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Companywide	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 09/18/13
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*The current revision can be verified on EDMS.

1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for ensuring that designs are defined, controlled, and verified.

2. APPLICABILITY

This PRD applies to organizations involved in *design control* (see def.).

3. RESPONSIBILITY

3.1 Engineering Organizations

The engineering organizations are responsible for:

- A. Establishing engineering organization policies and procedures for controlling design, engineering, *configuration management* (see def.), regulatory positions, and nuclear safety processes
- B. Ensuring that engineering activities are executed in accordance with the requirements of this quality assurance (QA) PRD
- C. Implementing appropriate *corrective actions* (see def.), up to and including stop work, when work is not in compliance with the applicable design control requirements
- D. Determining the need for and controlling facility design and modifications
- E. Ensuring *design input* (see def.) documents, including functional requirements and other authorization basis documents, are developed
- F. Evaluating environmental and safety impacts
- G. Reviewing *design change* (see def.) documents, as required
- H. Participating in peer/technical reviews, as required
- I. Identifying commercial items to be dedicated and establishing acceptance criteria for dedicating those commercial items per PRD-5069, “Dedication of Purchased Commercial Grade Items and Services”

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- J. Implementing configuration management for facilities, systems, and components under its control
- K. Ensuring *design output* (see def.) documents are consistent with design inputs and authorization basis documents
- L. Developing detailed design output documents
- M. Maintaining alignment of design output documents with design input document requirements
- N. Providing *technical support organization* (see def.) interface
- O. Coordination of resources during the execution of a project
- P. Successful turnover of the project to the user
- Q. Establishing inspection and test acceptance criteria
- R. Ensuring test and inspection plans are prepared
- S. Approving test and inspection plans.

3.2 Quality Assurance Organization

The Quality Assurance organization is responsible for establishing the QA program requirements for design control.

3.3 Cognizant Quality Engineer

The *cognizant quality engineer* (see def.) associated with the organization requesting or providing the design activities/documents is responsible for:

- A. Providing input, reviewing, and approving quality requirements for selected design documents, and subsequent changes
- B. Approving inspection plans for quality *items* (see def.)
- C. Performing or coordinating performance of required independent inspections
- D. Approving test and inspection plans.

3.4 Technical Support Organization

The Technical Support organization is responsible for:

- A. Developing functional acceptance criteria

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- B. Accepting design input documents
- C. Developing facility/system descriptions
- D. Preparing technical baseline documents and approving changes thereto
- E. Participating in technical reviews, as required
- F. Assisting Engineering in performing the activities listed.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection meet the requirements in “Quality Assurance Requirements for Nuclear Facility Application,” American Society of Mechanical Engineers (ASME) NQA-1-2008 with Addenda through NQA-1a-2009 and Department of Energy (DOE) O 414.1D, “Quality Assurance.” The requirements apply to the entire company as defined by FWD-7, “Foreword.”

4.1.1 Basic

- 4.1.1.1 The design will be defined, controlled, and verified.
- 4.1.1.2 Design inputs will be specified, translated into design documents, and approved on a timely basis.
- 4.1.1.3 Design interfaces will be identified and controlled.
- 4.1.1.4 Design adequacy will be verified by individuals other than those who designed the item or *computer program* (see def.).
- 4.1.1.5 Design changes will be governed by control measures commensurate with those applied to the original design.
- 4.1.1.6 Procurement, development, modification, maintenance, operation, use, and retirement of computer *software* (see def.) used in the design analysis and verification *process* (see def.) will comply with the requirements of PRD-5092, “Software Quality Assurance.”

4.1.2 Design Input

- 4.1.2.1 Applicable design inputs will be identified and documented and their selection reviewed and approved by those responsible for the design.

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4.1.2.2 The design input will 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.

4.1.2.3 Design inputs based on assumptions that require confirmation will be identified and controlled as the design proceeds.

4.1.3 Interface Control

4.1.3.1 Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

4.1.3.2 Design information transmitted across interfaces will be documented and controlled. They will identify the status of the design information or document provided, and identify designs or portions of designs that require further development, analysis, review, or approval.

4.1.3.3 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal will be confirmed promptly by a controlled document.

4.1.4 Design Process

4.1.4.1 The responsible design organization will prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the *design process* (see def.) to be carried out in a correct manner, and to permit verification that the design meets requirements.

4.1.4.2 Design documents will adequately support facility design, fabrication, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

4.1.4.3 The design methods, materials, parts, equipment, and processes that are essential to the function of the items will be selected and reviewed for suitability of application.

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- 4.1.4.4 Applicable information derived from experience, as set forth in reports or other documentation, will be made available to cognizant design personnel.
- 4.1.4.5 The final design, including drawings, specifications, and other design output documents, will:
- A. Be relatable to the design input by documentation in sufficient detail to permit design verification.
 - B. Specify required inspections and tests and include or reference appropriate acceptance criteria.
 - C. Identify assemblies and components that are part of the item being designed. When such an assembly or component part is a *commercial grade item* (see def.), critical *characteristics* (see def.) of the item that must be verified for acceptance and the acceptance criteria for those critical characteristics will meet the requirements of PRD-5069, “Dedication of Purchased Commercial Grade Items and Services.”
- 4.1.4.6 Critical characteristics to be verified are those that will provide reasonable assurance that an item will perform its intended function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier’s published product description, the component part will be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

4.1.5 Design Analyses

- 4.1.5.1 Design analyses will be planned, controlled, and documented. Design analyses will be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and *verify* (see def.) the adequacy of the results without recourse to the originator.
- 4.1.5.2 Documentation of design analyses will include:
- A. The objective of the analyses
 - B. Design inputs and their sources

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- C. Results of literature searches or other applicable background *data* (see def.)
 - D. Assumptions and indication of those assumptions that must be verified as the design proceeds
 - E. Identification of any computer calculation, including: identification of the computer type, computer program name, and revision; inputs; outputs; evidence of or reference to computer program verification; and the basis (or reference thereto) supporting application of the computer program to the specific physical problem
 - F. Identification of the originator, reviewer(s), and approver.
- 4.1.5.3 To the extent required in Subsection 4.1.5.4 of this PRD, computer program acceptability will be preverified or the results verified with the design analysis for each application. Preverified computer programs will be controlled in accordance with the requirements of this PRD.
- 4.1.5.4 The computer program will be verified to show that it produces correct solutions for the encoded mathematical *model* (see def.) within defined limits for each parameter employed. The encoded mathematical model will be shown to produce a valid solution to the physical problem associated with the particular application.

4.1.6 Design Verification

- 4.1.6.1 Design verification will be performed to determine the adequacy of the design. Acceptable verification methods include, but are not limited to, any one or a combination of *design reviews* (see def.), alternate calculations, and *qualification testing* (see def.).
- 4.1.6.2 The extent of the design verification will 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.
- 4.1.6.3 Design verification will be performed prior to releasing the design for procurement, manufacture, construction, or use by another organization except where this timing cannot be met, such as when insufficient data exist. In those cases, the

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unverified portion of the design will be clearly identified and controlled. In all cases, the design verification will be completed prior to relying upon *structures, systems, and components* (SSCs) (see def.), or computer programs to perform its function.

4.1.6.4 Where the design has been subjected to verification in accordance with this PRD, the verification process need not be duplicated for identical designs. However:

- A. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application
- B. Known problems affecting the standard or previously proven designs and their effects on other features will be considered
- C. The original design and associated verification documentation will be referenced in records of subsequent application of the design.

4.1.6.5 If the design is modified to resolve verification findings, the modified design will be verified prior to release for use.

4.1.6.6 Design verification will be performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. This verification may be performed by the originator's supervisor, provided: 1) 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 2) the supervisor is the only individual in the organization competent to perform the verification.

NOTE: *Cursory supervisory reviews do not satisfy the intent of this process.*

4.1.6.7 The responsible design organization will identify and document the particular design verification method(s) used.

4.1.6.8 The results of design verification will be documented with the identification of the verifier clearly indicated.

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4.1.7 Design Reviews

- 4.1.7.1 Design reviews will be controlled and performed to ensure that:
- A. The design inputs were correctly selected and incorporated into the design
 - B. Assumptions necessary to perform the design activity are adequately described, reasonable, and where applicable, are identified as requiring confirmation as the design proceeds
 - C. Where necessary, the assumptions are identified for subsequent reverifications when the detailed design activities are completed
 - D. Appropriate design methods and computer programs were used, when applicable
 - E. The design output is reasonable compared to design inputs
 - F. The necessary design inputs for interfacing organizations are specified in the design documents or in supporting procedures or instructions
 - G. Suitable materials, parts, processes, and inspection and testing criteria have been specified.

4.1.8 Alternate Calculations

- 4.1.8.1 Alternate calculations will use alternate methods to verify the correctness of original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used will also be reviewed.

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4.1.9 Qualification Tests

- 4.1.9.1 Qualification tests will demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Required tests will be controlled under appropriate operating modes and environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and test criteria. Where the test is intended to verify only specific design features, the other features of the design will be verified by other means.
- 4.1.9.2 Test procedures will include or reference the test *configuration* (see def.) and *test* (see def.) objectives. Test procedures will also include provisions for ensuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.
- 4.1.9.3 Test results will be documented and evaluated by a responsible authority to ensure that they satisfy test requirements and conform with acceptance criteria.
- 4.1.9.4 When tests are being performed on models or mockups, scaling laws will be established, reviewed, and approved.
- 4.1.9.5 The results of model test work will be subject to error analysis, where applicable, before using the results in final design work.

4.1.10 Design Change Control

- 4.1.10.1 Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities will be justified and will be subject to design control measures commensurate with those applied to the original design.

These design control measures will include provisions to evaluate the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid. The evaluation will include facility configurations that occur during operation, maintenance, test, *surveillance* (see def.), and inspection activities.

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- 4.1.10.2 Reviews are to be performed by personnel of the same disciplines who approved the original design, and typically only if their areas are affected by the change.
- 4.1.10.3 The design organization approving the design will have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design.
- 4.1.10.4 When a significant design change is necessary because of an incorrect design, the design process and design verification methods and implementing documents will be reviewed and modified, as necessary. These design deficiencies will be documented in accordance with PRD-5087, “Corrective Action.” In addition, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items will be controlled in accordance with PRD-5086, “Control of Nonconforming Items.”
- 4.1.10.5 Nonconformances to design requirements dispositioned *use-as-is* (see def.) or *repair* (see def.) will be subject to design control measures commensurate with those applied to the original design. Required as-built records will reflect the use-as-is or repair condition.
- 4.1.10.6 Field changes will be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected design documents.

4.1.11 Configuration Management of Operating Facilities

- 4.1.11.1 Procedures implementing configuration management requirements will be established and documented at the earliest practical time prior to facility operation. These procedures will include the responsibilities and authority of the organizations whose functions affect the configuration of the facility, including activities such as operations, training, design, maintenance, construction, licensing, and procurement.
- 4.1.11.2 Configuration management requirements will include measures to ensure changes that may affect the approved configuration are recognized and processed.

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- 4.1.11.3 The configuration will be established and approved at the earliest practical time prior to the initial operation of the facility, and maintained for the life of the facility.
- 4.1.11.4 The configuration will 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.
- 4.1.11.5 Interface controls will include the integration of activities of organizations that can affect the approved configuration.
- 4.1.11.6 Documentation will identify the design bases and the approved configuration for the approved modes of operation.
- 4.1.11.7 Measures will be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.
- 4.1.11.8 The implementation sequence for approved configuration changes will be reviewed to determine that the configuration conforms to the design bases.
- 4.1.11.9 Approval by the *design authority* (see def.) will be required prior to implementation of a change to the design bases.
- 4.1.11.10 The configuration of the facility will be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process utilized to control the current revision and issuance of these documents will take into account the use of the document and the need for revision to support operation.

4.1.12 Software Design Control

- 4.1.12.1 The software design process will be documented, approved by the responsible design organization, and controlled.
- 4.1.12.2 The requirements of PRD-5092, “Software Quality Assurance,” will apply to computer software design control and will be used instead of Subsections 4.1.2, 4.1.4, 4.1.6, and 4.1.10.

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4.2 Specific Requirement for DOE/RW-0333P, Quality Assurance Requirements and Descriptions, Application

This subsection contains additional requirements from the Quality Assurance Requirements and Descriptions (Department of Energy/Office of Civilian Radioactive Waste [DOE/RW-0333P]) that are specific to spent nuclear fuel and high-level waste activities as defined in FWD-7, “Foreword.”

4.2.1 Design Input Control

4.2.1.1 Data from scientific investigation activities used as design input shall be qualified in accordance with PRD-5094, “Spent Nuclear Fuel and High-Level Waste Scientific Investigation.” If not qualified prior to use in a design product, it shall be identified as such and tracked until qualified. Unqualified data directly relied on to address safety or waste-isolation issues shall be qualified or it shall not be used in the license application.

4.2.1.2 Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

4.2.2 Design Process

4.2.2.1 When specified by controlling procedures, design drawings and specifications are reviewed by individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts, to ensure that the documents are prepared, reviewed, and approved in accordance with applicable implementing procedures and contain the necessary QA requirements, such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented. Training and qualification on non-QA organization individuals shall be in accordance with PRD-5072, “Personnel Training and Qualification.”

NOTE: *PRD-5072 addresses the requirements for the training and qualification of non-QA personnel.*

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4.2.3 Design Analyses

- 4.2.3.1 Computer programs may be utilized for design analysis without individual verification of the program for each application, provided:
- A. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
 - B. The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.
- 4.2.3.2 Computer programs shall be controlled to ensure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes to 4.2.3.1 A and B.

4.2.4 Design Verification

- 4.2.4.1 Design verification shall be performed to determine the adequacy of design, such as by one or a combination of the following methods:
- A. Design reviews
 - B. Alternate or simplified calculations
 - C. Qualification testing.
- 4.2.4.2 Guidelines or criteria shall be established and described for determining method of design verification. The particular design verification method will be identified and documented

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- 4.2.4.3 Design verification shall be performed by competent individuals or groups other than those who performed the original design but may be from the same organization. In exceptional circumstances, this verification may be performed by the originator's immediate 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 the supervisor is the only individual in the organization competent to perform the verification
 - B. The verification is not cursory review
 - C. The determination to use the supervisor is documented and approved, in advance by the supervisor's management
 - D. QA audits are conducted to evaluate the frequency and effectiveness of the use of supervisors as design reviewers.
- 4.2.4.4 Design verification shall be performed at appropriate times and in a timely manner. In all cases, design verification shall be completed before waste package placement in the repository or before relying on the SSC to perform its safety function.
- 4.2.4.5 Where changes in previously verified designs have been made, design verification shall be required for the changes, including evaluation of effects of those changes on the overall design. Design changes are controlled in accordance with Subsection 4.2.6 of this PRD.

4.2.5 Design Verification Method

- 4.2.5.1 If design adequacy is to be verified by qualification tests, the tests will be in accordance with PRD-5082, "Test Control."

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4.2.6 Design Change Control

4.2.6.1 Design changes, including field changes, will be controlled according to the following requirements.

4.2.6.1.1 Changes to final designs, field changes, and nonconforming items dispositioned “use-as-is” or “repair” shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

4.2.6.1.2 Changes shall be approved by the same affected groups of organizations that reviewed and approved the original design documents. Except where an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization will be designated.

4.2.6.1.3 Errors and deficiencies in approved design documents, including design methods (i.e., computer software supporting a safety or waste isolation function), that could adversely affect SSCs important to safety or waste isolation shall be documented and action taken to ensure all errors and deficiencies are corrected.

4.2.6.1.4 Deviations from quality standards shall be identified and formally documented. Procedures shall be established to ensure control of these deviations.

4.2.7 Design Interface Control

4.2.7.1 Design efforts shall be coordinated among participating design organizations and across technical disciplines. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSCs are compatible geometrically, functionally, and with processes and environment.

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4.2.8 Sampling Plans

4.2.8.1 The basis, including any support analyses for the use of sampling plans for SSCs and barriers, and activities thereto, such as inspection and commercial dedication, shall be documented. The following apply to use of sampling plans.

4.2.8.1.1 Sampling plans used for high-safety-risk significant activities shall use a criterion that provides at least a 95% percent confidence that there are only 5% defective items in a lot (95/5).

4.2.8.1.2 Reduced sampling plans may be used for low-safety-risk significant activities.

4.2.8.1.3 Lots sampled shall be essentially homogenous.

5. RECORDS

5.1 All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

5.2 Design documentation and records will 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.

6. DEFINITIONS

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for the definitions of the following terms:

characteristics

cognizant quality engineer

commercial grade item

computer program

configuration

configuration management

corrective action

data

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design authority

design change

design control

design input

design output

design process

design review

item

model

process

qualification testing

quality assurance records

repair

software

structures, systems, and components (SSCs)

surveillance

technical support organization

test

use-as-is

verify

7. REFERENCES

ASME NQA-1-2008 with Addenda through NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," American Society of Mechanical Engineers

DOE/RW-0333P, *Quality Assurance Requirements and Description*, Revision 20, Office of Civilian Radioactive Waste Management Program

DOE O 414.1D, "Quality Assurance"

FWD-7, "Foreword"

LST-199, "Quality Assurance Program Requirements Document Definitions"

PRD-5069, "Dedication of Purchased Commercial Grade Items and Services"

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PRD-5072, “Personnel Training and Qualification”

PRD-5082, “Test Control”

PRD-5086, “Control of Nonconforming Items”

PRD-5087, “Corrective Action”

PRD-5088, “Quality Assurance Records”

PRD-5092, “Software Quality Assurance”

PRD-5094, “Spent Nuclear Fuel and High-Level Waste Scientific Investigation”