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| **NQA-1 Requirement 1** |
| REQ. 1 200  Verify that:  1) The organizational structure and responsibility assignments are such that:  (a) senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result;  **Objective Evidence:**  **SATISFACTORY:** |
| **NQA-1 Requirement 2**  **REQ 2 400**  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  (b) test results, where applicable  (c) capability demonstration results; training  (5) results of periodic evaluation;  (6) results of physical examinations, when required  (7) signature of employer’s designated representative  (8) date of certification or recertification and certification expiration.  The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. 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.  **Objective Evidence:** |
| **NQA-1 Requirement 3**  REQ 3 601  Verify that:  1) Procedures implementing configuration management requirements are established and documented at the earliest practical time prior to facility operation. These procedures 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.  2) Configuration management requirements include measures to ensure changes that may affect the approved configuration are recognized and processed.  3) The configuration is established and approved at the earliest practical time prior to initial operation of the facility and maintained for the life of the facility.  4) The configuration includes, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.  5) Interface controls include the integration of activities of organizations that can affect the approved configuration.  6) Documentation identifies the design bases and the approved configuration for the approved modes of operation.  7) Measures are established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases.  8) The implementation sequence for approved configuration changes are reviewed to determine that the configuration conforms to the design bases.  9) Approval by the design authority is required prior to implementation of a change to the design bases.  10) The configuration of the facility is 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 takes into account the use of the document and the need for revision in support of operation.  Objective Evidence: |
| **NQA-1 Requirement 4**  **REQ 4 300**  Verify that:   1. A review of the procurement documents, and changes thereto, is 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 QA program changes made as a result of bid evaluations or negotiations are incorporated into the procurement documents prior to their issuance to the Supplier. Procurement document review is performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.   **Objective Evidence:** |
| **NQA-1 Requirement 7**  REQ 7 500  Verify that:  2) the Purchaser methods used to accept an item or service from a Supplier are a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the nuclear facility site, or a combination of these methods.  3) when a Certificate of Conformance is used (a) through (f) are met:  (a) identification of purchased material/equip., such as by purchase order number  (b) identification of procurement req. met, such as codes/standards.  (c) identification of procurement req. not met, along with an explanation of resolution.  (d) signed/authenticated by resp. QA function  (e) procedures to be followed for completing and approving the certificate shall be documented  (f) validity of certificates and effectiveness of certification system shall be verified.  4) Post installation testing is not applicable.  **Objective Evidence:** |
| **NQA-1 Requirement 10**  REQ 10 200  Verify that inspection requirements and acceptance criteria include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.  REQ 10 300  Verify that 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 are indicated in appropriate documents. Consent to waive specified hold points is recorded prior to continuation of work beyond the designated hold point.  REQ 10 500  Verify that inspection of items under construction or otherwise in process are 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 is provided. Process monitoring is performed by qualified personnel or qualified automated means. Both inspection and process monitoring is provided when control is inadequate without both.  REQ 10 600  Verify that:  3) any modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or retest, as appropriate, to verify acceptability.  4) the acceptance of the item is approved by authorized personnel.  **Objective Evidence:** |
| **NQA-1 Requirement 11**  REQ. 11 Para 200  a) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled.  Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.  (b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.  (c) If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test  (d) Test requirements and acceptance criteria for computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:  (1) Software design verification testing shall demonstrate the capability of the computer  program(s) to provide valid results for test problems encompassing the range of documented permitted usage.  (2) Computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.  (3) In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.  REQ. 11 Para 400  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 procedures 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.  (c) Test procedures or plans shall specify the following, as applicable:  (1) required tests and test sequence  (2) required ranges of input parameters  (3) identification of the stages at which testing is required  (4) criteria for establishing test cases  (5) requirements for testing logic branches (6) requirements for hardware integration (7) anticipated output values  (8) acceptance criteria  (9) reports, records, standard formatting, and conventions  **Objective Evidence:** |
| **NQA-1 Requirement 12**  Req12 100  Verify that tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.  Req12 200  Verify that selection of measuring and test equipment is based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.  Req12 300  Verify that:  3) Calibration procedures identify or reference required accuracy. Methods and frequency of checking accuracy are defined in procedures. The calibration method and interval of calibration for M&TE are defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting capability, Out-of-calibration devices are tagged or segregated, or both, and not used until they have been recalibrated. M&TE consistently found to be out of calibration is repaired or replaced.  4) M&TE is traceable to its application and use.  6) M&TE is properly handled and stored to maintain accuracy.  **Objective Evidence:** |
| **NQA-1 Requirement 13**  REQ 13 100  Verify that handling, storage, cleaning, packaging, shipping, and preservation of items is controlled to prevent damage or loss and to minimize deterioration. These activities are 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.  REQ 13 200  Verify that, 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) are specified and provided and their existence verified.  REQ 13 300  Verify that, when required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation are used.  REQ 13 400  Verify that special handling tools and equipment are utilized and controlled, where necessary, to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use.  REQ 13 500  Verify that operators of special handling and lifting equipment are experienced or trained in use of the equipment.  **Objective Evidence:** |
| **NQA-1 Requirement 15**  **REQ 15 200**  Verify that nonconforming **items are 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.  **REQ 15 300**  Verify that:  (a) nonconforming items are 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 are employed to preclude inadvertent use of a nonconforming item.**  **REQ 15 400**  Verify that:  1) nonconforming items are evaluated and recommended dispositions are proposed. Further processing, delivery, installation, or use of a nonconforming item is controlled pending the evaluation and an approved disposition by authorized personnel.  2) 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.  3) personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information.  4) a disposition, (use-as-is, reject, repair, or rework) of nonconforming items is made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is is documented. Nonconformances to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those applied to the original design. Required as-built records reflect the use-as-is or repair condition.  5) reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria; repaired items are reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.  **Objective Evidence:** |
| **NQA-1 Requirement 17**  **REQ 17 300**  Verify that:  (a**)** documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents are reviewed and approved by the responsible individual from the originating or authorized organization.  (b) electronic documents are authenticated with comparable information as the above, as appropriate:  (1) with identification on the media, or  (2) with authentication information contained within or linked to the document itself.  **REQ 17 500**  Verify that each organization responsible for the receipt of records designates a person or organization responsible for receiving the records. The designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage. Receipt controls provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.  **REQ 17 600**  Verify that:  2) There are two equally satisfactory methods of providing storage, single or dual:  (a) single storage consists of a storage facility, vault, room, or container with a minimum two-hour fire rating. The design and construction of a single storage facility; vault room, or container is reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.  (b) dual facilities, containers, or a combination thereof are at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements above, but are required to meet the requirements on the previous checklist page.  3) When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container provides a one-hour fire rating, unless dual storage requirements above are met.  **REQ 17 800**  Verify that:  (c) The methods for record changes are documented.  (d) provisions are established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.  (e) provisions are made to ensure that records remain retrievable after hardware, software, or technology changes.  f) provisions shall be established to assure the  following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:  (1) duplication or transfer is appropriately authorized;  (2) record content, legibility, and retrievability are maintained.  **Objective Evidence:** |
| **NQA-1 Requirement 18**  REQ 18 300  Verify that:  1) the auditing organization develops an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.  2) audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.  3) an audit team is identified prior to the beginning of each audit. This team contains one or more Auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team has experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.  REQ 18 500  Verify that the audit report is signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall:  (a) describe the audit scope  (b) identify Auditors and persons contacted  (c) summarize audit results, including a statement on the effectiveness of the elements audited  (d) describe each reported adverse audit finding  REQ 18 800  Verify that audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.  **Objective Evidence** |

**DOE O 414.1d Suspect/Counterfeit Items**

**Objective Evidence**