptance of the item shall be approved by authorized personnel.

700 INSPECTIONS DURING OPERATIONS

Periodic inspections (e.g., in-service inspections) or surveillances of structures, systems, or components shall be planned and executed to ensure the continued performance of their required functions.

800 RECORDS

Appropriate records shall be established, maintained, and, as a minimum, identify the following:

(a) item inspected
(b) date of inspection
(c) inspector

(d) type of observation
(e) results or acceptability
(f) reference to information on action taken in connection with nonconformances

REQUIREMENT 11
Test Control

100 GENERAL

Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

200 TEST REQUIREMENTS

(a) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements.

(c) 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.

300 TEST PROCEDURES (OTHER THAN FOR COMPUTER PROGRAMS)

(a) Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include the following, as applicable:

(1) calibrated instrumentation
(2) appropriate equipment
(3) trained personnel
(4) condition of test equipment and the item to be tested
(5) suitable environmental conditions
(6) provisions for data acquisition

(b) As an alternative to (a), appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria from (a) to assure adequate procedures for the test are used.

400 COMPUTER PROGRAM TEST PROCEDURES

Requirements for computer program test procedures are defined in Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

500 TEST RESULTS

Test results shall be documented and maintained. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

600 TEST RECORDS

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602 of this Requirement.

601 Test Records

(a) item tested
(b) date of test
(c) tester or data recorder
(d) type of observation
(e) results and acceptability

(f) action taken in connection with any deviations
(g) person evaluating test results

602 Computer Program Test Records

Requirements for computer program test records are defined in Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

REQUIREMENT 12
Control of Measuring and Test Equipment

100 GENERAL

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

200 SELECTION

Selection of measuring and test equipment shall be based on the type, range, and accuracy needed to accomplish the required measurements for determining conformance to specified requirements.

300 CALIBRATION AND CONTROL

301 Calibration

Measuring and test equipment shall be calibrated at prescribed times or intervals and whenever the accuracy of the results obtained using the measuring and test equipment is suspect. Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the basis for calibration shall be defined.

302 Reference Standards

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

303 Control

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. Measuring and test equipment, which is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated. Measuring or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

303.1 Application. Measuring and test equipment shall be traceable to its application and use.

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

303.3 Handling and Storage. Measuring and test equipment shall be properly handled and stored to maintain accuracy.

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

303.5 Precalibration Checks. Measuring and test equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

303.6 Status Indication. Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

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.

400 RECORDS

401 General

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

402 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. The calibration record report shall include as found calibration data when calibrated items are found to be out of tolerance.

REQUIREMENT 13
Handling, Storage, and Shipping

100 GENERAL

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

200 SPECIAL REQUIREMENTS

When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

300 PROCEDURES

When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

400 TOOLS AND EQUIPMENT

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

500 OPERATORS

Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

600 MARKING OR LABELING

Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

REQUIREMENT 14
Inspection, Test, and Operating Status

100 GENERAL

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

The operating status of nuclear facility structures, systems, and components shall be identified to prevent inadvertent operation.

200 AUTHORITY

The authority for application and removal of status indicators shall be specified.

300 STATUS INDICATION

Status indication shall be maintained through physical means such as tags, markings, labels, stamps, or other suitable methods to prevent inadvertent installation, use, or operation.

REQUIREMENT 15
Control of Nonconforming Items

100 GENERAL

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

200 IDENTIFICATION

Nonconforming items shall be identified by legible marking, tagging, or other methods, such as identifying and controlling the item as nonconforming in an electronic system. If identification of each nonconforming item is not practical, the container or the package containing the item shall be identified. The identification method shall not be detrimental to the item.

300 SEGREGATION

(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to prevent inadvertent use of a nonconforming item.

400 DISPOSITION

401 Control

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

402 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

403 Personnel

Personnel performing evaluations to determine a disposition shall have:

(a) demonstrated competence in the specific area they are evaluating;

(b) an adequate understanding of the requirements; and

(c) access to pertinent background information.

404 Disposition

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned as repair or as use-as-is shall be documented. Nonconformances to design requirements dispositioned as use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.

405 Reexamination

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.

Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

REQUIREMENT 16
Corrective Action

100 GENERAL

Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

REQUIREMENT 17
Quality Assurance Records

100 GENERAL

The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.

200 GENERATION OF RECORDS

(a) Records shall be legible.

(b) Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

(c) Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures.

300 AUTHENTICATION OF RECORDS

(a) Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

(b) Electronic documents shall be authenticated with comparable information as in (a), as appropriate

(1) with identification on the media or

(2) with authentication information contained within or linked to the document itself

400 CLASSIFICATION

Records shall be classified as *lifetime* or *nonpermanent* and maintained by the Owner, or authorized agent, in accordance with the criteria given in paras. 401 and 402 of this Requirement and consistent with applicable regulatory requirements.

401 Lifetime Records

401.1 Lifetime records are those that meet one or more of the following criteria:

(a) those that would be of significant value in demonstrating capability for safe operation

(b) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item

(c) those that would be of significant value in determining the cause of an accident or malfunction of an item

(d) those that provide required baseline data for inservice inspections

401.2 Lifetime records are required to be maintained for the life of the particular item while it is installed in the facility or stored for future use.

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 records shall be maintained for the identified retention period.

500 RECEIPT CONTROL OF RECORDS

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing receipt controls for permanent and temporary storage. Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.

600 STORAGE

601 General

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

(1) natural disasters such as winds, floods, or fires

(2) environmental conditions such as high and low temperatures and humidity

(3) infestation of insects, mold, or rodents
(4) dust or airborne particles

(b) Activities detrimental to the records shall be prohibited in the storage area.

(c) Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.

(d) Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

602 Facility Types

There are two equally satisfactory methods of providing storage, single or dual.

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

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

603 Temporary Storage

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

700 RETENTION

(a) Record retention periods shall be documented.

(b) Records shall be maintained for their retention periods.

800 MAINTENANCE OF RECORDS

(a) Records shall be protected from damage or loss.

(b) Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

(c) The methods for record changes shall be documented.

(d) Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

(e) Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

(f) Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

(1) duplication or transfer is appropriately authorized

(2) record content, legibility, and retrievability are maintained

REQUIREMENT 18
Audits

100 GENERAL

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

200 SCHEDULING

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

A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance. When the grace period is used, the next scheduled date for the activity shall be based on the activity schedule date and not on the date the activity was actually performed. If the activity is performed early, the next schedule date shall be based on the date the activity was actually performed.

201 Internal Audits

Except where specific regulatory guidance exists or Code restrictions apply, organizations shall audit internal activities at the following intervals.

201.1 Nuclear Facilities Prior to Placing the Facility Into Operation. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter.

201.2 Nuclear Facilities After Placing the Facility Into Operation. All applicable quality assurance program elements for each functional area[1] shall be audited within a period of 2 yr. For well-established activities, the period may be extended 1 yr at a time beyond the 2-yr interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit interval shall not exceed a maximum of 4 yr.

201.3 Suppliers and Other Nuclear Support Organizations. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to 2 yr based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.

202 External Audits

External audits (e.g., Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance to determine if the regular schedule audit frequency shall be maintained or decreased or if other corrective action is required. A continuous or ongoing evaluation of the Supplier's performance may be conducted in lieu of the annual evaluations, provided that the results are reviewed in order to determine if corrective action is required.

300 PREPARATION

301 Audit Plan

The auditing organization shall develop an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

302 Personnel

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

[1] "Functional area" denotes activities such as engineering, construction, procurement, operations, maintenance, radiological protection, chemistry, and security.

303 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

400 PERFORMANCE

Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

500 REPORTING

The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall

(a) describe the audit scope

(b) identify Auditors and persons contacted

(c) summarize audit results, including a statement on the effectiveness of the elements audited

(d) describe each audit finding

600 RESPONSE

Management of the audited organization or activity shall investigate 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 shall be evaluated by or for the auditing organization.

700 FOLLOW-UP ACTION

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

800 RECORDS

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.