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| **NQA-1 Requirement 1** | **NIAC** | **GAP** |
| **REQ. 1 100**  Verify that:  1) Responsibilities for the establishment and implementation of the QA program are defined.  2) The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality are documented. | 1.A.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;**  (b) quality is achieved and maintained by those assigned responsibility for performing work;  (c) quality achievement is verified by those not directly responsible for performing the work;  (d) those responsible for assuring that an appropriate QA Program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include the following:  (1) identifying quality problems  (2) **initiating, recommending, or providing solutions to quality problems through designated channels**  (3) verifying implementation of solutions  (4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.  2) The individual(s) or organization(s) responsible for establishing and executing a QA program may delegate any or all of the work to others but shall retain responsibility therefore. | 1.A.1  1.A.2 | Does not adequately address  REQ 1 - 200 1) (a)  Does not adequately address  REQ 1 - 200 2) |
| **REQ. 1 300**  Verify that:  1) 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.  2) The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented. |  | Does not adequately address  REQ 1 - 300 1) 2) |

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| **NQA-1 Requirement 2** | **NIAC** | **GAP** |
| **REQ 2 100**  Verify that:  (a) A documented quality QA has been planned, implemented, and maintained. The program shall identify the activities and items to which it applies; provide control over activities affecting quality to an extent consistent with their importance; include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily; and 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 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 QA program.  Verify that:  1) Indoctrination and training is commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.  2) Personnel performing or managing activities affecting quality receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments, company procedures, and QA program requirements.  3) The need for a formal training program for personnel performing or managing activities affecting quality is determined. Training is provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training is used if direct hands-on applications or experience is needed to achieve and maintain proficiency. | 1.A.1  1.A.2  1.A.3  1.E.1 |  |
| **REQ 2 300**  Verify that:  1) The responsible organization designates those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization establishes 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.  2) For NDE personnel ASNT Rec. Practice No. SNT-TC-1 A, December 1988 Edition, and its applicable Supplements apply.  3) For inspection and test personnel the initial capabilities of a candidate are 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 least every 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200. If 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.  The Lead Auditor (LA) organizes and directs audits, reports audit findings, and evaluates corrective action. Verify that prior to being designated a LA that the candidate:  1) is **capable of communicating effectively, both in writing and orally and that these skills** are attested to in writing by the LA’s employer.  2) receives training to the extent necessary to assure auditing competence including:  (a) Knowledge and understanding of standards, regulations, and regulatory guides.  (b) General structure of QA programs as a whole and applicable elements.  (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. | 1.E.1  1.E.2 | SNT-TC-1  Has note for additional checklist  Does not adequately address  REQ 2 - 300 1) |

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| **NQA-1 Requirement 2** | **NIAC** | **GAP** |
| **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. | 1.E.1  1.E.2 | Does not adequately address  REQ 2 - 400 (1) thru (8) |
| **REQ 2 500**  Verify that:  1) records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.  2) records of indoctrination and training include one or more of the following:  (a) attendance sheets  (b) training logs  (c) personnel training records  The employer establishes and maintains records for indoctrination and training. Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification. |  | Does not adequately address REQ 2 - 500 1) and 2) |

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| **NQA-1 Requirement 3** | **NIAC** | **GAP** |
| **REQ 3 100**  Verify that design is defined, controlled, and verified. Design inputs are specified on a timely basis and translated into design documents. Design interfaces are identified and controlled. Design adequacy is verified by individuals other than those who designed the item or computer program. Design changes are governed by control measures commensurate with those applied to the original design. | 2.1  2.2  2.5 |  |
| **REQ 3 200**  Verify that applicable design inputs are identified and documented, and their selection reviewed and approved. The design input is 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. | 2.1  2.2 |  |
| **REQ 3 300**  (a) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.  (b) The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.  (c) The final design shall  (1) be relatable to the design input by documentation in sufficient detail to permit design verification.  (2) specify required inspections and tests and include or reference appropriate acceptance criteria.  (3) identify assemblies and/ or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.  Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended safety 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 | 2.2  2.4  2.6 | Does not adequately address  REQ 3 - 300  (c) (2) (3) |
| REQ 3 400  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 Analyses  Documentation of design analyses shall include the following:  (a) the objective of the analyses  (b) design inputs and their sources  (c) results of literature searches or other applicable background data  (d) assumptions and indication of those assumptions that must be verified as the design proceeds  (e) identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of  the computer program to the specific physical problem  (f) review and approval | 9.1 |  |

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| **NQA-1 Requirement 3** | **NIAC** | **GAP** |
| REQ 3 500  Verify that:  1) The responsible design organization identifies and documents the design verification method used. The results of design verification are documented with the verifier clearly indicated. Design verification is performed by any competent individual or group other than those who performed the original design.  2) Design verification is performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met. In those cases, the unverified  portion of the design is identified and controlled. In all cases the design verification is completed prior to relying upon the item being designed.  3) If the design is modified to resolve verification findings, the modified design is verified prior to release for use.  4) The extent of the design verification is a function of importance to safety, complexity, degree of standardization, state of the art, and similarity with previously proved designs. Where the design has been subjected to a verification process the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, is verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features are considered. The original design and associated verification documentation is referenced in records of subsequent application of the design.  Verify that acceptable verification methods include any one or a combination of the following: design reviews, alternate calculations, and qualification testing.  1) Design reviews provide assurance that the final design is correct and satisfactory  by addressing, where applicable:  (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 re-verifications 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?  2) Alternate calculations 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 are also reviewed.  3) Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other means. When tests are being performed on models or mockups, scaling laws are established and verified. The results of model test work are subject to error analysis, where applicable, prior to use in the final design. | 2.4  2.6  2.7  2.1  2.2  2.4  2.6 |  |
| REQ 3 600  Verify that:  1) Changes to design inputs, final designs, field  changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design and on any analyses upon which the design is based. The evaluation includes facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. The design organization approving the change has demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.  2) When a design change is approved other than by revision to the affected design documents, measures are established to incorporate the change into these documents, where such incorporation is appropriate.  3) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure are reviewed and modified as necessary | 2.6  2.7 |  |
| **NQA-1 Requirement 3** | **NIAC** | **GAP** |
| 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. |  | Does not adequately address  REQ 3 - 600  1) – 10) |
| REQ 3 700  Verify that Design information transmitted across interfaces identifies the status of the design information or document provided and identifies 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 is confirmed promptly by a controlled document. | 2.5 |  |
| REQ 3 800  Verify that:  1) Software design requirements are identified and documented and their selection reviewed and approved. The software requirements identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.  2) The software design is documented and defines the computational sequence necessary to meet the software requirements. The documentation includes, as applicable,  numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements, or the computer program listings resulting from implementation of the software design.  3) The software design is translated into computer program(s) using the programming organization's or design organization's programming standards and conventions. | 9.1 |  |

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| **NQA-1 Requirement 3** | **NIAC** | **GAP** |
| 4) Software design verification is performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. This verification may be performed by the originator’s supervisor, provided:  (a) 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  (b) the supervisor is the only individual in the organization competent to perform the verification.  The results of verification are documented with the identification of the verifier indicated. Software verification methods include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, the degree of standardization, the similarity with previously proved software, and the importance to safety.  5) Computer program testing is performed and shall be in accordance with Requirement 11.  Verify that:  1) Software configuration management includes configuration identification, change control, and status control. Configuration items are maintained under configuration management until the software is retired.  2) A software baseline is established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline are added to the baseline. A baseline defines the most recently approved software configuration. A labeling system is implemented that:  (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.  3) Changes to software are formally documented. The documentation includes:  (a) a description of the change;  (b) the rationale for the change; and  (c) the identification of affected software baselines. The change is formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes are made to software baselines. Appropriate verification activities are performed for the change. The change is appropriately reflected in documentation and traceability of the change to the software design requirement is maintained. Appropriate acceptance testing shall be performed for the change.  4) The status of configuration items resulting from software design are maintained current. Configuration item changes are controlled until they are incorporated into the approved product baseline. The controls include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls provide for notification of this information to affected organizations. | 9.1 |  |
| REQ 3 900  Verify that:  Design documentation and records include  not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design. | 2.6 |  |
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| **NQA-1 Requirement 4** | **NIAC** | **GAP** |
| **REQ 4 100**  Verify that applicable design bases and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard. | 3.1 |  |
| **REQ 4 200**  Verify that:  1) Procurement documents issued at all tiers of procurement include provisions for the following, as deemed necessary by the Purchaser:  a) Procurement documents include a statement of the scope of work to be performed by the supplier.  b) Technical requirements are specified in the procurement documents. These requirements are 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 identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.**  c) QA program requirements are specified in the procurement documents. These requirements are consistent with importance and/or complexity of the item or service being procured. The procurement documents require the Supplier to incorporate appropriate QA  program requirements in subtier procurement documents.  d) The procurement documents provide for access to the Supplier's and subtier Supplier's facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others  authorized by the Purchaser.  e) The procurement documents identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal is also established. When the Purchaser requires the Supplier to maintain specific records, the retention times and disposition requirements are prescribed.  f) The procurement documents specify the  Purchaser's requirements for the Supplier's reporting of nonconformances.  g) The procurement documents specify the  Supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies | 3.1 | Does not adequately address  REQ 4 - 200 b) |
| **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. | 3.4  3.2 |  |
| **REQ 4 400**  Verify that Procurement document changes affecting the technical or QA program requirements are subject to the same degree of control as utilized in the preparation of the original documents. | 3.2 |  |

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| **NQA-1 Requirement 5** | **NIAC** | **GAP** |
| REQ. 5 Para 100  Verify that activities affecting quality and services are prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. The activity is described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions is determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience) | 4.1  6.1 |  |
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| **NQA-1 Requirement 6** | **NIAC** | **GAP** |
| **REQ. 6 Para 100**  Verify that the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings are controlled to assure that correct documents are being employed. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel. | 4.1 (f)  6.1 |  |
| **REQ. 6 Para 200**  Verify that the following controls are 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;  (d) the review of controlled documents for adequacy, completeness, and approval prior to distribution;  (e) a method to ensure the correct documents are being used. | 4.1  6.1 |  |
| **REQ. 6 Para 300**  Verify that:  1) Changes to documents, other than those defined as minor changes, are considered major changes and are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.  2) Minor changes to documents, such as inconsequential editorial corrections, do 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 are clearly delineated. | 4.1 (g) |  |

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| **NQA-1 Requirement 7** | **NIAC** | **GAP** |
| **REQ 7 100**  Verify that the procurement of items and services are controlled to assure conformance with specified requirements. Such control provides 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. | 3.1  3.4 |  |
| **REQ 7 200**  Verify that prior to award of a contract, the Purchaser shall evaluate the Supplier’s capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of (a) through (c) 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. | 3.4 |  |
| **REQ 7 300**  **Verify that if bids are solicited,** the bid evaluation includes 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 resolves or obtains commitments to resolve  unacceptable technical and quality assurance  conditions resulting from the bid evaluation. |  | Does not adequately address  REQ 7 - 300  Bid evaluation |
| **REQ 7 400**  Verify that controls are implemented to assure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. | 3.2  3.3 |  |
| REQ 7 500  Verify that:  1) prior to offering the item or service for acceptance, the Supplier verifies 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 is available  at the nuclear facility site prior to installation or use.  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.  1) 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. | 3.1  3.2 |  |

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| **NQA-1 Requirement 7** | **NIAC** | **GAP** |
| REQ 7 500  Verify that:  1) prior to offering the item or service for acceptance, the Supplier verifies 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 is available at the nuclear facility site prior to installation or use.  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.  2) when source verification is used, it is performed at intervals consistent with the importance and complexity of the item or service, and includes monitoring, witnessing, or observing selected activities. Source verification is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented  evidence of acceptance is furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.  3) when receiving inspection is used, purchased  items are inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection verifies by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection is coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished  prior to receiving inspection.  4) when post installation testing is used, post installation test requirements and acceptance documentation are mutually established by the Purchaser and Supplier.  Verify that 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 accepts 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 | 3.1  3.4 | Does not adequately address REQ 7 - 503 Certificate of Conformance (a) through (f). |
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| **NQA-1 Requirement 7** | **NIAC** | **GAP** |
| **REQ 7 600**  Verify that methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements include:  (a) evaluation of nonconforming items;  (b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals 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, are 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. | 3.1 |  |
| **REQ 7 700**  When Commercial Grade Items or services are utilized, the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply and are an acceptable alternative to sections 200 through 600 of this Requirement, except that Supplier evaluation and selection, where determined necessary by the Purchaser, shall be in accordance with section 200 of this Requirement. | 7.4 |  |

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| **NQA-1 Requirement 8** | **NIAC** | **GAP** |
| **REQ 8 100**  Verify that controls are established to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained. | 5.1 |  |
| **REQ 8 200**  Verify that:  1) items of production (batch, lot, component, part) are identified from the initial receipt and fabrication of items up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document.  2) physical identification is used to the maximum extent possible. Where **physical identification on the item is either impractical or insufficient,** physical separation, procedural control, or other appropriate means are employed. Identification markings are applied using materials and methods that provide a clear and legible identification and do not **degrade the function or service life of the item.** **Markings are transferred to each part of an identified item when subdivided** and are not obliterated or hidden by surface treatment or coating unless other means of identification are substituted. |  | Does adequately not address  REQ 8 - 200 |
| **REQ 8 300**  Verify that:  1) when codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program provides identification and traceability control.  2) items having limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired.  3) provisions are 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. |  | Does not adequately address  REQ 8 - 300  1) & 3) |

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| **NQA-1 Requirement 9** | **NIAC** | **GAP** |
| REQ 9 100  Verify special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements. | 6.2 |  |
| REQ 9 200  verify that:  1) special processes are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions include or reference procedure, personnel, and equipment qualification requirements. Conditions  necessary for accomplishment of the process are included. These conditions include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.  2) the requirements of applicable codes and standards, including acceptance criteria for the process, are specified or referenced in procedures or instructions.  3) for special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel,  procedures, or equipment are specified or  referenced in procedures or instructions. | 6.2  6.3  6.4  6.5 |  |
| REQ 9 300  Verify that the organization performing the special process adheres to the approved procedures and processes. | 6.1  6.2  6.3  6.4  6.5 |  |
| REQ 9 400  Verify that records are maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process. | 6.1  6.2  6.3  6.4  6.5 |  |

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| **NQA-1 Requirement 10** | **NIAC** | **GAP** |
| REQ 10 100  Verify that inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service are planned and executed. Characteristics subject to inspection and inspection methods are specified. Inspection results are documented. Inspection for acceptance is performed by qualified persons other than those who performed or directly supervised the work being inspected. | 7.1  7.2  7.3  7.4  1.E.2 |  |
| 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. |  | Does not adequately address  REQ 10 - 200 |
| 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. |  | Does not adequately address  REQ 10 - 300 |
| REQ 10 400  Verify that:  1) characteristics to be inspected, methods of inspection, and acceptance criteria are identified during the inspection planning process.  2) sampling procedures, when used, are based upon standard statistical methods with engineering approval. | 7.1  7.3  7.4  7.5 |  |
| 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. |  | Does not adequately address  REQ 10 500 |
| REQ 10 600  Verify that:  1) final inspections include a records review of the results and resolution of nonconformances identified by prior inspections.  2) completed items are inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.  3) any modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or retest, as appropriate, to verify acceptabiIity.  4) the acceptance of the item is approved by authorized personnel. |  | Does not adequately address  REQ 10 600 |
| REQ 10 700  Verify that periodic inspections (e.g., in service inspections) or surveillance of structures, systems, or components are planned and executed to assure the continued performance of their required functions. | 7.1 |  |
| REQ 10 800  Verify that appropriate records are established, maintained and, as a minimum, identify the following:  (a) item inspected  (b) date of inspection;  (c) inspector;  (d) type of observation;  (e) results or acceptability; and  (f) reference to information on action taken in  connection with nonconformances. | 7.3 |  |

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| **NQA-1 Requirement 11** | **NIAC** | **GAP** |
| REQ. 11 Para 100  Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated. | 7.2 |  |
| 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. |  | Does not adequately address  REQ 11 200 |
| REQ. 11 Para 300  (a) Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include the following, as applicable:  (1) calibrated instrumentation (2) appropriate equipment  (3) trained personnel  (4) condition of test equipment and the item to be tested  (5) suitable environmental conditions (6) provisions for data acquisition  (b) As an alternative to para. 300(a) of this (08) Requirement, appropriate sections of related documents,  such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented  with appropriate criteria from para. 300(a) to assure adequate procedures for the test are used. | 7.2 |  |
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| **NQA-1 Requirement 11** | **NIAC** | **GAP** |
| 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 |  | Does not adequately address  REQ 11 400 |
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| **NQA-1 Requirement 12** | **NIAC** | **GAP** |
| **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**. | 8.2 | Does not adequately address  REQ 12 100 |
| **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.** | 8.1 | Does not adequately address  REQ 12 200 |
| **Req12 300**  Verify that:  1) measuring and test equipment (M&TE) is calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect. Calibration is against and traceable to certified equipment or references standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no nationally recognized standards exist, the basis for calibration is defined.  2) reference standards have a minimum accuracy four times greater than that of the M&TE being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. where 4:1 ratio cannot be maintained, the basis for selection of the standard in question is technically justified.  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.**  5) when M&TE is lost, damaged, or found to be out of calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested are evaluated. This evaluation is from at least the last acceptable calibration of the M&TE. The evaluation and the resulting actions are commensurate with the significance of the condition.  6) **M&TE is properly handled and stored to maintain accuracy.**  7) M&TE is used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.  8) M&TE and reference standards submitted for calibration are checked and the results recorded before any required adjustments or repairs are made.  9) M&TE is suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.  10) Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy. | 8.1  8.2  8.3  8.1  8.3  8.3  8.1  8.2 | Does not adequately address  REQ 12 300  3) 4) 6) |
| **Req 12 400**  Verify that:  1) records are established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform their intended function.  2) calibration reports and certificates reporting the results of calibrations include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. | 8.2  8.3 |  |
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| **NQA-1 Requirement 13** | **NIAC** | **GAP** |
| **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. | 5.3 | Does not fully address  REQ 13 100 |
| **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. |  | Does not adequately address  REQ 13 200 |
| **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. |  | Does not adequately address  REQ 13 300 |
| **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. |  | Does not adequately address  REQ 13 400 |
| **REQ 13 500**  Verify that **operators of special handling and lifting equipment are experienced or trained in** use of the equipment. |  | Does not adequately address  REQ 13 500 |
| **REQ 13 600**  Verify that marking or labeling is utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls. | 5.1  5.2  5.3 |  |

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| **NQA-1 Requirement 14** | **NIAC** | **GAP** |
| **REQ 14 100**  Verify that the status of inspection and test activities is 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 is 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 is specified. Status indicators 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. | 5.2 |  |
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| **NQA-1 Requirement 15** | **NIAC** | **GAP** |
| **REQ 15 100**  Verify that items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of non conforming items, and for notification to affected organizations | 1.B.1  1.D |  |
| **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. |  | Does not adequately address  REQ 15 200 |
| **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. | 1.B.1 |  |
| **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. | 1.B.2  1.D | Does not adequately address  REQ 15 400 4) |
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| **NQA-1 Requirement 16** | **NIAC** | **GAP** |
| **REQ 16 100**  Verify that conditions adverse to quality are identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management. Completion of corrective action is verified. | 1D |  |
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| **NQA-1 Requirement 17** | **NIAC** | **GAP** |
| **REQ 17 100**  Verify that the control of quality assurance records is established consistently with the schedule for accomplishing work activities. Quality assurance records furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records are identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities are documented. | 1.F.1 |  |
| **REQ 17 200**  Verify that:  (a) records are legible.  (b) records are traceable to associated items and activities and accurately reflect the work accomplished or information required.  (c) records to be generated, supplied, or maintained are specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures. | 1.F.2 |  |
| **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. | 1.F.1  1.F.2 | Does not adequately address  REQ 17 300 a) |
| **REQ 17 400**  Verify that records are classified as lifetime or non-permanent and maintained by the Owner, or authorized agent, as follows:  1) Lifetime records are those that meet one  (a) those which would be of significant value in  or more of the following criteria: 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.  2) Lifetime records are maintained  by or for the Owner for the life of the  particular item while it is installed in the plant or stored for future use.  3) Non-permanent 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. Non-permanent records are maintained for the identified retention period. | 1.F.1 |  |
| **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. |  | Does not adequately address  REQ 17 500 |
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| **NQA-1 Requirement 17** | **NIAC** | **GAP** |
| **REQ 17 600**  Verify that:  1)  (a) records are stored at a predetermined location in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from:  (1) natural disasters such as winds, floods, or  fires;  (2) environmental conditions such as high and  low temperatures and humidity;  (3) infestation of insects, mold, or rodents;  (4) dust or airborne particles  (b) activities detrimental to the records are prohibited in the storage area.  (c) access to the processing, storage, and retrieval of records is limited to authorized personnel.  (d) provisions are made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.  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.** | 1.F.2 | Does not adequately address  REQ 17 600  2) 3) |
| REQ 17 700  Verify that:  (a) record retention periods are documented.  (b) records are maintained for their retention periods. | 1.F.2 |  |
| **REQ 17 800**  Verify that:  (a) records are protected from damage or loss.  (b) record controls provide for retrievability within planned retrieval times based upon the record type or content.  (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. | 1.F.2 | Does not adequately address  REQ 17 800  c) thru f) |

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| **NQA-1 Requirement 18** | **NIAC** | **GAP** |
| REQ 18 100  Verify that audits are performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met and to determine the effectiveness of the program. These audits are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and reported to and reviewed by responsible management. Follow-up action is taken where indicated. | 1.C |  |
| REQ 18 200  Verify that audits are scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits are supplemented by additional audits of specific subjects when necessary to provide adequate coverage. | 1.C |  |
| 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. | 1.C | Does not adequately address  REQ 18 300  1) 2) 3) |
| REQ 18 400  Verify that elements selected for audit are evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization. |  | Does not adequately address  REQ 18 400 |
| 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 |  | Does not adequately address  REQ 18 500 |
| REQ 18 600  Verify that management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notifies the appropriate organization in writing of action taken or planned. Audit responses are evaluated by or for the auditing organization. |  | Does not adequately address  REQ 18 600 |
| REQ 18 700  Verify that follow-up action is taken to verify that corrective action is accomplished as scheduled. |  | Does not adequately address  REQ 18 700 |
| REQ 18 800  Verify that audit records include audit plans, audit reports, written replies, and the record of completion of corrective action. |  | Does not adequately address  REQ 18 800 |