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1 General Requirements	**INTRODUCTION**	**INTRODUCTION**
The QAP must address the following management, performance, and assessment criteria: **(a) Criterion 1 - Management/Program** (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. (2) Establish management processes, including planning, scheduling, and providing resources for the work. **(j) Criterion 10 - Assessment / Management Assessment** (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.	**1. ORGANIZATION** **BASIC REQUIREMENT** The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to: (1) identify quality problems; (2) initiate; recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.	**REQUIREMENT 1** **ORGANIZATION** **100 BASIC** Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organization structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.
	SUPPLEMENT 1S-1 **2 RESPONSIBILITY** **2.1 Purpose** The organizational structure and the responsibility assignments shall be such that: (a) quality is achieved and maintained by those who have	**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

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	been assigned responsibility for performing work; and (b) quality achievement is verified by persons or organizations not directly responsible for performing the work. **2.2 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 there for. **2.3 Nonconforming Items** Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing. **3 MULTIPLE ORGANIZATIONS** **3.1 Responsibility** Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented. **3.2 Interface Control** **3.2.1** The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented. **3.2.2** Interface responsibilities shall be defined and documented.	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; and (d) those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function. **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 there for. **300 INTERFACE CONTROLS** 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.
(b) Criterion 2 – Management / Personnel Training and Qualification.	**2. QUALITY ASSURANCE PROGRAM** **BASIC REQUIREMENT**	**REQUIREMENT 2** **QUALITY ASSURANCE PROGRAM**

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(1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency. **(a) Criterion 1 - Management/Program** (2) Establish management processes, including planning, scheduling, and providing resources for the work. **(i) Criterion 9 – Assessment / Management Assessment.** (1) Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. **(j) Criterion 10 - Assessment / Management Assessment** (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof. The program shall identify the activities and items to which it applies The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance. 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. Control led 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 and for verification of quality. The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained. Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.	**100 BASIC** (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 assure that suitable proficiency is achieved and maintained. (c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.
	Supplement 2S-1 **Qualification of Inspection and Test Personnel** **General**	**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.

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	This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of non-destructive examination. **2 CERTIFICATION** **2.1 Qualification Requirements** The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities. When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual. **2.2 Personnel Selection** Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. **2.3 Indoctrination**	**201 Indoctrination** Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. **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. **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 as follows. **301 Nondestructive Examination (NDE)** This section 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 Recommended Practice No. SNT-TC-1 A, December 1988 Edition, and its applicable Supplements shall apply as requirements to NDE.

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	Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed. **2.4 Training** The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on firsthand experience gained through actual performance of inspections and tests. **2.5 Determination of Initial Capability** The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration. **2.6 Evaluation of Performance** The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or re-determination of capability in accordance with the requirements of para. 2.5 above. 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 his qualified area for a period of 1 year shall be reevaluated by a re-determination of required capability in accordance with the requirements of para. 2.5	**MINOR CHANGE revise QM, QP** **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 years. Reevaluation shall be by evidence of continued satisfactory performance or re-determination 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 year 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 following requirements prior to being designated a Lead Auditor. **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

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	above. **2.7 Certificate of Qualification** The qualification of personnel shall be certified in writing in an appropriate form, including the following information: (a) employer's name; (b) identification of person being certified; (c) activities certified to perform; (d) basis used for certification, which includes such factors as: (1) education, experience, indoctrination, and training (2) test results, where applicable (3) results of capability demonstration *(e)* results of periodic evaluation; (f) results of physical examinations, when required; (g) signature of employer's designated representative who is responsible for such certification; (h) date of certification and date of certification expiration. **2.8 Physical** 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. **3 RECORDS** **3.1 Record Files** Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required by para. 2.7 above. **SUPPLEMENT 2S-2** **QUALIFICATION OF NONDESTRUCTIVE**	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 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification. **303.4 Examination.** Prospective Lead Auditors shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof. **303.5 Maintenance of Proficiency.** Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s). Based on annual assessment, management may extend the qualifications, require retraining, or require requalification. **303.6 Requalification.** Lead Auditors who fail to maintain their proficiency for a period of 2 years 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

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	EXAMINATION PERSONNEL **1 GENERAL** This supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It 2.2 Program supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this standard. **2 CERTIFICATION** **2.1 Applicable Documents** The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition and its applicable supplements shall apply as requirements to NDE personnel covered by this supplement. **2.2 Program** The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification. **2.3 Records** Records of personnel qualifications shall be established and maintained by the employer. **SUPPLEMENT 2S-3** **QUALIFICATION OF QUALITY ASSURANCE**	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. **400 CERTIFICATION OF QUALIFICATION** (a) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information: (1) employer's name; (2) identification of person being certified; (3) activities certified to perform; (4) basis of qualification (a) education, experience, indoctrination, and training (b) test results, where applicable (c) capability demonstration results; (5) results of periodic evaluation; (6) results of physical examinations, when required; (7) signature of employer's designated representative who is responsible for such certification; (8) date of certification or recertification and Certification expiration; (b) The responsible organization shall identify any special

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	PROGRAM AUDIT PERSONNEL **1 GENERAL** This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a Lead Auditor, who organizes and directs audits; reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives and auditors-in-training. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 QUALIFICATION OF AUDITORS** **2.1 Responsibility of Auditing Organization** The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below: (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) training programs to provide general and specialized training in audit performance. General training shall include	physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. 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 below. **500 RECORDS** Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of qualification, including requalification, for Auditors and Lead Auditors and for inspection and test personnel shall be established and maintained by the employer and for indoctrination and training. **MINOR CHANGE Tech. Spc. Not in 2000** **(revise QM, QP)**

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	fundamentals, objectives, characteristics, organization, performance, and results of quality auditing**.** 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. **3 QUALIFICATION Of LEAD AUDITORS** An individual shall meet the requirements of paras. 11 through 3.4 below prior to being designated a Lead Auditor. **3.1 Communication Skills** The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer. **3.2 Training** Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor. **3.2.1** Knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable. **3.2.2** General structure of quality assurance programs as a whole and applicable elements as defined in this Standard. **3.2.3** Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and	

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	following up on corrective action items; and closing out audit findings. **3.2.4** Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility. **3.2.5** On-the-job training to include applicable elements of the audit program. **3.3 Audit Participation** The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification. **3.4 Examination** The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in para. 3.2 above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement. **4 MAINTENANCE OF QUALIFICATION** **4.1 Maintenance of Proficiency** Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards,	

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	procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s). Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented. **4.2 Requalification** Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 3.2 above, reexamination in accordance with para. 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit. **5 ADMINISTRATION** **5.1 Organizational Responsibility** Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. **5.2 Qualification Examination** The development and administration of the examination for a Lead Auditor required by para. 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where appli-	

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	cable, 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 6 be-low. **6 RECORDS** **6.1 General** Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. **6.2 Certification of Qualification** Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following: (a)employer's name; (b) Lead Auditor's name; (c)date of certification or recertification; (d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); (e)signature of employer's designated representative who is responsible for such certification **6.3 Updating of Lead Auditors' Records** Records for each Lead Auditor shall be maintained and updated annually. **SUPPLEMENT 2S-4** **PERSONNEL INDOCTRINATION AND TRAINING** **1 GENERAL** This Supplement provides amplified requirements for the	

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	indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to, the extent specified by the organization invoking this Standard. **2 APPLICABILITY** This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following: (a) the scope, complexity, and nature of the activity; and (b) the education, experience, and proficiency of the person. Activities affecting quality include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying. **3 INDOCTRINATION** Personnel shall be indoctrinated in the following subjects as they relate to a particular function: (a) general criteria, including applicable codes, standards, and company procedures; (b) applicable quality assurance program elements; and (c) job responsibilities and authority. **4 TRAINING** Training shall be provided, if needed, to: (a) achieve initial proficiency; (b) maintain proficiency; and (c) adapt to changes in technology, methods, or job responsibilities.	

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	5 RECORDS Records of the implementation of indoctrination and training may take the form of: (a) attendance sheets; (b) training logs; or (c) personnel training records.	
(f) Criterion 6 – Performance / Design (1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design bases in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify or validate work before approval and implementation of the design.	**3. Design Control** **BASIC REQUIREMENT** The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design. **SUPPLEMENT 3S-1** **DESIGN CONTROL** **1 GENERAL** This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 DESIGN INPUT** Applicable design inputs, such as design bases, performance	**REQUIREMENT 3** **Design Control** **100 BASIC** 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

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	requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity 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. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled. **3 DESIGN PROCESS** The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component 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. The final design (approved design output documents and approved changes thereto) shall: (a) be relatable to the design input by documentation in sufficient detail to permit design verification; and (b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection	carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation. (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; and (3) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be 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 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. **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.

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	and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference. **3.1 Design Analyses** Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units 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. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable. (a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided: (1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and (2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application. Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above. (b) Documentation of design analyses shall include (1)through (6) below:	**401 Use of Computer Programs** To the extent required in paras. 401(a) and (b) of this Requirement, computer program acceptability shall be preverified or the results verified with the design analysis for each application. Preverified computer programs shall be controlled in accordance with the requirements of this Standard. (a) The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. (b) The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application. **402 Documentation of Design Analysis** Documentation of design analyses shall include (a) through (f) below: (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; and (f) review and approval. **500 DESIGN VERIFICATION** (a) The responsible design organization shall identify and document the particular design verification method used. The results of design verification shall be documented with the

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	(1) definition of the objective of the analyses; (2) definition of design inputs and their sources; (3) results of literature searches or other applicable background data; (4) identification of assumptions and indication of those that must be verified as the design proceeds; (5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, 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; (6) review and approval. **4 DESIGN VERIFICATION** Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs shall include appropriate testing. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly 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 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, pro vided 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.	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. (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 for 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: design reviews, alternate calculations, and qualification testing. **501.1 Design Reviews.** Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable, (a) through (g) below.

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	Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases 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 ver-ification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function. **4.1 Extent of Design Verification** The extent of the design verification required 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 proven designs. Where the design has been subjected to *a* verification process in accordance with this Standard, 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 proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design. Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design. **4.2 Methods**	(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. 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**

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	Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing. **4.2.1 Design Reviews,** These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below shall be addressed. (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) Was an appropriate design method used? (d) Were the design inputs correctly incorporated into the design? (e) Is the design output reasonable compared to design inputs? (1) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions? **4.2.2 Alternate Calculations.** These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed. **4.2.3 Qualification Tests.** Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily 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. Test	(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 analyses upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. 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

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	results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. 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 final design work. **5 CHANGE CONTROL** Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the structure, system, or component are still valid. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner's engineering organization. The designated organization 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. 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. 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.	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 assure 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 which reflect the operational status of the facility. The process utilized to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation. **700 INTERFACE CONTROL** Design information transmitted across interfaces shall identify the status of the design information or document provided and identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit

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	6 INTERFACE CONTROL Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment oi procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces, Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which 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. **7 DOCUMENTATION AND RECORDS** Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documented procedures. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.	design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document. **800 SOFTWARE DESIGN CONTROL** **MINOR CHANGE, revise QM3-1, WVDP-201** The requirements of Section 800 apply to computer software design control and shall be used instead of sections 200, Design Input; 300, Design Process; 500, Design Verification; and 600, Change Control. **801 Software Design Process** The software design process shall be documented, approved by the responsible design organization, and controlled. This process shall include the activities described in the following subparagraphs. **801.1 Identification of Software Design Requirements.** Software design requirements shall be identified and documented and their selection reviewed and approved. The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program. **801.2 Software Design.** The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements, or the computer program listings resulting from implementation of the software design. **801.3 Implementation of the Software Design.** The software

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		design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions. **801.4 Software Design Verification.** Software design verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. The results of verification shall be documented with the identification of the verifier indicated. Software verification methods shall 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: (a) the complexity of the software; (b) the degree of standardization; (c) the similarity with previously proved software; (d) the importance to safety. **801.5 Computer Program Testing.** Computer program testing shall be performed and shall be in accordance with Requirement 11. **802 Software Configuration Management.** Software configuration management includes, but is not limited to, configuration identification, change control, and status control. Configuration items shall be maintained under configuration management until the software is retired. **802.1 Configuration Identification.** A software baseline shall be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recently approved software configuration. A labeling system for configuration items shall be implemented that:

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		(a) uniquely identifies each configuration item; (b) identifies changes to configuration items by revision; and (c) provides the ability to uniquely identify each configuration of the revised software available for use. **802.2 Configuration Change Control.** Changes to software shall be formally documented. The documentation shall include: (a) a description of the change; (b) the rationale for the change; and (c) the identification of affected software baselines. The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained. Appropriate acceptance testing shall be performed for the change. **802.3 Configuration Status Control.** The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls shall also provide for notification of this information to affected organizations. **900 DOCUMENTATION AND RECORDS** Design documentation and records shall include not only final

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		design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important design inputs that support the final design.
(d) Criterion 4 – Management/Documents and Records (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve and maintain records. **(g) Criterion 7 – Performance/ Procurement** (1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	**4 PROCUREMENT DOCUMENT CONTROL** **BASIC REQUIREMENT** 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. **SUPPLEMENT 4S-1** **PROCUREMENT DOCUMENT CONTROL** **1 GENERAL** This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 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. **2.1 Scope of Work** A statement of the scope of the work to be performed by the	**REQUIREMENT 4** **Procurement Document Control** **100 BASIC** 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 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.

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	Supplier shall be in the procurement documents. **2.2 Technical Requirements** Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified 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 provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance. **2.3 Quality Assurance Program Requirements** Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard. The extent of the program required shall depend upon the type and use 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. **2.4 Right of Access** At each tier of procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser. **2.5 Documentation Requirements** The procurement documents at all tiers 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	**203 Quality Assurance Program Requirements** Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with 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 sub tier procurement documents. **MINOR CHANGE, Revise QPR,QP** **204 Right of Access** The procurement documents shall provide for access to the Supplier's and sub tier 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 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 document 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.

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	Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed. **2.6 Nonconformances** The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances. **2.7 Spare and Replacement Parts** The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies. **3 PROCUREMENT DOCUMENT REVIEW** A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: (a) appropriate requirements specified in Section 2 of this Supplement; (b) determination of any additional or modified design criteria; **(**c) analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents	**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.

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	or quality of the item or service to be furnished. Reviews required by this Section 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. **4 PROCUREMENT DOCUMENT CHANGES** Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.	
(e) Criterion 5 – Performance / Work Process (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection.	**5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS** **BASIC REQUIREMENT** Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that proscribed activities have been satisfactorily accomplished.	**REQUIREMENT 5** **Instructions, Procedures, and Drawings** **100 BASIC** 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 acceptance criteria for determining that prescribed results have been satisfactorily attained. 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 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).
(d) Criterion 4 – Management/Documents and Records (1) Prepare, review, approve, issue, use, and revise	**6 DOCUMENT CONTROL** **BASIC REQUIREMENT** The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality	**REQUIREMENT 6** **Document Control** **100 BASIC**

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documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve and maintain records.	shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel. **SUPPLEMENT 6S-1** **DOCUMENT CONTROL** **1 GENERAL** This Supplement provides amplified requirements for a document control system. It supplements the requirements of Basic Requirement 6 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings. The term *document control* used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. **2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE** The control system shall be documented and shall provide for (a) through (c) below: (a) identification of documents to be controlled and their specified distribution; (b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents; (c) review of documents for adequacy, completeness, and correctness prior to approval and issuance. **3 DOCUMENT CHANGES**	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel. **200 DOCUMENT CONTROL** The following controls shall be applied to documents and changes thereto: (a) the identification of controlled documents; (b) the specified distribution of controlled documents for use at the appropriate location; (c) the *identification of individuals* responsible for the preparation, review, approval, and distribution of controlled documents; **MAJOR? CHANGE discuss with R&C/DC** (d) the review of controlled documents for completeness, and approval prior to distribution; and (e) a method to ensure the correct documents are being used. **MINOR CHANGE, revise DCIP** **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.

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	3.1 Major Changes Changes to documents, other than those defined as minor changes in para. 3.2 below, are considered as 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. **3.2 Minor Changes** Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.	**302 Minor Changes** Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.
(g) Criterion 7 – Performance/ Procurement (1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	**7. CONTROL OF PURCHASED ITEMS AND SERVICES** **BASIC REQUIREMENT** The procurement of items and services shall be controlled to assure 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. **SUPPLEMENT 7S-1** **CONTROL OF PURCHASED ITEMS AND SERVICES** **1 GENERAL**	**REQUIREMENT 7** **Control of Purchased Items and Services** **100 BASIC** The procurement of items and services' shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: 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 there from shall be documented and shall include one or more of (a) through (c)

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	This Supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance. **2 PROCUREMENT PLANNING** Procurement activities shall be planned and documented to assure *a* systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. Planning shall determine the following: (a) what is to be accomplished; (b) who is to accomplish it; (c) how it is to be accomplished; (d) when it is to be accomplished. Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process. Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of (a) through (i) below: (a) procurement document preparation, review, and change control; (b) selection of procurement sources; (c) bid evaluation and award; (d) Purchaser control of Supplier performance; (e) verification (surveillance, inspection, or audit)	below. (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. (c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality assurance program. **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 assure that the submittal and evaluation of Supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. **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. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall

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	activities by Purchaser, including notification for hold and witness points; (f) control of nonconformances; (g) corrective action; (h) acceptance of item or service; (i) quality assurance records. **3 SUPPLIER SELECTION** **3.1 Source Evaluation and Selection** The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract. Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability. Measures for evaluation and selection of procurement sources, and the results there from, shall be documented and shall include one or more of (a) through (c) below: (a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The Supplier's history shall retiect current capability. (b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated; (c) Supplier's technical and quality capability *as* determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program. **4 BID EVALUATION** Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be	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 paras. 503(a) through (f) of this Requirement 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,

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	performed by individuals or organi- zations designated to evaluate the following subjects, as applicable to the type of procurement: (a) technical considerations (b) quality assurance requirements (c) Supplier's personnel (d) Supplier's production capability (e) Supplier's past performance (f) alternates (g) exceptions Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation. **5 SUPPLIER PERFORMANCE EVALUATION** The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below: (a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents; (b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements; (c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements; (d) identifying and processing necessary change in-formation; (e) establishing method of document information exchange between Purchaser and Supplier; (f) establishing the extent of source surveillance and inspection activities. These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for	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 configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. **506 Post installation Testing** When post installation testing is used, post installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier. **507 Acceptance of Services Only**

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	verification of quality achievement. **5.1 Extent of Activities** The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers. **5.2 Records** Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. The Purchaser shall assure that his documentation is evaluated to determine the Supplier's quality assurance program effectiveness. **6 CONTROL OF SUPPLIER GENERATED DOCUMENTS** Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the pro-curement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria. **7 CONTROL OF CHANGES IN ITEMS OR SERVICES** The Purchaser and Supplier shall assure that measures to	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; and (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 documentation requirements shall include paras. 600(a) through (e) of this Requirement: (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; and (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; and (e) maintenance of records of Supplier-submitted nonconformances.

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	control changes in procurement documents are established, implemented, and documented and are in accordance with this Standard. **8 ACCEPTANCE OF ITEM OR SERVICE** **8.1 General** Methods shall be established for the acceptance of an item or service being furnished by the Supplier. 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. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use. **8.2 Methods of Acceptance** Purchaser methods used to accept an item or related service from a Supplier shall be Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site or a combination thereof. **8.2.1 Certificate of Conformance.** When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below 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	**700 COMMERCIAL GRADE ITEMS** Where the design utilizes commercial grade items, the Purchaser can utilize the following requirements as an acceptable alternative to other requirements of this section for procuring and accepting items: (a) The commercial grade item is identified in an approved design output document. 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. (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with section 200 of this Requirement. (c) Commercial grade items shall be identified in the purchase order by the Manufacturer's published product description (for example, catalog number). (d) One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance: (1) special test(s) or inspection(s) or both; (2) commercial grade survey of the Supplier; (3) source verification; (4) acceptable Supplier/item performance records (e) Prior to acceptance of a commercial grade (1) damage was not sustained during shipment; (2) the item has satisfied the specified acceptance criteria; and (3) specified documentation, as applicable to the item, was received and is acceptable.

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	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 non-conformances. (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. **8.2.2 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 it shall be implemented to monitor, witness, or observe 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. **8.2.3 Receiving Inspection.** When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into	

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	account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. **8.2.4 Post~InstalIation Testing.** When post installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier. **8.3 Acceptance of Services Only** In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; 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 such as certifications, stress reports, etc. **9 CONTROL OF SUPPLIER NONCONFORMANCES** The Purchaser and Supplier shall establish and document methods for disposition of items and services that do not meet procurement documentation requirements. These methods shall contain provision for (a) through (e) below: (a) evaluation of nonconforming items; (b) submittal of nonconformance notice to Purchaser by	

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	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 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 or the implementation of the disposition; (e) maintenance of records of Supplier-submitted nonconformances. **10 COMMERCIAL GRADE ITEMS** Where the design utilizes commercial grade items, the following requirements are an acceptable alternate to other requirements of this Supplement, except as noted in (b) below and the requirements of Supplement 4S-1. (a) The commercial grade item is identified in an approved design output document. 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. (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with para. 3.1 of	

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	this Supplement. (c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number). (d) After receipt of a commercial grade item, the Purchaser shall determine that: (1) damage was not sustained during shipment; (2) the item received was the item ordered; (3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements; (4)documentation, as applicable to the item, was received and is acceptable.	

(h) Criterion 8 – Performance / Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. **(e) Criterion 5 – Performance / Work Process** . (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration.	**8. IDENTIFICATION AND CONTROL OF ITEMS** **BASIC REQUIREMENT** 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 which assures that identification is established and maintained. **SUPPLEMENT 8S-1** **IDENTIFICATION AND CONTROL OF ITEMS** **1 GENERAL** This Supplement provides amplified requirements for identification and control of items. It supplements the requirements of Basic Requirement 8 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 IDENTIFICATION METHODS** **2.1 Item Identification** Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document. **2.2 Physical Identification** Physical identification shall be 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 shall be employed.	**REQUIREMENT 8** **Identification and Control of Items** **100 BASIC** 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. 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

	2.3 Markings Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect 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 coatings unless other means of identification are substituted. **3 SPECIFIC REQUIREMENTS** **3.1 Identification and Traceability of Items** When specified by codes, standards, or specifications that 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 be designed to provide such identification and traceability control. **3.2 Limited Life Items** Where specified, 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. **3.3 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: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identifications on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing plant records.	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.

(e) Criterion 5 – Performance / Work Processes (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection.	**9 CONTROL OF PROCESSES** **BASIC REQUIREMENT** Processes affecting quality of items or services shall be controlled. 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. **SUPPLEMENT 9S-1** **CONTROL OF PROCESSES** **1 GENERAL** This Supplement provides amplified requirements for control of processes. It supplements the requirements of Basic Requirement 9 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 PROCESS CONTROL** Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained. **3 SPECIAL PROCESSES** Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements. **3.1 Responsibility** It is the responsibility of the organization performing the	**REQUIREMENT *9*** **Control of Special Processes** **100 BASIC** 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

	special process to adhere to the approved procedures and processes. 3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements. 3.1.2 Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements. **3.2 Acceptance Criteria** The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions. **3.3 Records** Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process. **3.4 Special Requirements** For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.	processes. **400 RECORDS** Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

(h) Criterion 8 – Performance / Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. **(j) Criterion 10 – Assessment / Independent Assessment** (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	**10 INSPECTION** **BASIC REQUIREMENT** Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected. **SUPPLEMENT 10S-1** **INSPECTION** **1 GENERAL** This Supplement provides amplified requirements for inspection of items and activities. It supplements the requirements of Basic Requirement 10 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 PERSONNEL** **2.1 Reporting Independence** Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected. **2.2 Qualification** Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. Inspections by persons during on-the job training for qualification shall be performed under the direct	**REQUIREMENT 10** **Inspection** **100 BASIC** 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.* **MINOR CHANGE, revise QM,QP** **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**

	observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved. **3 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. **4 INSPECTION PLANNING** **4.1 Planning** Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results. **4.2 Sampling** Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices. **5 IN-PROCESS INSPECTION** **5.1 Inspection** Inspection of items in-process or under construction shall be performed for work activities where 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. Both inspection and process monitoring shall be provided when control is inadequate without both.	Sampling procedures, when used, shall be based upon valid statistical methods. **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. Both inspection and process monitoring shall be provided when control 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. **700 RECORDS** Appropriate records shall be established, maintained and, as a minimum, identify the following paras. (a) through (f) reference to information on action taken in (a) item inspected; (b) date of inspection;

	5.2 Combined Inspection and Monitoring **5.2.1** A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. 5.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction. **6 FINAL INSPECTIONS** **6.1 Resolution of Nonconformances** Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. **6.2 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 conformances of the item to specified requirements. Quality records shall be examined for adequacy and completeness if not previously so examined. **6.3 Acceptance** The acceptance of the item shall be documented and approved by authorized personnel. **6.4 Modifications, Repairs, or Replacements**	(c) inspector; (d) type of observation; (e) results or acceptability; and (f) reference to information on action taken in connection with nonconformances.

	Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability. **7 INSERVICE INSPECTION** **7.1 Planning and Performance** Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation. **7.2 Methods** Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate. **8 RECORDS** Records shall, as a minimum, identify (a) through (f) below: (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	
(h) Criterion 8 – Performance / Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	**11 TEST CONTROL** **BASIC REQUIREMENT** Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be	**REQUIREMENT 11** **Test Control** **100 BASIC** 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

(j) Criterion 10 – Assessment / Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	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 acceptance criteria shall be evaluated. Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated. **SUPPLEMENT 11S-1** **TEST CONTROL** **1 GENERAL** This Supplement provides amplified requirements for test control. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 TEST REQUIREMENTS** Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents. **3 TEST PROCEDURES** Tests procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable Calibrated instrumentation, appropriate equipment,	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, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, operational tests, and computer program tests such as 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: calibrated instrumentation,

	trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work. **4 TEST RESULTS** Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. **5 TEST RECORDS** Test records shall, as a minimum, identify (a) through (g) below: (a) item tested (b) date of test (c) tester or data recorder (d) type of observation (e) results and acceptability (I) action taken in connection with any deviations noted (g) person evaluating test results **SUPPLEMENT 11S - 2** **COMPUTER PROGRAM TESTING** **1 GENERAL** This Supplement provides amplified requirements for testing of computer programs and associated computer systems. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic	appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. (b) As an alternative to para. 300(a) above, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. **400 COMPUTER PROGRAM TEST PROCEDURES** The requirements of section 400 of Requirement 11 apply, instead of section 300, Test Procedures, to testing of computer programs, and as appropriate, the computer hardware and operating system. (a) Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces correct results. For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedure shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature. (b) In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

	Requirement when and to the extent specified by the organization invoking this Standard. **2 TEST REQUIREMENTS** Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents. **2.1 Verification Tests** Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows: (a) hand calculations; (b) calculations using comparable proven programs; or (c) empirical data and information from technical literature. For programs used for operational control, testing shall demonstrate required performance over the range of operation of the controlled function or process. Depending on the complexity of the computer program being tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test. Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.	**500 TEST RESULTS** Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization. **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.

	2.2 In-Use Tests Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Test problems shall be run whenever the computer program is installed on *a* different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance. **3 TEST PROCEDURES** Test procedures or plans shall specify the following, as applicable: (a) required tests and test sequence (b) required ranges of input parameters (c) identification of the stages at which testing is required (d) criteria for establishing test cases (e) requirements for testing logic branches (f) requirements for hardware integration (g) anticipated output values (h) acceptance criteria (i) reports, records, standard formatting, and conventions **4 TEST RESULTS** Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied. **5 TEST RECORDS** (a) Verification test records shall identify (1) through (10) below. (1) computer program tested (2) computer hardware used	

	(3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6)simulation models used, where applicable (7) test problems (8) results and acceptability (9) action taken in connection with any deviations noted (10) person evaluating test results (b)In-use test results shall identify (1) through (6) below. (1) computer program tested (2) computer hardware used (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) acceptability	
(e) Criterion 5 – Performance / Work Processes (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection. **(h) Criterion 8 – Performance / Inspection and Acceptance Testing**	**12 CONTROL OF MEASURING AND TEST EQUIPMENT** **BASIC REQUIREMENT** Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits. **SUPPLEMENT 12S-1** **CONTROL OF MEASURING AND TEST EQUIPMENT** **1 GENERAL** This Supplement provides amplified requirements for control of measuring and test equipment. It supplements the requirements of Basic Requirement 12 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	**REQUIREMENT 12** **Control of Measuring and Test Equipment** **100 BASIC** Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits. **200 SELECTION** Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. **300 CALIBRATION AND CONTROL** **301 Calibration** Measuring and test equipment shall be calibrated at prescribed time periods or usage and whenever the accuracy of the

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspection and tests.	**2 SELECTION** Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. **3 CALIBRATION AND CONTROL** **3.1 Calibration** Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented. **3.2 Control** The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect. **3.3 Commercial Devices** Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.	equipment is suspect. Calibration shall be against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented. **302 Control** Calibration procedures shall identify or reference required accuracy. Methods and frequency of checking accuracy shall be defined in procedures. The calibration method and interval of calibration for measuring and test equipment shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting capability. Out-of-calibration devices shall be tagged or segregated, or both, and not used until they have been recalibrated. Measuring or test equipment consistently found to be out of calibration shall be repaired or replaced. **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 shall be made and documented including the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. **302.2 Handling and Storage.** Measuring and test equipment shall be properly handled and stored to maintain accuracy. **302.3 Status Indication.** Equipment shall be suitably marked or otherwise identified to indicate calibration status. **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. **400 RECORDS** Records shall be established and maintained to indicate

	4 HANDLING AND STORAGE Measuring and test equipment shall be properly handled and stored to maintain accuracy. **5 RECORDS** Records shall be maintained and equipment shall be suitably marked to indicate calibration status.	calibration status and the capability of measuring and test equipment to satisfactorily perform their intended function.
(e) Criterion 5 – Performance / Work Processes (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration.	**13 HANDLING, STORAGE, AND SHIPPING** **BASIC REQUIREMENT** Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. **SUPPLEMENT 13S-1** **HANDLING, STORAGE, AND SHIPPING** **1 GENERAL** This Supplement provides amplified requirements for handling, storage, and shipping. It supplements the requirements of Basic Requirement 13 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 INSTRUCTION** Handling, storage, and shipping of items 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. **3 REQUIREMENTS** **3.1 General**	**REQUIREMENT 13** **Handling, Storage, and Shipping** **100 BASIC** 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

	When required for particular items, 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, provided, and their existence verified. **3.2 Procedures** When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. **3.3 Tools and Equipment** Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained. **3.4 Operators** Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment. **4 MARKING** Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.	controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested periodically or prior to use as necessary to ensure performance. **500 OPERATORS** Operators of special handling and lifting equipment shall be experienced or trained in 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.
(e) Criterion 5 – Performance / Work Processes (1) Perform work consistent with technical standards, administrative controls, and other hazard controls	**14 INSPECTION, TEST, AND OPERATING STATUS** **BASIC REQUIREMENT**	**REQUIREMENT 14** **Inspection, Test, and Operating Status** **100 BASIC** The status of inspection and test activities shall be identified

adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent their damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection. **(h) Criterion 8 – Performance / Inspection and Acceptance Testing** (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	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 assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained 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 shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained 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 shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
(e) Criterion 3 – Management / Quality Improvement (1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem. (4) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement. **(j) Criterion 10 – Assessment /**	**15 CONTROL OF NONCONFORMING ITEMS** **BASIC REQUIREMENT** 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. **SUPPLEMENT 15S-1** **CONTROL OF NONCONFORMING ITEMS** **1 GENERAL** This Supplement provides amplified requirements for the control of nonconforming items. It supplements the requirements of Basic Requirement 15 of this	**REQUIREMENT 15** **Control of Nonconforming Items** **100 BASIC** 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 not detrimental to the item, on either the item, the container, or the package containing the item. **300 SEGREGATION** (a) Nonconforming items shall be segregated, when practical,

Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 IDENTIFICATION** (a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable. (b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified. **3 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 preclude inadvertent use of a nonconforming item. **4 DISPOSITION** **4.1 Control** Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel. **4.2 Responsibility and Authority**	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 preclude 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 demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have 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 repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-

	The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. **4.3 Personnel** Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. **4.4 Disposition** The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented. Technical justification for the acceptability of a non-conforming item, dispositioned repair, or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation. **4.5 Repaired or Reworked Items** Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.	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. **MINOR CHANGE, revise QM,EP** **405 Reexamination** Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.
(e) Criterion 3 – Management / Quality Improvement (1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items, services, and processes that do not meet established	**16 CORRECTIVE ACTION** **BASIC REQUIREMENT** Conditions adverse to quality shall be identified promptly and corrected as soon as practical. 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	**REQUIREMENT 16** **Corrective Action** **100 BASIC** 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.

requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem. (4) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement. **(j) Criterion 10 – Assessment / Independent Assessment** (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.	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.
(d) Criterion 4 – Management/Documents and Records (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve and maintain records.	**17 QUALITY ASSURANCE RECORDS** **BASIC REQUIREMENT** Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and, responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented. **SUPPLEMENT 17S-1** **QUALITY ASSURANCE RECORDS**	**REQUIREMENT 17** **Quality Assurance Records** **100 BASIC** 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. Requirements and responsibilities for these activities shall be documented. The term records**,** used throughout this section, is to be interpreted as quality assurance records.

	1 GENERAL This Supplement provides amplified requirements for quality assurance records. It supplements the requirements of Basic Requirement 1 *7* of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard**.** The requirements of this Supplement apply to quality assurance records which have been completed. The term *records,* used throughout this Supplement, is to be interpreted as *Quality Assurance Records.* **2 RECORDS ADMINISTRATION** **2.1 Records System** A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the genera! requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. **2.2 Generation of Records** The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner. Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished. **2.3 Record Validation** Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the	**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. **300 AUTHENTICATION OF RECORDS** Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. **400 CLASSIFICATION** Records shall be classified as lifetime or nonpermanent by the Owner, or his agent when authorized, in accordance with the criteria given in paras. 401 and 402 of this requirement. **401 lifetime Records** **401.1** Lifetime records are those that meet one or more of the following criteria: (a) those which would be of significant value in demonstrating capability for safe operation; (b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; (c) those which would be of significant value in determining the cause of an accident or malfunction of an item; (d) those which provide required baseline data for in-service inspections. **401.2** Lifetime records are required to be maintained by or for the plant Owner for the life of particular item while it is installed in the plant or stored for future use.

	form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies. **2.4 Index** The records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system. **2.5 Distribution** The records shall be distributed, handled, and controlled in accordance with written procedures. **2.6 Identification** Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activities to which it applies. **2.7 Classification** Records shall be classified as *Lifetime* or *Nonper*manent by the Owner, or his agent when authorized, in accordance with the criteria given in paras. 2.7.1 and 2.7.2 below. 2.7.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria: (a) those which would be of significant value in demonstrating capability for safe operation; (b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; **(**c) those which would be of significant value in determining the cause of an accident or malfunction of an item; (d) those which provide required baseline data for in-	**402 Nonpermanent Records** Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. **500 RECEIPT CONTROL AND RETENTION OF RECORDS** Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing. 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 a system of receipt control of records for permanent and temporary storage. **600 STORAGE** (a) Records shall be stored in facilities, containers, : or a combination thereof, constructed and maintained in a manner which minimizes the risk of dam- age or destruction from the following: (1) natural disasters such as winds, floods, or (2) environmental conditions such as high and (3) infestation of insects, mold, or rodents. (b) 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. **700 DISPOSITION** (a) Record retention periods shall be documented.

	service inspections. Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. 2.7.2 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. **2.8 Retention of Records** Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing. **2.9 Corrected Information in Records** Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction. **3 RECEIPT** **3.1 Responsibility** The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession. **3.2 Receipt Control** 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 a system of receipt control of records for permanent and temporary storage.	(b) Records shall be maintained for their retention periods. **800 MAINTENANCE OF RECORDS** (a) Records shall be protected from damage or loss (b) Records shall be retrievable. (c) The methods for record changes shall be documented. (d) Provisions shall be 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.

	As a minimum, a receipt control system shall include the following: (a) a method for designating the required records; (b) a method for identifying records received; (c) procedures for receipt and inspection of incoming records; (d) a method for submittal of completed records to the storage facility without unnecessary delay. **3.3 Status** Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process. **4 STORAGE, PRESERVATION, AND SAFEKEEPING** **4.1 Storage** The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below: (a) a description of the storage facility; (b) the filing system to be used; (c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible; (d) a method of verifying that the records are those designated (see para. 3.2 above); (e) the rules governing access to and control of the files; (f) a method for maintaining control of and accountability for records removed from the storage facility; (g) a method for filing supplemental information (see para. 2.9 above) and disposing of superseded records.	**MINOR CHANGE not in 2000 but still in 0333P . no change to implementing documents.**

	4.2 Preservation Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the requirements of (a) through (c) below shall apply. (a) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure. (b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. (c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. **4.3 Safekeeping** Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records. **4.4 Storage Facilities** Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: (a) natural disasters such as winds, floods, or fires; (b) environmental conditions such as high and low temperatures and humidity; (c) infestation of insects, mold, or rodents. There are two satisfactory methods of providing storage facilities, single or dual. **4.4.1 Single Storage Facility.** Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below:	

	(a) reinforced concrete, concrete block, masonry, or equal construction; (b) floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included. (c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating; (d) sealant applied over walls as a moisture or condensation barrier; (e) surface sealant on floor providing a hard wear surface to minimize concrete dusting, (f) foundation sealant and provisions for drainage; (g) forced air circulation with filter system; (h) fire protection system; (i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/ humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating, The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. If the storage facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria. **4.4.2 Alternate Single Storage Facility.** The following are acceptable alternatives to the criteria of para. 4.4.1 above for a single storage facility: (a) 2 hr fire rated vault meeting NFPA 232-1986 or NFPA 232AM-1 986 or both;' (b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both;' or (c) 2 hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1 986 or both' with the following additional provisions: (1) early warning fire detection and automatic fire suppression capability with electronic supervision at a	

	constantly attended central station; (2) records storage in fully enclosed metal cabinets; (3)adequate access and aisle ways; (4) prohibition in the room of work not directly associated with record storage or retrieval; (5)prohibition in the room of smoking, eating, or drinking; (6) 2 hr fire rated dampers or doors in all boundary penetrations. **4.4.3 Temporary Storage.** When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1 hr fire rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1 hr fire protection or be certified by a person competent in the technical field of fire protection. **4.4.4 Dual Storage Facilities.** If dual storage facilities for each record are provided, the storage facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each storage facility is not required to satisfy the requirements of either para. 4.4.1, or para. 4.4.2 above, but shall meet the other requirements of this Standard, **5 RETRIEVAL** Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the files. Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner. **6 DISPOSITION**	

	Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard. Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition. The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied: (a) items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed; (b) regulatory requirements are satisfied; (c) operational status permits; (d) warranty consideration is satisfied; (e) Purchaser's requirements are satisfied.	
(j) Criterion 10 – Assessment / Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	**18 AUDITS** **BASIC REQUIREMENT** Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness. 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. **SUPPLEMENT 18S-1** **AUD1TS** **1 GENERAL**	**REQUIREMENT 18** **Audits** **100 BASIC** Audits shall be performed 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 organization coverage and coordination with ongoing activities based on the status and importance of the activity. Scheduled audits shall be

	This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 SCHEDULING** Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. **3 PREPARATION** **3.1 Audit Plan** The auditing organization shall develop and document 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. **3.2 Personnel** The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	supplemented by additional audits of specific subjects when necessary to provide adequate coverage. **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. **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. **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** **MINOR CHANGE no change to implementers** 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;

	3.3 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 and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit. **4 PERFORMANCE** Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall **be continued** at intervals consistent with the schedule for accomplishing the activity. Elements that have been 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. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. **5 REPORTING** The audit report shall be signed by the audit team leader and issued, and it shall include the following information, as appropriate: (a) description of the audit scope; (b) identification of the auditors; (c) identification of persons contacted during audit activities; (d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.	(b) identify Auditors and persons contacted; (c) summarize audit results, including a statement of the effectiveness of the elements audited; and (d) describe each reported adverse audit finding. Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action. **600 RESPONSE** Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of 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. **MINOR CHANGE, some of the 1989 words are not in 2000. No change to implementing documents.**

	6 RESPONSE Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization. **7 FOLLOW-UP ACTION** Follow-up action shall be taken to verify that corrective action is accomplished as scheduled. **8 RECORDS** Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.	

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