NTD-DES-PR-001-R04

Design Process in the Neutron Technologies Division

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OAK RIDGE NATIONAL LABORATORY
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Neutron Technologies Division

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1.0 Introduction

The Neutron Technologies Division (NTD) has many staff engaged in mechanical, electrical, and structural design of hardware and facilities. NScD-ENG-PR-001, "Engineering Design Change Process in the Neutron Sciences Directorate (NScD)" establishes the framework for the execution of design performed within NScD. Compliance with the guidance of NScD-ENG-PR-001 ensures that design effort satisfies the SNS Quality Manual requirements and Standards Based Management System (SBMS) guidance. However, neither NScD-ENG-PR-001 nor SBMS explicitly define the specific procedures for all sections or groups, since the types of design vary across NScD and Oak Ridge National Laboratory (ORNL). This document builds on the guidance of NScD-ENG-PR-001 and SBMS by specifying requirements for design processes applicable to NTD staff. The guidance herein is applicable to the design of any new hardware or modification of existing hardware by any member of NTD. Implementation and closeout activities performed by NTD will conform directly to NScD- ENG-PR-001 or follow specific work instructions developed to satisfy NScD-ENG-PR-001, including 106000000-WI0001, 802000000-WK10001, and 108000000-WI0004.

Design effort is typically required to provide a solution to an existing problem, to enhance the capability of an existing design, or to provide an entirely new capability or function. The design can be simple (a bracket or fixture) or complex (an entire instrument or building). In either case, the development of a successful design solution requires adherence to the following basic process:

- Assessment of need and resources: identifying the need for a design and assessing the resources needed to complete a design.
- Requirements definition: Defining and documenting the physical, functional, and operational requirements that the design must meet to provide an acceptable solution.
- Design development: Actual work performed to develop the design solutions.
- Design reviews: Communications with stakeholders to describe the specific design ideas and to solicit and incorporate feedback.
- Documentation: Documenting the design solution through drawings, analyses, specifications, and procedures that are archived in the appropriate record copy repository system, i.e., Enterprise Document and Records Management (EDRM), HFIR Drawing Database, or other applicable system.
- Design approval and release: formally reviewing and releasing the design package for use.

The elements above can be captured in a design process as shown in Figure 1, which is executed in three distinct phases: a request, definition, and assessment phase, a design development phase, and a final approval and release phase. Key documents developed in these phases are (note an equivalent electronic system may be substituted for physical documents):

- Design Change Request (DCR): generated in the request phase, the DCR documents the need, scope, basic requirements, the affected system(s), design grade, and resources needed. The DCR is reviewed and approved by management (Group Lead) prior to beginning work.
- Design Documentation: documents generated in the process of executing the design. These may include drawings, specifications, calculations, design criteria documents, and design review reports and presentations.
- Design Change Notice (DCN): generated during the design development and reviewed and approved in the final approval phase, the DCN is a record of the design product with all relevant documents listed with revision numbers. Approval of the DCN signifies the design product is satisfactory and is released for use.

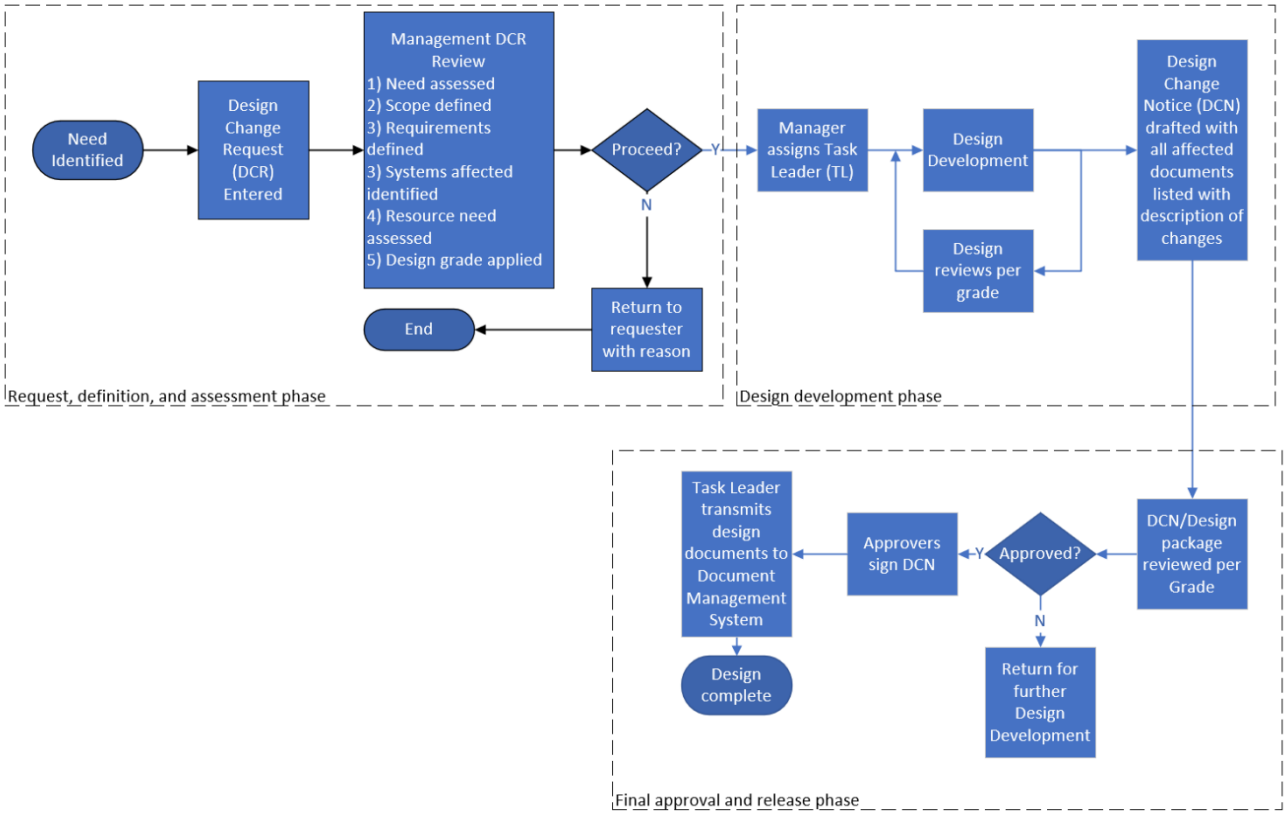

Figure 1: Basic design process in NTD.

All design efforts should include the steps above; however, the rigor and formality may vary greatly depending on the significance of the design and the design complexity. A graded approach (Refs. 1 – 2, and Table 1) shall be used to define the requisite rigor and formality. The graded approach defines the levels of review (drawing and documentation) in addition to the required design reviews and the formality for which each review shall be conducted. For instance, formal design reviews may not be required for simple designs which would not have significant impacts if the hardware failed to meet requirements, but the individual performing the design still needs to communicate with stakeholders to ensure that the design satisfies the requirements for capabilities and performance.

Table 1 provides guidance, not precise prescriptions for applications. For instance, the dollar amounts provided in Table 1 are only suggestions to maintain consistency throughout the division. Work practices are different within the different NTD sections and groups due to the nature of the work, flexibility of the systems, and customer-designer relationships. The onus is on each Group Leader to ensure that sufficient rigor, consistent with the guidance of this document, is applied to the design practice within their group. Additional procedures and/or work instructions should define this rigor.

The graded approach ensures that the degree of formality of the design stages and the extent and independence of the reviewers will match the potential impacts of failure associated with the design. Selection of the grade should be viewed relative to how much risk is assumed in the design effort and the consequences associated with the failure to meet design requirements.

Ideally, the selected grade should reflect:

- The technical risk of the change
- The probability/consequence of failure to meet requirements

- The costs associated with the change
- The complexity of the change (e.g. new technology, difficult interfaces, involvement of multiple organizations, etc.)
- Credited Engineering Control (CEC), HFIR Configuration Item (CI), Accelerator Safety Envelope (ASE), or Unqualified Safety Issue (USI) implications
- The specific hazards associated with the change (e.g., radiological, electrical, pressure, cryogenic, etc.)

Design grades are determined when the DCR is approved and reviewed at each checkpoint and each modification to scope.

2.0 Requirements Definition

Requirements definition is critical to achieve the following objectives:

- Establish the mutually agreed upon performance, cost, and schedule requirements to fully define the scope of the design effort
- Provide a well-defined set of requirements to enable a solution that meets the requirements in the most technically sound, cost effective, and expedient manner
- Ensure that the customer (end user of the design) receives a product that meets their expectations (requirements)

For all work above grade-level 5, and for some grade-level 6 work (see below), requirements necessary to define the scope of work prior to receiving authority to proceed with the design effort shall be documented in the Design Change Request (DCR). If the work is approved by the individual's Group Leader, or by an individual delegated by the Group Leader, it should be assigned to a Task Leader (*The Task Leader is the individual responsible for executing the design change in accordance with this procedure. This individual's job title could come from a variety of disciplines, such as engineer, designer, scientist, technician, etc.*.).

Grade 5 effort is documentation of a design that has already been implemented. Although a DCR is not required since there is no new design work proposed, the drawings and/or documentation created may require a more formal review (meetings, signatures, etc.) to ensure compliance to codes and regulations if the system includes:

- Any kind of stored energy, including gas pressure, vacuum, electrical, etc.
- Radiation safety
- Any other kind of personnel safety

Grade 6 effort is for design that does not affect configuration control.

Before beginning work requiring a DCR, a thorough list of requirements should be established for the design that are specific and verifiable. These requirements should also be documented. The formality of requirements documentation is dictated by the Graded Approach and can range from basic requirements documented in the DCR to a meeting involving many stakeholders and Subject Matter Experts (SMEs) with a subsequent drafting of a Design Criteria Document (DCD). It is critical that all relevant stakeholders and SMEs review and approve the requirements documentation.

The requirements documentation should describe the physical and functional requirements of the design including:

1. Purpose of design
2. Necessary performance or capabilities
3. Relevant interface requirements
4. Form requirements

2.1 Design Development

Once the requirements have been defined and the work is approved, the design phase can begin. The development of a design solution ranges from feasibility and trade studies to detailed equipment drawings,

supporting analyses, and computer models ready to implement. This design development process includes the following three general phases:

- Conceptual Design
- Preliminary Design
- Final Design

The effort in each phase should be determined based on the Graded Approach. However, at each phase in the process, feedback from stakeholders should be solicited to ensure compliance with the defined requirements.

2.2 Conceptual Design

The goal of the Conceptual Design phase is used to determine the technical feasibility of different potential design solutions. These concepts should have enough detail to demonstrate that the solution can meet the defined requirements with additional detailed design and analysis effort to follow. During this phase, reviews of commercially available equipment, preliminary solid modeling, and basic scoping analyses should be used to indicate the feasibility of the concepts. Multiple solutions for an adequate design may be identified.

2.2.1 Depending on the grade, a Conceptual Design Review (CDR) may or may not be required to vet potential design solutions. For simple design problems where the chosen design concept appears to adequately meet the defined requirements, an informal method of providing status to stakeholders is appropriate. If more than one competing design concept is developed, distillation of the best concept should be performed as a part of this review activity.

If the Graded Approach indicates that a formal CDR is required, a meeting should be conducted that satisfies the following considerations:

1. The Task Leader should generate a list of attendees.
2. Attendees should include a diverse group of reviewers that have expertise in the type of equipment and design represented by the presented concept, including all stakeholders, and technical SMEs.
3. Additional SMEs should be involved for those aspects such as fire safety, industrial safety, reactor safety, operations, waste handling, hoisting and rigging, etc., as appropriate to the concept
4. The Task Leader should present:
    a. The statement of design requirements
    b. An explanation of how the design concept(s) would meet the requirements
5. Comments and action items should be recorded
6. Documentation of review comments and action items and their disposition should be included as a follow-up to all attendees.

2.3 Preliminary Design

Following the selection of a suitable design concept, the Preliminary Design phase can commence. The preliminary design should advance the design concept to develop a workable solution and ensure a confidence exists that all requirements will be met by the final design. At the completion of this phase, the design should be at approximately 30-50% completion. The preliminary design effort should include (as a minimum):

- CAD model development as needed
- Interface identification and verification
- Controls/utility requirements
- Preliminary operational use/installation impacts
- Cost and Schedule estimates

When the preliminary design is completed, the preliminary design should satisfy all interface requirements in addition to the defined form, fit, and function requirements. The fidelity of the design and analyses should be at a point where all technical challenges have been met. Analyses should be at a completion level appropriate to establish a high degree of confidence that the final design will meet all requirements.

If the design solution requires procurement of commercial items or components to be designed and fabricated by outside vendors, selection of these commercial items and development of any specification documents should be underway.

2.3.1 Depending on the Graded Approach, a Preliminary Design Review (PDR) may or may not be required. The PDR is intended to establish that the design and will meet all the design requirements (as defined in the requirements document) when it becomes final.

If the Graded Approach indicates that a formal PDR is required, a meeting should be conducted that satisfies the following considerations:

1. The Task Leader should generate a list of attendees.
2. The attendees should include a diverse group of reviewers that have expertise in the type of equipment and design represented by the presented concept, including all stakeholders and technical SMEs
3. Additional SMEs should be involved for those aspects such as fire safety, industrial safety, reactor safety, operations, waste handling, hoisting and rigging, etc. as appropriate to the concept
4. The Task Leader should present:
    a. Summary of the purpose for the design
    b. A review of the requirements
    c. Demonstrate how the design will meet the requirements
    d. A review of the analysis supporting the design
    e. A review of the CDR action items/comments and how they were resolved
    f. A review of the cost and schedule elements of the design
5. All comments and action items should be recorded.
6. Documentation of review comments and action items and their disposition should be included as a follow-up to all attendees.

2.4 Final Design

The final design effort should take the preliminary design and move it to completion. Optimization or minor changes to the design can occur as the result of analysis or operational realities, but the basic design solution should be maintained. If a PDR was conducted, and major obstacles to the preliminary design solution are found that require significant changes to the design, then a “delta PDR” should be held to solicit feedback and confirm compliance with the defined requirements.

2.4.1 A final design review is always required for Grade-3 and higher work but is recommended for all design work.

A final design review (FDR) should be held when the design is at least 90% complete. Assembly and parts drawings should be almost complete. Calculations should be performed such that there is a high level of confidence in the important conclusions. Specifications should be complete with only final release remaining. Preliminary outline procedures for installation and operation should be complete.

The primary focus of the FDR is to present the >90% completed design and to obtain a consensus that the final design meets all the requirements and that there are no impediments to moving forward with fabrication or procurement.

The formality of the FDR is determined by the Graded Approach. If a meeting is warranted, it should satisfy the following considerations:

1. The Task Leader should generate a list of attendees.
2. Attendees should include a diverse group of reviewers that have expertise in the type of equipment and design represented by the presented concept, including all stakeholders and technical SMEs.

3. Additional SMEs should be involved for those aspects such as: fire safety, industrial safety, reactor safety, operations, waste handling, hoisting and rigging, etc., as appropriate to the design.
4. The Task Leader should present:
    a. Summary of the purpose for the design
    b. A review of the requirements
    c. Explanation of how the design meets the requirements
    d. A review of the completed analysis supporting the design
    e. A review of the PDR action items and how they were resolved, if applicable
    f. A review of the cost and schedule elements of the design
5. All comments and action items should be recorded.
6. Documentation of review comments and action items and their disposition should be included as a follow-up to all attendees before the Design Change Notice (DCN) is issued.
7. Release all documentation in the document control system.

The final design documentation effort should include (as a minimum):

- Completion of all models
- Completion of all analyses
- Completion of the detailed assembly and parts drawings
- Completion of specification or other documentation
- Completion of checking of drawings, specifications, and analyses
- Preliminary effort on installation/operational procedures as required

3.0 Release of Design

Following successful completion of the FDR and the completion of any remaining design documentation, design approval is signified by approval of the DCN. Following DCN approval and the release of all design documentation by submittal to EDRM or the HFIR Drawing Database, the package is now ready for the intended use as specified on the DCN.

3.1 Approver Responsibilities

The required DCN approvers are based on the project Grade and given in Table 1. Additional approvers may be added by the Task Leader, or the design organization Group Leader as deemed necessary. Approval of the DCN signifies the approver has reviewed the design package per their role defined below, and concurs the design meets the requirements of their approval scope.

At a minimum, the role of each Approver is as follows:

Task Leader

- Oversee the preparation of a design that meets requirements
- Review and confirm comments and action items generated during the design process were adequately addressed
- Review and confirm project documents were properly prepared in accordance with SNS-NTD-ENG-PC-0001

Technical Reviewer

- Review and confirm the design meets the design requirements
- Review and confirm the appropriate SMEs were engaged throughout the design process and their design concerns were adequately addressed
- Review and confirm critical design concerns are adequately addressed and documented

Group Leader

- Review and confirm the design was prepared per this process and per the appropriate Grade
- Review and confirm all safety concerns were adequately addressed
- Review and confirm the appropriate SME(s) were involved at the appropriate level and are satisfied with the design result
- Review and confirm the appropriate staff were involved in the design and are satisfied the final design and individuals are qualified for their roles
- Review and confirm all Credited Engineering Control (CEC), HFIR Configuration Item (CI), Accelerator Safety Envelope (ASE), or Unqualified Safety Issue (USI) implications have been appropriately addressed by the appropriate staff and documented as required

Design Change Authority

- Ensure the design change has been adequately reviewed, formally approved, and properly documented before fabrication, procurement, or making physical changes in the field.

RRD SREL, HFIR NS CI and/or CEC System Engineer(s)

- Review and confirm the design does not affect the ability of the Research Reactor Division (RRD) Safety Related Equipment List (SREL) or HFIR Neutron Scattering (NS) CI or CEC system to perform its function, or
- Review and confirm any documentation required to update the design and configuration integrity of the Research Reactor Division (RRD) Safety Related Equipment List (SREL) or HFIR Neutron Scattering (NS) CI or CEC system of concern has been properly reviewed and revised

HFIR or SNS Beamline Operations Section Head (OSH) (applicable to instrument work only)

- Review and confirm all concerns unique to installation and operation of equipment at HFIR or SNS have been satisfactorily addressed

HFIR Configuration Manager (CM) (applicable to HFIR instrument work)

- Review and confirm all concerns unique to installation and operation of equipment at HFIR have been satisfactorily addressed

All approvers reserve the right to raise any concern not specifically mentioned above and withhold approval until the concern is addressed to their satisfaction.

Table 1. NTD Graded Approach guidance for design of structures, systems, and components.

Grade	Guidelines	Design Reviews Required	DCN Approvals Required
1 (High)	High cost ($5M+) Affects CEC/ASE, RRD SREL, or USI High adverse consequences High technical risk	CDR, PDR and FDR required	Task Leader CEC and/or SREL System Engineer(s), if applicable Technical Reviewer Group Leader Design Change Approver HFIR or SNS Beamline OSH, if applicable HFIR CM, if applicable
2 (Medium)	Moderate cost ($500k-$5M) Affects HFIR Neutron Scattering Facility CI Affects HFIR Neutron Scatting Instrument CI Moderate consequences Moderate technical risk	CDR required PDR Optional FDR required	Task Leader CI System Engineer(s), if applicable Technical Reviewer Group Leader Design Change Approver HFIR or SNS Beamline OSH, if applicable HFIR CM, if applicable
3 (Low)	Low cost (<$500k) Low consequences Low technical risk	CDR and PDF optional FDR required	Task Leader Group Leader Technical Reviewer Design Change Approver HFIR or SNS Beamline OSH, if applicable HFIR CM, if applicable
4 (Expedited or Routine)	Schedule constraints require immediate attention or low cost (<$50K) and low consequences	Reviews as dictated by the complexity/risk as determined by task leader and management	Task Leader Group Leader Design Change Approver
5 (Documentation)	“Documentation only” effort – no new hardware	No reviews required unless safety significant	Task Leader Others as determined by Group Leader Design Change Approver
6 (Test Hardware)	Test/development hardware not intended for installation into configuration-controlled systems*	Reviews as dictated by the complexity/risk	Engineer Group Leader Design Change Approver

**Configuration-controlled systems include all SNS and HFIR beamlines, Neutron Source, Conventional Facilities, etc. Development Labs and some temporary equipment are not configuration- controlled systems, but safety related equipment still requires drawings and reviews. Each group should have clear definition and oversight for configuration-controlled equipment.*

4.0 References

1. 106000000-WI0001, Target Systems Work Instruction for the Design Change Process Implementation Procedure
2. 802000000-WK10001, Instrument Engineering Work Instruction for the Design Change Process Implementation
3. 108000000-WI0004, Work Instructions for Site Services Group Design Change Process
4. NScD-ENG-PR-001, Engineering Design Change Process in the Neutron Sciences Directorate
5. SNS-NTD-ENG-PC-0001, General Policy on Engineering Practices
6. 802000000-PLC10001, Spallation Neutron Source Design Change Approver List

5.0 Revision Log

0	Initial Issue
1	Updated approvers based on new division structure. Revised wording to Introduction to mention sections to reflect the new division structure. Revised wording to Introduction to mention facilities and structural design due to the addition of the Site Services section to the division. Added references to site services work instruction. Updated Table 1 to include CEC system engineers and group leader in approvers for clarity. Changed title of Section 4 and revised wording to add installation as a possible reason for release.
2	General rewrite to make the process applicable to instrument engineering and to add appropriate reviewers for instrument engineering work. Removed reference to IEP-0100 (obsoleted by this revision). Added Figure 1 design process chart. Added approver responsibilities in section 3.1. Clarified purpose of DCN as releasing document. Modified the graded approach on Table 1 by adjusting limits, adjusting required reviews per grade, and modified required approvers per grade.
3	Refined the terminology of HFIR CI to ensure appropriate grading. Split neutron scattering CIs from RRD SRELs.
4	Added Design Change Approver to Section 3.1. Updated Table 1. Added SNS Design Change Approver List as Reference 6.