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|  | **NQA-1 2008/2009 Part II, Subpart 2.7** | **NQA-1 2017 Part II, Subpart 2.7** |
| **DOE O 414.1D Attachment 4, First Paragraph****This attachment provides information and/or requirements associated with DOE O 414.1D and is applicable to contracts in which the associated CRD (Attachment 1) is inserted.****DOE O 414.1D Attachment 4, 1- Purpose, bullet a.****a. Prescribe the safety software quality assurance (SSQA) requirements for DOE nuclear facilities.****DOE O 414.1D Attachment 4, 1- Purpose, bullet b.****b. Software, other than safety software as defined in this Order, is not subject to requirements in this Attachment1.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, sentences 1, 2 and 3.****Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(a).****Management of safety software must include the following elements.****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****(a) Software project management and quality planning** | **Part II, Subpart 2.7, 100, GeneralSubpart 2.7 provides requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of this Subpart shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities.Subpart 2.7 supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking the Subpart.** | **Part II, Subpart 2.7, 100, General** **This Subpart provides requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of this****Subpart shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities. This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking the Subpart.1** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (1).****Management of safety software must include the following elements.****(1) Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(d).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(d) Procurement and supplier management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(e).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(e) Software requirements identification and management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation** | **Part II, Subpart 2.7, 101, Software EngineeringThe scope of software engineering activities include the following elements, as appropriate: (a) software acquisition method(s) for controlling the acquisition process for software and software services (b) software engineering method(s) used to manage the software life-cycle activities (c) application of standards, conventions, and other work practices that support the software life cycle (d) controls for support software used to develop, operate, and maintain computer programs.** | **Part II, Subpart 2.7, 101, Software Engineering The scope of software engineering activities includes the following elements, as appropriate:*(a)* software acquisition method(s) for controlling the acquisition process for software and software services *(b)* software engineering method(s) used to manage the software life-cycle activities*(c)* application of standards, conventions, and other work practices that support the software life cycle *(d)* controls for support software used to develop, operate, and maintain computer programs.** |
|  | **Part II, Subpart 2.7, 200, General RequirementsThe following general requirements shall be applied to the software engineering elements described in paragraph 101 of this Subpart.** | **Part II, Subpart 2.7, 200, General Requirements** **The following general requirements shall be applied to the software engineering elements described in para. 101 of this Subpart.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(b).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(b) Software risk management** | **Part II, Subpart 2.7, 201, DocumentationThe appropriate software engineering elements, described in paragraph 101 of this Subpart, shall define the baseline documents that are to be maintained as records, in accordance with Part I, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents.** | **Part II, Subpart 2.7, 201, Documentation and Records The appropriate software engineering elements, described in paragraph 101 of this Subpart, shall define the baseline documents that are to be maintained as records, in accordance with Part I, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents.****Note: Title change but no content changed.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (1).****Management of safety software must include the following elements.****(1) Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(g).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(g) Software safety analysis and safety design methods** | **Part II, Subpart 2.7, 202, ReviewThe appropriate software engineering elements, described in paragraph 101 of this Subpart, shall define the control points and associated reviews. Reviews of software shall ensure compliance with the approved software design requirements. Although multiple review requirements are specified within this Subpart, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method. The following two reviews are required: (a) One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification. (b) The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review. Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle. Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.** | **Part II, Subpart 2.7, 202, Verification The appropriate software engineering elements, described in paragraph 101 of this Subpart, shall define the control points and associated reviews. Reviews of software shall ensure compliance with the approved software design requirements. Although multiple review requirements are specified within this Subpart, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method. The following two reviews are required: (a) One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification. (b) The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review. Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle. Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.****Note: Title change but no content changed.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (1).****Management of safety software must include the following elements.****(1) Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(c).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(c) Software configuration management** | **Part II, Subpart 2.7, 203, Software Configuration ManagementIn addition to the requirements of Part I, Requirement 3, software configuration management activities shall include the following: (a) The appropriate software engineering elements, described in paragraph 101 of this Subpart, shall identify when configuration baselines are to be established. Configuration items to be controlled shall include, as appropriate: (1) documentation (e.g., software design requirements, instructions for computer program use, test plans, and results) (2) computer program(s) (e.g., source, object, backup files) (3) support software (b) The software configuration change control process shall include (1) initiation, evaluation, and disposition of a change request (2) control and approval of changes prior to implementation (3) requirements for retesting (e.g. Regression testing) and acceptance of the test results** | **Part II, Subpart 2.7, 203, Software Configuration Management Software configuration management includes, but is not limited to, configuration identification, change control, and configuration status control. Configuration items shall be maintained under configuration management until the software is retired. The appropriate software engineering elements, described in para. 101 of this Subpart, shall identify when configuration baselines are to be established.****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 802** |
|  |  | **Part II, Subpart 2.7, 203.1, Configuration Identification A labeling system for configuration items shall be implemented that** ***(a)* uniquely identifies each configuration item** ***(b)* identifies changes to configuration items by revision** ***(c)* provides the ability to uniquely identify each configuration of the revised software available for use.****Note: New addition to Section 203 but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 802.1, 2nd paragraph.** |
|  |  | **Part II, Subpart 2.7, 203.2, Configuration Change Control*****(a)* The software configuration change control process shall include*****(1)* initiation, evaluation, and disposition of a change request*****(2)* control and approval of changes prior to implementation*****(3)* requirements for retesting (e.g., regression testing) and acceptance of the test results*****(b)* A software baseline shall be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recently approved software configuration. Configuration items to be controlled as part of the baseline shall include, as appropriate*****(1)* documentation (e.g., software design requirements, instructions for computer program use, test plans, and results)*****(2)* computer program(s) (e.g., source, object, backup files)*****(3)* support software*****(c)* Changes to software shall be formally documented. The documentation shall include*****(1)* a description of the change*****(2)* the rationale for the change*****(3)* the identification of affected software baselines****The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in documentation, and traceability of the change to the software design requirement shall be maintained. Appropriate acceptance testing shall be performed for the change.****Note: New addition to Section 203 but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 802.1 and 802.2 and/or Part II, Subpart 2.7, 203, Software Configuration Management** |
|  |  | **Part II, Subpart 2.7, 203.3, Configuration Status Control****The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved but not implemented. The controls shall also provide for notification of this information to affected organizations.****Note: New addition to Section 203 but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 802.3** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(i).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(i) Problem reporting and corrective action** | **Part II, Subpart 2.7, 204, Problem Reporting and Corrective Action(a) Method(s) for documenting, evaluating, and correcting software problems shall (1) describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake) (2) define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation (b) When the problem is determined to be an error, the method shall provide, as appropriate, for (1) how the error relates to appropriate software engineering elements (2) how the error impacts past and present use of the computer program (3) how the corrective action impacts previous development activities (4) how the users are notified of the identified error, its impact; and how to avoid the error, pending implementation of corrective actions The problem reporting and corrective action process shall address the appropriate requirements of Part I, Requirement 16.** | **Part II, Subpart 2.7, 204, Problem Reporting and Corrective Action(a) Method(s) for documenting, evaluating, and correcting software problems shall (1) describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake) (2) define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation (b) When the problem is determined to be an error, the method shall provide, as appropriate, for (1) how the error relates to appropriate software engineering elements (2) how the error impacts past and present use of the computer program (3) how the corrective action impacts previous development activities (4) how the users are notified of the identified error, its impact; and how to avoid the error, pending implementation of corrective actions The problem reporting and corrective action process shall address the appropriate requirements of Part I, Requirement 16.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(d).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(d) Procurement and supplier management** | **Part II, Subpart 2.7, 300, Software AcquisitionSoftware acquisition includes software or software services procured in accordance with Part I, or otherwise acquired for use in activities within the scope of Part I.** | **Part II, Subpart 2.7, 300, Software AcquisitionSoftware acquisition includes software or software services procured in accordance with Part I, or otherwise acquired for use in activities within the scope of Part I.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(d).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(d) Procurement and supplier management** | **Part II, Subpart 2.7, 301, Procured Software and Software ServicesPart I, Requirements 4 and 7 for items and services shall be applied to the procurement of software and software services. The Purchaser shall be responsible for the appropriate requirements of this Subpart upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for Supplier’s reporting of software errors to the Purchaser and, as appropriate, the Purchaser’s reporting of software errors to the Supplier** | **Part II, Subpart 2.7, 301, Procured Software and Software ServicesPart I, Requirements 4 and 7 for items and services shall be applied to the procurement of software and software services. The Purchaser shall be responsible for the appropriate requirements of this Subpart upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for Supplier’s reporting of software errors to the Purchaser and, as appropriate, the Purchaser’s reporting of software errors to the Supplier** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(d).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(d) Procurement and supplier management** | **Part II, Subpart 2.7, 302, Otherwise Acquired SoftwarePart I, Requirement 7, and Part II, Subpart 2.14,Quality Assurance Requirements for Commercial Grade Items and Services, shall be applied to the acquisition software that has not been previously approved under a program consistent with this Standard for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software). The acquired software shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following: (a) identification of the capabilities and limitations for intended use as critical characteristics (b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations (c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities The dedication process shall be documented and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of accepted software received from organizations not required to follow this Subpart shall be dedicated in accordance with this section.** | **Part II, Subpart 2.7, 302, Otherwise Acquired Software****Part I, Requirement 7, and Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall be applied to acquired software that has not been previously approved under a program consistent with Part I of this Standard for use in its intended application. This includes computer programs not obtained using the procurement requirements of Part I, such as freeware, shareware, and computer programs from corporate repositories. Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in Part I, Requirement 3, para. 401 are excluded from the requirements of Part II, Subpart 2.14.****Otherwise acquired computer programs shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:*****(a)* identification of the capabilities and limitations for intended use as critical characteristics*****(b)* utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations*****(c)* instructions for use (e.g., user manual) within the limits of the dedicated capabilities****The dedication process documentation and associated computer program(s) shall establish the current baseline.****Subsequent revisions of the software shall be dedicated in accordance with this section.****Note: Yellow highlighted area is partially addressed by the 2008/1a-2009 Part II, Subpart 2.7, Paragraph 302 except for examples used in the 2017 edition.****Yellow highlighted red text is basically addressed in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 401.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(g).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(g) Software safety analysis and safety design methods** | **Part II, Subpart 2.7, 400, Software Engineering MethodSoftware engineering method(s) shall be documented. The selected software engineering method shall ensure that software life cycle activities are planned and performed in a traceable and orderly manner. The appropriate requirements of Part I, Requirement 3 shall be met.** | **Part II, Subpart 2.7, 400, Software Engineering Method Software engineering method(s) shall be documented. The selected software engineering method shall ensure that software life-cycle activities are planned and performed in a traceable and orderly manner. The software design process shall be documented, approved by the responsible design organization, and controlled. This process shall include the activities described in paras. 401 through 404. Part II, Subpart 2.7, 400, Software Engineering Method****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 801.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(g).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(g) Software safety analysis and safety design methods** | **Part II, Subpart 2.7, 401, Software Design RequirementsSoftware design requirements shall specify technical and software engineering (i.e., paragraph 101 of this Subpart) requirements, including security features (e.g., vulnerability protection, and cyber-security).2 Identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. Software design requirements shall be traceable throughout the software life cycle.** | **Part II, Subpart 2.7, 401, Software Design Requirements****Software design requirements shall specify technical and software engineering (i.e., para. 101 of this Subpart) requirements, including security features (e.g., vulnerability protection and cybersecurity).3 Identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program. Software design requirements shall be traceable throughout the software life cycle. Software design requirements shall be identified and documented and their selection reviewed and approved.** **Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 801.1****Footnote reference changed.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(g).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(g) Software safety analysis and safety design methods****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(i).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(i) Problem reporting and corrective action** | **Part II, Subpart 2.7, 402, Software DesignAn integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program’s operating environment. Measures to mitigate the consequences of problems, as identified through analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.** | **Part II, Subpart 2.7, 402, Software Design****An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program’s operating environment. Measures to mitigate the consequences of problems, as identified through** **analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.****The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 801.2** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(h).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(h) Software verification and validation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(g).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(g) Software safety analysis and safety design methods** | **Part II, Subpart 2.7, 402.1, Software Design VerificationSoftware design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.** | **Part II, Subpart 2.7, 402.1, Software Design Verification****Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.****Software design verification shall be performed by a 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****Cursory supervisory reviews do not satisfy the intent of this Standard.****The results of verification shall be documented with the identification of the verifier indicated. Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and methods chosen are a function of the complexity of the software, degree of standardization, similarity with previously proved software, and importance to safety.****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 801.4** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (2).****Management of safety software must include the following elements.****(2) Identify, document, control and maintain safety software inventory. The inventory entries must include at a minimum the following: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and, the responsible individual.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (3).****Management of safety software must include the following elements.****(3) Establish and document grading levels for safety software using the graded approach. Grading levels must be submitted to and approved by the responsible DOE approval authority.****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(e).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(e) Software requirements identification and management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation** | **Part II, Subpart 2.7, 403, ImplementationThe implementation process shall result in software products such as computer program listings and instructions for computer program use. A review shall be performed in accordance with paragraph 202 of this Subpart.** | **Part II, Subpart 2.7, 403, Implementation****The software design shall be translated into computer program(s) using the programming organization’s or design organization’s programming standards and conventions.****The implementation process shall result in software products such as computer program listings and instructions for computer program use. A review shall be performed in accordance with para. 202 of this Subpart.****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 3, Paragraph 801.3** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(c).****Management of safety software must include the following elements.****(c) Software configuration management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(i).****Management of safety software must include the following elements.****(i) Problem reporting and corrective action** | **Part II, Subpart 2.7, 404, Acceptance TestingThe acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing shall demonstrate, as appropriate, that the computer program (a) properly handles abnormal conditions and events as well as credible failures (b) does not perform adverse unintended functions (c) does not degrade the system either by itself, or in combination with other functions or configuration item. Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. Testing shall include a comprehensive acceptance test performed in the operating environment prior to use. The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program in accordance with Part I, Requirement 11. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements** | **Part II, Subpart 2.7, 404, Acceptance Testing****The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.****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:*****(a)* 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.*****(b)* 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.*****(c)* In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 11, Paragraph 200. (There is some slight wording differences but the requirements are addressed)** |
|  |  | **Part II, Subpart 2.7, 404.1, Test Coverage** **Acceptance testing shall demonstrate, as appropriate, that the computer program*****(a)* properly handles abnormal conditions and events as well as credible failures*****(b)* does not perform adverse unintended functions*****(c)* does not degrade the system either by itself or in combination with other functions or configuration items****Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. Testing shall include a comprehensive acceptance test performed in the operating environment prior to use.****Note: New addition but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part II, Subpart 2.7, 404.** |
|  |  | **Part II, Subpart 2.7, 404.2, Test Plans and Procedures****The requirements of this section apply to testing of computer programs and, as appropriate, the computer hardware and operating system.****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 ensuring 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.****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 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.****The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program.****Test procedures or plans shall specify the following, as applicable:*****(a)* required tests and test sequence*****(b)* required ranges of input parameters*****(c)* identification of the stages at which testing is required*****(d)* criteria for establishing test cases*****(e)* requirements for testing logic branches*****(f)* requirements for hardware integration*****(g)* anticipated output values*****(h)* acceptance criteria*****(i)* reports, records, standard formatting, and conventions****Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.****Note: New addition but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 11, Paragraphs 400 and Part II, Subpart 2.7, 404.** |
|  |  | **Part II, Subpart 2.7, 404.3, Computer Program Test Records****Test records shall be established and maintained to indicate the ability of the computer program to satisfactorily perform its intended function or to meet its documented requirements.****Test records shall include*****(a)* computer program tested, including system software used*****(b)* computer hardware used*****(c)* test equipment and calibrations, where applicable*****(d)* date of test*****(e)* tester or data recorder*****(f)* simulation models used, where applicable*****(g)* test problems*****(h)* results and applicability*****(i)* action taken in connection with any deviations noted*****(j)* person evaluating test results*****(k)* acceptability****Note: Revised but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part I, Requirement 11, Paragraphs 600 and 602.** |
|  |  | **Part II, Subpart 2.7, 404.4, Acceptance Testing of Changes****The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program and shall verify that a modified system(s) or system component(s) still meets specified software design requirements.****Note: New addition but no change as Yellow highlighted red text was previously in NQA-1-2008/1a-2009 Part II, Subpart 2.7, 404.** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(e).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(e) Software requirements identification and management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(c).****Management of safety software must include the following elements.****(c) Software configuration management****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(f).****(4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.****Management of safety software must include the following elements.****(f) Software design and implementation****DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(i).****Management of safety software must include the following elements.****(i) Problem reporting and corrective action** | **Part II, Subpart 2.7, 405, OperationAfter the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. These include, as appropriate (a) application documentation (e.g., application log) (b) access control specifications (c) computer system vulnerability protections (d) problem reporting and corrective action (e) in-use tests (f) the configuration change control process** | **Part II, Subpart 2.7, 405, OperationAfter the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. These include, as appropriate (a) application documentation (e.g., application log) (b) access control specifications (c) computer system vulnerability protections (d) problem reporting and corrective action (e) in-use tests (f) the configuration change control process** |
| **DOE O 414.1D Attachment 4, 2 – Requirements, bullet a, last sentence and sub bullet (4)(i).****Management of safety software must include the following elements.****(i) Problem reporting and corrective action** | **Part II, Subpart 2.7, 406, MaintenanceThe appropriate software engineering elements, as described in paragraph 101 of this Subpart, shall identify how changes to the software are controlled. Typically, changes are in response to any of the following: (a) enhancement requests from the user community (b) revisions to software based on software design requirements (c) changes to the operating environment and changes to computer system vulnerability protections (d) reported software problems that must be corrected** | **Part II, Subpart 2.7, 406, MaintenanceThe appropriate software engineering elements, as described in paragraph 101 of this Subpart, shall identify how changes to the software are controlled. Typically, changes are in response to any of the following: (a) enhancement requests from the user community (b) revisions to software based on software design requirements (c) changes to the operating environment and changes to computer system vulnerability protections (d) reported software problems that must be corrected** |
|  | **Part II, Subpart 2.7, 407, RetirementDuring retirement, support for the software product is terminated, and the routine use of the software shall be prevented.** | **Part II, Subpart 2.7, 407, RetirementDuring retirement, support for the software product is terminated, and the routine use of the software shall be prevented.** |
|  | **Part II, Subpart 2.7, 500, Standards, Conventions, and Other Work PracticesAs appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life cycle activities (e.g., software design and implementation activities). Standards, conventions, and other required work practices shall be documented.** | **Part II, Subpart 2.7, 500, Standards, Conventions, and Other Work PracticesAs appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life cycle activities (e.g., software design and implementation activities). Standards, conventions, and other required work practices shall be documented.** |
|  | **Part II, Subpart 2.7, 600, Support SoftwareSupport software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools** | **Part II, Subpart 2.7, 600, Support SoftwareSupport software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools** |
|  | **Part II, Subpart 2.7, 601, Software ToolsSoftware tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control. In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required** | **Part II, Subpart 2.7, 601, Software ToolsSoftware tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control. In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required** |
|  | **Part II, Subpart 2.7, 602, System SoftwareSystem software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities. System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software shall be placed under configuration change control. Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required** | **Part II, Subpart 2.7, 602, System SoftwareSystem software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities. System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software shall be placed under configuration change control. Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required** |
|  | **NQA-1 2008/2009 Sub-Part 2.14** | **NQA-1 2017 Sub-Part 2.14** |
|  | **Part II, Subpart 2.14, 100, GeneralSubpart 2.14 provides amplified requirements to provide reasonable assurance that a commercial grade item (CGI) or service will perform its safety function. These requirements are intended to supplement the requirements of Part I and shall be used in conjunction with the applicable requirements of Part I by organizations performing commercial grade dedication for accepting items or services. The amplified requirements specified in this Subpart are considered adequate for nuclear facilities identified in Part I, Introduction, section 200, Applicability.** | **Part II, Subpart 2.14, 100, GeneralSubpart 2.14 provides amplified requirements to provide reasonable assurance that a commercial grade item (CGI) or service will perform its safety function. These requirements are intended to supplement the requirements of Part I and shall be used in conjunction with the applicable requirements of Part I by organizations performing commercial grade dedication for accepting items or services. The amplified requirements specified in this Subpart are considered adequate for nuclear facilities identified in Part I, Introduction, section 200, Applicability.** |
|  | **Part II, Subpart 2.14, 200, CGI Definition ApplicationsA facility utilizing commercial grade items or services shall utilize the appropriate commercial grade item definitions to determine if the item or service can be procured commercial grade. An item or service performing a safety function that does not meet the commercial grade definition is subject to the requirements in Part I of the Standard.** | **Part II, Subpart 2.14, 200, CGI Definition ApplicationsA facility utilizing commercial grade items or services shall utilize the appropriate commercial grade item definitions to determine if the item or service can be procured commercial grade. An item or service performing a safety function that does not meet the commercial grade definition is subject to the requirements in Part I of the Standard.** |
|  | **Part II, Subpart 2.14, 300, UtilizationTo utilize a commercial grade item or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. These controls shall include the following: (a) determination that the item or service performs a safety function (b) confirmation that the item or service meets the applicable commercial grade item definitions (c) identification and documentation of the critical characteristics, including acceptance criteria (d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.** **Only items or services that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Items or services that successfully complete the dedication process are subsequently subject to the controls of Part I and Part II of the Standard.** | **Part II, Subpart 2.14, 300, UtilizationTo utilize a commercial grade item or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. These controls shall include the following: (a) determination that the item or service performs a safety function (b) confirmation that the item or service meets the applicable commercial grade item definitions (c) identification and documentation of the critical characteristics, including acceptance criteria (d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.** **Only items or services that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Items or services that successfully complete the dedication process are subsequently subject to the controls of Part I and Part II of the Standard.** |
|  | **Part II, Subpart 2.14, 400, Technical Evaluation** | **Part II, Subpart 2.14, 400, Technical Evaluation** |
|  | **Part II, Subpart 2.14, 401, GeneralThe technical evaluation(s) shall be performed by the responsible engineering organization to (a) determine the safety function(s) of the item or service (b) identify performance requirements, the component/ part functional classification, and applicable service conditions (c) confirm that the item or service meets the commercial grade definition criteria (d) identify the critical characteristics, including acceptance criteria (e) identify the dedication method(s) for verification of the acceptance criteria (f) determine if a replacement item is a like-for-like or equivalent item. The requirements of this Subpart are only applicable to commercial grade items or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation. Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment. The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations. If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item’s design parameters and allowables become the critical characteristics and acceptance criteria. If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, and section 600, Change Control.** | **Part II, Subpart 2.14, 401, GeneralThe technical evaluation(s) shall be performed by the responsible engineering organization to (a) determine the safety function(s) of the item or service (b) identify performance requirements, the component/ part functional classification, and applicable service conditions (c) confirm that the item or service meets the commercial grade definition criteria (d) identify the critical characteristics, including acceptance criteria (e) identify the dedication method(s) for verification of the acceptance criteria (f) determine if a replacement item is a like-for-like or equivalent item. The requirements of this Subpart are only applicable to commercial grade items or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation. Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment. The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations. If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item’s design parameters and allowables become the critical characteristics and acceptance criteria. If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, and section 600, Change Control.** |
|  | **Part II, Subpart 2.14, 402, Like-For-Like ItemsItems may be considered identical or like-for-like if one of the following applies: (a) The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes. (b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification. (c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination. If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.** | **Part II, Subpart 2.14, 402, Like-For-Like ItemsItems may be considered identical or like-for-like if one of the following applies: (a) The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes. (b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification. (c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination. If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.** |
|  | **Part II, Subpart 2.14, 403, Equivalent ItemsWhen difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function. The equivalency evaluation shall be documented and include the following: (a) identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the original item (b) evaluation of the change(s) (c) confirmation that the change(s) does not adversely affect the current design or safety function of the item If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part I, Requirement 3, section 600, Change Control. Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.** | **Part II, Subpart 2.14, 403, Equivalent ItemsWhen difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function. The equivalency evaluation shall be documented and include the following: (a) identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the original item (b) evaluation of the change(s) (c) confirmation that the change(s) does not adversely affect the current design or safety function of the item If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part I, Requirement 3, section 600, Change Control. Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.** |
|  | **Part II, Subpart 2.14, 500, Critical CharacteristicsCritical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include the part number, physical characteristics, identification markings, and performance characteristics, as appropriate. The critical characteristic acceptance criteria shall include tolerances, when appropriate. An item’s part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer’s product description and published data. The dedication process shall not rely on the part number alone as the only critical characteristic to be verified. Commercial grade items or services can have numerous characteristics that are related to the composition, identification, or performance of the item or service. However, for acceptance, not all of these characteristics need to be verified to provide reasonable assurance that the item or service will perform its intended safety function. The manufacturer’s published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing of the item. The manufacturer can employ standard tests or inspections as part of the manufacturing process and utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria. In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer’s documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria. Critical characteristics selected for acceptance shall include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility or criteria addressing the most severe location criteria/design basis conditions (or manufacturing design limits) of the item in the facility, unless controls are in place to prevent usage in undesignated locations. Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.** | **Part II, Subpart 2.14, 500, Critical CharacteristicsCritical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include the part number, physical characteristics, identification markings, and performance characteristics, as appropriate. The critical characteristic acceptance criteria shall include tolerances, when appropriate. An item’s part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer’s product description and published data. The dedication process shall not rely on the part number alone as the only critical characteristic to be verified. Commercial grade items or services can have numerous characteristics that are related to the composition, identification, or performance of the item or service. However, for acceptance, not all of these characteristics need to be verified to provide reasonable assurance that the item or service will perform its intended safety function. The manufacturer’s published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing of the item. The manufacturer can employ standard tests or inspections as part of the manufacturing process and utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria. In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer’s documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria. Critical characteristics selected for acceptance shall include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility or criteria addressing the most severe location criteria/design basis conditions (or manufacturing design limits) of the item in the facility, unless controls are in place to prevent usage in undesignated locations. Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.** |
|  | **Part II, Subpart 2.14, 600, Methods of Accepting Commercial Grade Items and Services** | **Part II, Subpart 2.14, 600, Methods of Accepting Commercial Grade Items and Services** |
|  | **Part II, Subpart 2.14, 601, Dedication(a) To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, the dedicating entity shall verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods: (1) Method 1: inspections, tests, or analyses performed after delivery (2) Method 2: commercial grade survey of the supplier (3) Method 3: source verification of the item or service (4) Method 4: acceptable supplier/item performance record (b) Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable: (1) Damage was not sustained during shipment. (2) The item or service has satisfied the specified acceptance criteria for the identified critical characteristics. (3) Specified documentation was received and is acceptable. (c) The dedication method(s) described in paragraphs 602 through 605 shall provide a means to assure that the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic. (d) The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.** | **Part II, Subpart 2.14, 601, Dedication(a) To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, the dedicating entity shall verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods: (1) Method 1: inspections, tests, or analyses performed after delivery (2) Method 2: commercial grade survey of the supplier (3) Method 3: source verification of the item or service (4) Method 4: acceptable supplier/item performance record (b) Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable: (1) Damage was not sustained during shipment. (2) The item or service has satisfied the specified acceptance criteria for the identified critical characteristics. (3) Specified documentation was received and is acceptable. (c) The dedication method(s) described in paragraphs 602 through 605 shall provide a means to assure that the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic. (d) The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.** |
|  | **Part II, Subpart 2.14, 602, Method 1: Special Test(s), Inspection(s), and/or AnalysesSpecial test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include post-installation testing and may be performed utilizing a sampling plan, when appropriate. Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan. Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item. When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the commercial grade item or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities. When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met. Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.** | **Part II, Subpart 2.14, 602, Method 1: Special Test(s), Inspection(s), and/or AnalysesSpecial test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include post-installation testing and may be performed utilizing a sampling plan, when appropriate. Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan. Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item. When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the commercial grade item or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities. When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met. Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.** |
|  | **Part II, Subpart 2.14, 603, Method 2: Commercial Grade Survey of the Supplier(a) A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier’s commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier’s facility and includes or addresses the following: (1) identification of the item(s), or product line, or service included within the scope of the survey (2) identification of the critical characteristics to be controlled by the supplier (3) verification that the supplier’s processes and quality program controls are effectively implemented for control of the critical characteristics (4) identification of the survey methods or verification activities performed with results obtained (5) documentation of the adequacy of the supplier’s processes and controls. (b) A commercial grade survey shall not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier’s own specified processes and controls. After a supplier’s processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls including revision level as a part of the purchase order or control requirements for the commercial grade item or service and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls. (c) When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met. (d) Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if (1) the distributor acts only as a broker and does not warehouse or repackage the items (2) in cases where traceability can be established by other means such as verification of the manufacturer’s markings or shipping records (e) Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier’s processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity’s dedication requirements. (f) The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the commercial grade item or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of commercial grade items or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier. (g) If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier’s sub supplier(s), the dedicating entity shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic. (h) Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys. The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier’s process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s). (i) The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier’s process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.** | **Part II, Subpart 2.14, 603, Method 2: Commercial Grade Survey of the Supplier(a) A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier’s commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier’s facility and includes or addresses the following: (1) identification of the item(s), or product line, or service included within the scope of the survey (2) identification of the critical characteristics to be controlled by the supplier (3) verification that the supplier’s processes and quality program controls are effectively implemented for control of the critical characteristics (4) identification of the survey methods or verification activities performed with results obtained (5) documentation of the adequacy of the supplier’s processes and controls. (b) A commercial grade survey shall not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier’s own specified processes and controls. After a supplier’s processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls including revision level as a part of the purchase order or control requirements for the commercial grade item or service and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls. (c) When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met. (d) Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if (1) the distributor acts only as a broker and does not warehouse or repackage the items (2) in cases where traceability can be established by other means such as verification of the manufacturer’s markings or shipping records (e) Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier’s processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity’s dedication requirements. (f) The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the commercial grade item or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of commercial grade items or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier. (g) If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier’s sub supplier(s), the dedicating entity shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic. (h) Organizations performing surveys shall establish processes for performing those surveys. Collectively, personnel assigned to conduct commercial grade surveys shall have the necessary capabilities in auditing functions and shall have appropriate technical knowledge to evaluate the supplier’s controls associated with the critical characteristics to be verified. (i) The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier’s process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits. (j) For a supplier of calibration or testing services, the Purchaser may utilize the requirements of Part II, Subpart 2.19 as an alternative to the commercial grade survey requirements of (a).****Note: paragraph (h) was reworded and paragraph (j) was added.** |
|  | **Part II, Subpart 2.14, 604, Method 3: Source VerificationSource verification is a method of acceptance conducted at the supplier’s facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It shall also include verification of the supplier’s design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics. Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier’s activities for the identified characteristics were observed and evaluated for acceptance. Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier’s facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following: (a) identification of the item(s) or service(s) included within the scope of the source verification (b) identification of the critical characteristics, including acceptance criteria, being controlled by the supplier (c) verification that the supplier’s processes and controls are effectively implemented for the identified critical characteristics (d) identification of the activities witnessed during the source verification and the results obtained (e) identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item (f) documentation of the adequacy of the supplier’s processes and controls associated with the critical characteristics and acceptance criteria.** | **Part II, Subpart 2.14, 604, Method 3: Source VerificationSource verification is a method of acceptance conducted at the supplier’s facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It shall also include verification of the supplier’s design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics. Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier’s activities for the identified characteristics were observed and evaluated for acceptance. Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier’s facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following: (a) identification of the item(s) or service(s) included within the scope of the source verification (b) identification of the critical characteristics, including acceptance criteria, being controlled by the supplier (c) verification that the supplier’s processes and controls are effectively implemented for the identified critical characteristics (d) identification of the activities witnessed during the source verification and the results obtained (e) identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item (f) documentation of the adequacy of the supplier’s processes and controls associated with the critical characteristics and acceptance criteria.** |
|  | **Part II, Subpart 2.14, 605, Method 4: Acceptable Supplier Item or Service Performance RecordA documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier’s performance record for identical or similar services. This allows the dedicating entity to have reasonable assurance of the item’s or service’s performance based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data. Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service. (a) An acceptable supplier item or service performance record shall include the following: (1) identification of the supplier item or service being evaluated (2) identification of previously established critical characteristics specific to the supplier item or service (3) identification of data examined to evaluate the supplier item or service (4) identification of basis for determining that performance data substantiates acceptability of the supplier item or service (5) documentation of the adequacy and acceptance of the supplier/item/service performance record (b) An acceptable item or service performance record shall not be employed alone as a method of acceptance unless (1) the established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance. (2) the manufacturer’s/supplier’s measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey. Continued application of an acceptable supplier/ item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.** | **Part II, Subpart 2.14, 605, Method 4: Acceptable Supplier Item or Service Performance RecordA documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier’s performance record for identical or similar services. This allows the dedicating entity to have reasonable assurance of the item’s or service’s performance based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data. Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service. (a) An acceptable supplier item or service performance record shall include the following: (1) identification of the supplier item or service being evaluated (2) identification of previously established critical characteristics specific to the supplier item or service (3) identification of data examined to evaluate the supplier item or service (4) identification of basis for determining that performance data substantiates acceptability of the supplier item or service (5) documentation of the adequacy and acceptance of the supplier/item/service performance record (b) An acceptable item or service performance record shall not be employed alone as a method of acceptance unless (1) the established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance. (2) the manufacturer’s/supplier’s measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey. Continued application of an acceptable supplier/ item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.** |
|  | **Part II, Subpart 2.14, 606, Supplier Deficiency CorrectionDeficiencies with the supplier’s processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.** | **Part II, Subpart 2.14, 606, Supplier Deficiency CorrectionDeficiencies with the supplier’s processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.** |
|  | **Part II, Subpart 2.14, 700, Commercial Grade ServicesSome examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item’s critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services. Part I, Requirement 7, section 507 shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity’s or other organization’s quality program and procedures that meet the requirements of this Standard. Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer’s service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a quality assurance program that meets the requirements of this Standard. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.** | **Part II, Subpart 2.14, 700, Commercial Grade ServicesSome examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item’s critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services. Part I, Requirement 7, section 507 shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity’s or other organization’s quality program and procedures that meet the requirements of this Standard. Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer’s service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a quality assurance program that meets the requirements of this Standard. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.** |
|  | **Part II, Subpart 2.14, 800, DocumentationDocumentation of the commercial grade item or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method: (a) dedication plans or procedures including the essential elements of the dedication process (b) commercial grade item or service procurement documents (c) technical evaluations (d) critical characteristic identification and acceptance criteria (e) test reports or results, inspection reports, analysis reports (f) commercial grade survey reports (g) source verification reports (h) historical performance information (i) dedication report containing sufficient data to accept the item or service** | **Part II, Subpart 2.14, 800, DocumentationDocumentation of the commercial grade item or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method: (a) dedication plans or procedures including the essential elements of the dedication process (b) commercial grade item or service procurement documents (c) technical evaluations (d) critical characteristic identification and acceptance criteria (e) test reports or results, inspection reports, analysis reports (f) commercial grade survey reports (g) source verification reports (h) historical performance information (i) dedication report containing sufficient data to accept the item or service** |