

**QUALITY PLAN IMPLEMENTING MATRIX
 CRITERION 6, “DESIGN”**

Item No.	Requirement	Source Document*	Implementation Location**
General Requirements			
1.	Design items and processes using sound engineering/scientific principles and appropriate standards.	10CFR830.122(f)(1) AND DOE O 414.1C(6)(a)	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.
2.	Incorporate applicable requirements and design bases in design work and design changes.	10CFR830.122(f)(1) AND DOE O 414.1C(6)(a)	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.
3.	Identify and control design interfaces.	10CFR830.122(f)(1) AND DOE O 414.1C(6)(a)	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.
4.	Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.	10CFR830.122(f)(1) AND DOE O 414.1C(6)(a)	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.

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5.	Verify/validate work before approval and implementation of the design. AND Design verification must be required prior to approval and implementation of the design.	10CFR830.122(f)(1) AND DOE O 414.1C(6)(a) AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.6, Design Verification	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.
Basic Requirements			
6.	The design shall be defined, controlled, and verified.	ASME NQA-1-2000, 100, Basic	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 3.6, Design Control, addresses this requirement.
7.	Design inputs shall be specified on a timely basis and translated into design documents. AND Design engineers must prescribe and document facility and programmatic design activities on a timely basis.	ASME NQA-1-2000, 100, Basic AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
8.	Design interfaces shall be identified and controlled.	ASME NQA-1-2000, 100, Basic	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.4, Interface Control, addresses this requirement.

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9.	Design adequacy shall be verified by individuals other than those who designed the item or computer program.	ASME NQA-1-2000, 100, Basic	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
10.	Design changes shall be governed by control measures commensurate with those applied to the original design.	ASME NQA-1-2000, 100, Basic	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.7, Design Change Control, addresses this requirement.
Design Input			
11.	Applicable design inputs shall be identified and documented, and their selection reviewed and approved.	ASME NQA-1-2000, 200, Design Input	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.1, Design Inputs, addresses this requirement.
12.	The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.	ASME NQA-1-2000, 200, Design Input	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.1, Design Inputs, addresses this requirement.

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Design Process			
13.	Appropriate technical and industrial standards must be identified and documented by technically qualified persons, and the selection of these standards must be reviewed and approved by technically qualified persons.	IP 300-SD3.2, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
14.	<p>The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.</p> <p style="text-align: center;">AND</p> <p>The level of detail must be as necessary to permit the design process to be carried out, to permit verification that the design meets requirements, and to assure that the required inspections and tests are specified and include appropriate acceptance criteria.</p>	ASME NQA-1-2000, 300, Design Process AND IP 330.0, LANL Quality Assurance Program, Section 6, Design, Subsection 6.2.1, Design Process	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.1, Design Inputs, addresses this requirement.
15.	<p>Design documents shall support facility design, construction, and operation.</p> <p style="text-align: center;">AND</p> <p>Design output documents must be adequate to support facility, product, and process/activity design, construction, installation, operation, modification, and maintenance.</p>	ASME NQA-1-2000, 300, Design Process AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.5, Design Outputs, addresses this requirement.
16.	The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.	ASME NQA-1-2000, 300, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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17.	Applicable information derived from experience, as set forth in reports or other documentation shall be made available to cognizant design personnel.	ASME NQA-1-2000, 300, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
18.	The final design shall: 1. be relatable to the design input by documentation in sufficient detail to permit design verification; 2. specify required inspections and tests and include or reference appropriate acceptance criteria; and 3. identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.	ASME NQA-1-2000, 300, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
19.	Characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function.	ASME NQA-1-2000, 300, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
20.	If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	ASME NQA-1-2000, 300, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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21.	<p>The design process shall include (but not be limited to) consideration and development of detailed specifications for:</p> <ul style="list-style-type: none"> a) assessments needed during the project (e.g., surveillances, audits, performance evaluations); b) data reporting requirements; c) data validation and verification methods; d) integrating cost or schedule constraints into design; e) protection of health and safety of workers and of the public; f) readiness reviews prior to data collection; g) requirements for calibration and performance evaluation samples for analytical methods used; h) requirements for data (and data base) retrieval, security, QA and QC, storage, and retention; i) requirements for field and laboratory QA/QC activities; j) requirements and qualifications for sampling and analysis personnel; k) sample handling, packaging, shipping, and custody requirements; l) sample types, numbers, and quantities, and sampling location requirements; m) selection of analytical methods and their quality performance expectations; n) selection of analytical facility (or laboratory); o) selection of field sampling or testing methodology, including specific sampling or field analytical instrumentation requirements and other analytical testing requirements; p) techniques for assessing limitations on data use; and q) disposal or minimization procedures for wastes produced during sampling and analysis operations. 	ANSI/ASQ E4-2004, Subsection 6.3.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
22.	Key variables that determine or directly affect the quality of results shall be identified and controlled as appropriate according to the specifications determined during design.	ANSI/ASQ E4-2004, Subsection 6.3.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
23.	Engineered items must be identified by process design documents.	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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24.	The systems, structures, and components identified in the hazard and risk analyses must be linked to the quality requirements for hazard/risk mitigation in the design specifications, drawings, and process procedures.	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
25.	Installation criteria must be established for facility and process equipment.	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
26.	These criteria must include any special tools and/or torque requirements for components and should be clearly defined in the manufacturers' product documentation (manuals, specifications), process specifications, procedures, and/or design drawings and documents.	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
Design Analyses			
27.	<p>Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.</p> <p style="text-align: center;">AND</p> <p>Design analyses must be sufficiently detailed so that a technically qualified person can independently review and comprehend the analyses and verify the adequacy of the results.</p>	ASME NQA-1-2000, 400, Design Analysis AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.4, Design Analyses	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
28.	<p>Documentation of design analyses shall include the following:</p> <ol style="list-style-type: none"> a. the objective of the analyses; b. design inputs and their sources; c. results of literature searches or other applicable background data; d. assumptions and indication of those assumptions that must be verified as the design proceeds; e. identification of any computer calculation, including identification of the computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem; and f. review and approval. 	ASME NQA-1-2000, 402, Documentation of Design Analysis	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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Design Verification			
29.	The responsible design organization shall identify and document the particular design verification method(s) used.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
30.	The results of design verification shall be documented with the identification of the verifier clearly indicated.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
31.	Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. AND Design processes must include design verification as a formal, documented process performed by technically knowledgeable persons who are not involved in the original design.	ASME NQA-1-2000, 500, Design Verification AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.6, Design Verification	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
32.	Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met, such as when insufficient data exist.	ASME NQA-1-2000, 500, Design Verification	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
33.	In those cases, the unverified portion of the design shall be identified and controlled.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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34.	In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.	ASME NQA-1-2000, 500, Design Verification	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
35.	If the design is modified to resolve verification findings, the modified design shall be verified prior to release for use.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
36.	The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. [NOTE: Where design has been subjected to a verification process in accordance with ASME NQA-1-2000, the verification process need not be duplicated for identical designs.]	ASME NQA-1-2000, 500, Design Verification	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
37.	However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
38.	Known problems affecting the standard or previously proved designs and their effects on other features shall be considered.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
39.	The original design and associated verification documentation shall be referenced in records of subsequent application of the design.	ASME NQA-1-2000, 500, Design Verification	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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Methods			
40.	<p>Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.</p> <p style="text-align: center;">AND</p> <p>Design verification methods include, but are not limited to, design reviews (or peer reviews for research), alternate calculations, or performance of qualification tests.</p>	<p>ASME NQA-1-2000, 501, Methods AND IP 330.0, LANL Quality Assurance Program, Subsection 6.2.6, Design Verification</p>	<p>LANL ISD 341-1.2, <i>Engineering Processes Manual</i>, Subsection 4.4.6, Design Verification and Approval, addresses this requirement.</p>
41.	<p>Design reviews shall provide assurance that the final design is correct and satisfactory by addressing the following, where applicable:</p> <ul style="list-style-type: none"> a. Were the design inputs correctly selected? b. Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed? c. Were appropriate design methods and computer programs used? d. Were the design inputs correctly incorporated into the design? e. Is the design output reasonable compared to design inputs? f. Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions? g. Have suitable materials, parts, processes, and inspection and testing criteria been specified? 	<p>ASME NQA-1-2000, 501.1, Design Reviews</p>	<p>LANL ISD 341-1.2, <i>Engineering Processes Manual</i>, Subsection 4.4.6, Design Verification and Approval, addresses this requirement.</p>
42.	<p>Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses.</p>	<p>ASME NQA-1-2000, 501.2, Alternate Calculations</p>	<p>LANL ISD 341-1.2, <i>Engineering Processes Manual</i>, Subsection 4.4.6, Design Verification and Approval, addresses this requirement.</p>

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43.	The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed.	ASME NQA-1-2000, 501.2, Alternate Calculations	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
44.	Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions.	ASME NQA-1-2000, 501.3, Qualification Tests	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
45.	Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.	ASME NQA-1-2000, 501.3, Qualification Tests	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
46.	Where tests are being performed on models or mockups, scaling laws shall be established and verified.	ASME NQA-1-2000, 501.3, Qualification Tests	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.

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47.	The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.	ASME NQA-1-2000, 501.3, Qualification Tests	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.6, Design Verification and Approval, addresses this requirement.
Change Control			
48.	<p>Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design.</p> <p style="text-align: center;">AND</p> <p>Design document changes must receive levels of processing and reviews/approvals equal to those for the original design document.</p> <p style="text-align: center;">AND</p> <p>Temporary modifications to designs and system configurations must receive the same level of control as permanent modifications.</p>	<p>ASME NQA-1-2000, 600, Change Control</p> <p style="text-align: center;">AND</p> <p>IP 330.0, LANL Quality Assurance Program, Subsection 6.2.5, Design Output</p> <p style="text-align: center;">AND</p> <p>IP 330.0, LANL Quality Assurance Program, Subsection 6.2.7, Design Change Controls</p>	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.7, Design Change Control, addresses this requirement.
49.	These measures shall include evaluation of effects of those changes on the overall design and on any analyses upon which the design is based.	ASME NQA-1-2000, 600, Change Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
50.	The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.	ASME NQA-1-2000, 600, Change Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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51.	The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	ASME NQA-1-2000, 600, Change Control	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.7, Design Change Control, addresses this requirement.
52.	When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.	ASME NQA-1-2000, 600, Change Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
53.	Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.	ASME NQA-1-2000, 600, Change Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
Configuration Management			
54.	Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
55.	These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
56.	Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
57.	The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility and maintained for the life of the facility.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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58.	The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
59.	Interface controls shall include the integration of activities of organizations that can affect the approved configuration.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
60.	Documentation shall identify the design bases and the approved configuration for the approved modes of operation.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
61.	Measures shall be established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
62.	The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
63.	Approval by the design authority shall be required prior to implementation of a change to the design bases.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
64.	The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents which reflect the operational status of the facility.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
65.	The process utilized to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.	ASME NQA-1-2000, 601, Configuration Management of Operating Facilities	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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Item No.	Requirement	Source Document*	Implementation Location**
Interface Control			
66.	Design interface controls must be established to formally communicate design information across organizational boundaries to indicate design document status for use (e.g., status indicator stamps) and the responsibilities for further evaluation, review, and/or approval.	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.3, Design Interface Controls	LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , Subsection 4.4.4, Interface Control, addresses this requirement.
67.	Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items which require further evaluation, review, or approval.	ASME NQA-1-2000, 700, Interface Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
68.	Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.	ASME NQA-1-2000, 700, Interface Control	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
69.	Multidisciplinary reviews must be conducted at designated intervals to preclude improper designed product coordination and sequencing for application, installation, or fabrication/production.	IP 330.0, LANL Quality Assurance Program, Section 6, Design, Subsection 6.2.1, Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.
Documentation and Records			
70.	Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.	ASME NQA-1-2000, 900, Documentation and Records	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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Computer Software Controls for Design			
71.	<p>Computer software utilized for safety analyses, design substantiation, and instrumentation and control must be controlled and verified as follows:</p> <ul style="list-style-type: none"> • In the case of commercial software used for analysis and calculation purposes, care must be taken that the original program is not degraded. A copy of the original program must be stored in a protected location. • Software written or modified by the user must be verified as to its ability to meet design specifications. Dry runs, modeling, or test equipment must be used to ensure the outcome. • Software owners must document software programs, including each revision and modification, and this documentation must be controlled as permanent records. • Hardware configurations used to display software pertinent to safety analyses, design substantiation, and instrumentation and control must also be documented with its associated software. • Software used in design substantiation calculations must be treated the same as in any design activity that requires the development of design requirements/specifications, design validation, and verification and acceptance testing to assure that the software meets the requirements/specifications. A change control process must be developed to ensure configuration control for critical process software. A master copy of this software must be controlled. 	IP 330.0, LANL Quality Assurance Program, Subsection 6.2.8, Computer Software Controls for Design	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
Software Design Control			
72.	The software design process shall be documented, approved by the responsible design organization, and controlled.	ASME NQA-1-2000, 801, Software Design Process	**LANL ISD 341-1.2, <i>Engineering Processes Manual</i> , addresses this requirement.

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Item No.	Requirement	Source Document*	Implementation Location**
73.	This process shall include the following activities: 1. Identification of Software Design Requirements 2. Software Design 3. Implementation of the Software Design 4. Software Design Verification 5. Computer Software Program Testing	ASME NQA-1-2000, 801, Software Design Process	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
74.	Software design requirements shall be identified and documented and their selection reviewed and approved.	ASME NQA-1-2000, 801, Software Design Process, 801.1, Identification of Software Design Requirements	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
75.	The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.	ASME NQA-1-2000, 801, Software Design Process, 801.1, Identification of Software Design Requirements	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
76.	The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.	ASME NQA-1-2000, 801, Software Design Process, 801.2, Software Design	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
77.	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. [NOTE: 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.]	ASME NQA-1-2000, 801, Software Design Process, 801.2, Software Design	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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78.	The software design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.	ASME NQA-1-2000, 801, Software Design Process, 801.3, Implementation of the Software Design	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
Software Verification and Validation			
79.	Computer program acceptability shall be pre-verified or the results verified with the design analysis for each application.	ASME NQA-1-2000, 401, Use of Computer Programs	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
80.	Pre-verified computer programs shall be controlled in accordance with the requirements of ASME NQA-1-2000.	ASME NQA-1-2000, 401, Use of Computer Programs	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
81.	The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.	ASME NQA-1-2000, 401, Use of Computer Programs	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
82.	The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.	ASME NQA-1-2000, 401, Use of Computer Programs	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
83.	Software development verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization.	ASME NQA-1-2000, 801, Software Design Process, 801.4, Software Design Verification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
84.	The results of verification shall be documented with the identification of the verifier indicated.	ASME NQA-1-2000, 801, Software Design Process, 801.4, Software Design Verification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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85.	Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development.	ASME NQA-1-2000, 801, Software Design Process, 801.4, Software Design Verification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
86.	The extent of verification and the methods chosen are a function of: a) the complexity of the software; b) the degree of standardization; c) the similarity with previously proved software; and d) the importance to safety.	ASME NQA-1-2000, 801, Software Design Process, 801.4, Software Design Verification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
87.	Computer program testing shall be performed in accordance with ASME NQA-1-2000 requirements for Test Control.	ASME NQA-1-2000, 801, Software Design Process, 801.5, Computer Program Testing	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
Software Configuration Identification			
88.	Configuration items shall be maintained under configuration management until the software is retired.	ASME NQA-1-2000, 802, Software Configuration Management	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
89.	A software baseline shall be established at the completion of each activity of the software design process.	ASME NQA-1-2000, 802, Software Configuration Management, 802.1, Configuration Identification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
90.	Approved changes created subsequent to a baseline shall be added to the baseline.	ASME NQA-1-2000, 802, Software Configuration Management, 802.1, Configuration Identification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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91.	A baseline shall define the most recently approved software configuration.	ASME NQA-1-2000, 802, Software Configuration Management, 802.1, Configuration Identification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
92.	A labeling system for configuration items shall be implemented that: a) uniquely identifies each configuration item; b) identifies changes to configuration items by revision; and c) provides the ability to uniquely identify each configuration of the revised software available for use.	ASME NQA-1-2000, 802, Software Configuration Management, 802.1, Configuration Identification	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
Software Configuration Change Control			
93.	Changes to software shall be formally documented.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
94.	The documentation shall include: a) a description of the change; b) the rationale for the change; and c) the identification of affected software baselines.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
95.	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.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
96.	Only authorized changes shall be made to software baselines.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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97.	Appropriate verification activities shall be performed for the change.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
98.	The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
99.	Appropriate acceptance testing shall be performed for the change.	ASME NQA-1-2000, 802, Software Configuration Management, 802.2, Configuration Change Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
Software Configuration Status Accounting			
100.	The status of configuration items resulting from software design shall be maintained current.	ASME NQA-1-2000, 802, Software Configuration Management, 802.3, Configuration Status Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
101.	Configuration item changes shall be controlled until they are incorporated into the approved product baseline.	ASME NQA-1-2000, 802, Software Configuration Management, 802.3, Configuration Status Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.
102.	The controls shall include a process for maintaining the status of changes that are proposed and approved, but not implemented.	ASME NQA-1-2000, 802, Software Configuration Management, 802.3, Configuration Status Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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103.	The controls shall also provide for notification of this information to affected organizations.	ASME NQA-1-2000, 802, Software Configuration Management, 802.3, Configuration Status Control	IPP 1004, <i>Software Quality Management Plan</i> , will cover this requirement.

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