9.A-3
RAD System, Structure, Component or Software Change Procedure

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Hand Processed Changes

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SNS Operations Manager — Date

Approved: _____ 08.28.2015
Research Accelerator Division Director — Date

Contacts: George Dodson (RAD Deputy Division Director)
SNS-OPM Editor

SNS-OPM 9.A-3
SNS System, Structure, Component or Software Change Procedure

1. Purpose

This procedure provides a graded process for the review, authorization, and implementation of design changes to existing SNS equipment or software ensuring that Structures, Systems, Components and Software (SSCS) continue to meet their functional and performance requirements.

Design change development shall be conducted in accordance with the graded approach described in SNS OPM 9.A-2, Design Development Procedure

For SNS facility design changes, SNS Site Work Control, 108000000-PR0061 and SNS-OPM 3.A-8.1 "Configuration Management Procedure for the Following Credited Engineering Controls: PPS, TBAC, SBDPMS and TPS" procedures ensure the configuration control aspects of changes to CEC designs and installations. Design changes to other SNS equipment configuration are controlled through the SNS configuration control Policies and Procedures.

1.1. Scope

This procedure delineates the process for authorizing design changes to Research Accelerator Division (RAD) equipment.

2. Responsibilities

2.1. All RAD personnel shall follow this procedure for Design Changes.

3. Prerequisites

3.1. None

4. Precautions

4.1. None

5. Procedure – Design Change Authorization Process

The process begins with an identified need and concept for improving the performance or reliability of a SSCS. Attachments A and B are flowcharts depicting the main flows and milestones of the design change process described herein. Attachment A is the standard Design Change flowchart. The process steps for implementing the standard Design Change are described below.

The possibility exists that an event could occur which causes an interruption of beam delivery to one or more neutron scattering instruments and requires an immediate re-design or modification to a SSCS in order to resume beam delivery. In this case, a more streamlined process is utilized. Attachment B is the flowchart for Time Critical Design Changes. The Time Critical Design Change process addresses the same steps as the standard Design Change process, but in an abbreviated manner, while assuring that adequate design review, approval, verification and documentation activities are completed.

5.1. Identification of a Design Change Need

5.1.1. Anyone has the possibility of recognizing a potential change to a SSCS that would enhance its performance, reliability or maintainability.

5.1.2. This potential change should be communicated to the individual's respective management.

5.2. Management Review of Suggested Design Change

5.2.1. The Requesting Organization shall perform an initial review of the suggested design change. Things to be considered are:

- What is the feasibility of the suggested design change?
- Would the change enhance performance, reliability, or maintainability?
- Are resources available to perform the change and install the modification?
- Is the change worth doing at this time?

5.2.2. Requesting Organization Management shall decide whether or not to proceed with the design change. The process may be placed on hold pending additional funding or a better opportunity to implement the change. If the decision is to proceed, the request is communicated to the appropriate design organization.

5.3. Conceptualization of the Design Change

If the Requesting Organization decides to proceed with the design change the Design Change Request (DCR) process will begin:

5.3.1. The design organization shall be responsible for assigning a unique identifier to the DCR using the NScD Document Reservation System "CR" document subcategory code and applicable work breakdown structure (WBS) number.

5.3.2. The design Group Leader shall assign the request to the appropriate responsible System Engineer.

a. The System Engineer will meet with the individual originally making the suggested change to fully understand the background of the request and to consider the possible conceptual options.
b. The engineer shall identify all affected SSCS, interfaces, and requirements necessary to implement a design solution that meets the intent of the initial request.
c. The responsible engineer shall develop a design concept that meets the technical and operational requirements of the initiator's request. Note that this concept may not be the same as that proposed by the change initiator.
d. The responsible engineer shall develop a preliminary estimate of the cost and schedule associated with implementation of the change.
e. The DCR shall be updated to include a description of the design concept along with the order of magnitude estimate.

5.3.3. If the SSCS originally was developed and certified by a Professional Engineer (PE) and the Requesting Organization wants to maintain that certification, then the services of an appropriate PE need to be incorporated into the team. PEs are required to be directly involved with design projects in order to affix their certification to the applicable design change documents.

5.4. Screening for Potential Unreviewed Safety Issues

5.4.1. As part of the conceptual design change review process, the change shall be screened for potential Unreviewed Safety Issues (USI) using the USI Determination (USID) form (SNS-OPM-ATT 2.B-10.a).

5.4.2. If the USID indicates that a USI does not exist, then retain the USID in the design change package and proceed with the design change process.

5.4.3. If the USID indicates that a USI does exist, then retain the USID in the design change package and proceed with processing the design change package through the USI approval process in accordance with USID procedure (SNS-OPM 2.B-10).

5.5. Decision to Proceed

5.5.1. The completed DCR shall be reviewed by the appropriate level of management for a formal Decision to Proceed. The appropriate level of management oversight required is a function of

a. The criticality of the intended change
b. Availability of resources and budget to implement the change

5.5.2. The formal Decision to Proceed shall be made by the stakeholders, with consideration given to the following criteria:

a. Technical merit of the requested change
b. Adequate definition of the scope and requirements needed to implement the change
c. Projected cost to implement the change
d. Sufficiency of time and resources available to implement the change by the required need date

5.5.3. The Decision to Proceed shall be granted by approval (signature) of the DCR. The approved DCR shall be entered into the Document Control System with distribution to all affected organizations.

5.5.4. If the DCR is not approved, the design organization shall be responsible for communicating to the initiating organization the reasons for disapproval. A DCR that is not approved may be either

a. placed on hold,
b. canceled

5.5.5. Attachment A is the flowchart for the standard Design Change process and shows the specifics of the Standard Design Review process. Attachment B is the flowchart for the Time Critical Design Change process and shows the specifics of the Time Critical Design Review process.

5.5.6. Attachment C "Change Control Review & Approvals" provides guidance in making the determination of the appropriate level of reviews required and the approval authority for design changes. The more critical the SSCS and the more complex the design change, the higher the level of review and approval are necessary to authorize its implementation. This process is shown on the flowcharts. Note that changes to Credited Engineering Controls include different procedures.

5.6. **Change Process Flow**

5.6.1. Attachment A is the flowchart for the standard Design Change process and shows the specifics of the Standard Design Review process. Attachment B is the flowchart for the Time Critical Design Change process and shows the specifics of the Time Critical Design Review process.

5.6.2. Attachment C "Change Control Review & Approvals" provides guidance in making the determination of the appropriate level of reviews required and the approval authority for design changes. The more critical the SSCS and the more complex the design change, the higher the level of review and approval are necessary to authorize its implementation. This process is shown on the flowcharts. Note that changes to Credited Engineering Controls include different procedures.

5.7. **Change Grade Classification of the SSCS**

5.7.1. **The Design Change may require a change to the Grade Classification (see Attachment C - Change Control Review & Approvals) based on a re-assessment of the following:**

- The technical risk of the intended change
- The cost associated with implementation of the change
- The complexity of the change, e.g., whether the change involves multiple disciplines or organizations, whether a potential Unreviewed Safety Item (USI) exists
- Specific hazards (e.g., radiological, pressure, cryogenic, electrical) inherent in the change

5.8. Develop a Conceptual Design

5.8.1. The design organization shall then design the change. Based on the graded approach determination, the following elements shall be included at a level of detail commensurate with the grade.

a. Define and document detailed scope and design requirements.
b. Obtain concurrence/approval from the change initiator that the requirements accurately define the scope of the design change requested.
c. Develop a conceptual design that meets the defined requirements.

5.9. **Conceptual Design Change Review(CDCR)**

The CDCR should have a reasonably diverse group of reviewers with expertise in the type of SSCS represented by the presented concept. Additional subject matter experts should be involved for those aspects such as fire safety, industrial safety, waste handling, hoisting and rigging, etc. as appropriate to the concept. The chair of the appropriate Configuration Control Committee (CCC) shall be notified of the CDCR so that the committee can be represented at the review.

The goal of the conceptual design review is to identify all of the significant technical challenges and issues, to present the design concept to interdisciplinary technical reviewers (including the change initiator) to solicit feedback and demonstrate how the concept has the potential to meet the design requirements. Records of the charge, presentations, conclusions, recommendations, and action items must be filed in the Document Control System.

5.10. Preliminary Design

Develop preliminary design solutions that have the capability to meet all design requirements.

5.11. Preliminary Design Review

5.11.1. Conduct a preliminary design review to present the preliminary design solution to interdisciplinary technical reviewers (including the change initiator) to demonstrate how the preliminary design solution has the capability to meet all defined

requirements. Additionally, the review should address recommendations and action items from the CDR. Records of the charge, presentations, conclusions, recommendations, and action items must be filed in the Document Control System.

5.11.2. Develop and document the final design. The final design should include the following, as required:

5.11.2.1. Drawings, specifications and procedures that fully define the design

5.11.2.2. Supporting analyses to validate the design

5.11.2.3. Equipment specifications, test plans, and acceptance plans required to facilitate procurement, fabrication, and implementation of the design

5.12. **Final Design Change Review (FDCR)**

5.12.1. The final design change should contain the optimized solution for technical issues and design documentation ready for release to modify the SSCS with a high degree of confidence that it will fully perform its intended function and fit into the available space. The chair of the appropriate Configuration Control Committee (CCC) shall be notified of the FDCR so that the committee can be represented at the review.

5.12.2. At the Final Design Review the final design solution is presented to interdisciplinary technical reviewers (including the change initiator) to obtain a consensus that the final design meets all requirements. This consensus shall serve as the design verification. Records of the charge, presentations, conclusions, recommendations, and action items must be filed in the Document Control System. The format for the final design review and design verification shall be determined by the design organization, but it should include the following elements:

- Review of design requirements
- Review of the details of the final design
- Review of supporting analyses and other documents that validate the design
- Review of action items from previous reviews
- Review of changes to planning (e.g., test plans, spares plans, maintenance and obsolescence plans)
- Review of procurement/fabrication planning

5.12.3. Create a Design Change Notice (DCN), using the form Attachment D, to document the design change. The DCN shall reference the original DCR and shall be assigned a unique identifier using the NScD Document Reservation System "CN" document subcategory code and applicable WBS number. The DCN should include the following as a minimum:

- Reason for the change
- Description of the change
- New documents created and existing documents affected
- Identification of impacts to Credited Engineering Controls (CECs), Accelerator Safety Envelope (ASE), etc.

Following the final design review, all documentation shall be reviewed as determined by the graded approach, approved, and released. All documentation

shall reference the DCN number and must be filed in the Document Control System.

5.13. Design Change Approval

The approval of the design shall be documented by review and approval of the DCN. The scope of review and approval of the DCN should be commensurate with the graded approach determination. The approved DCN must then be filed in the Document Control System.

5.14. Design Change Review Records

The principal documentation associated with the design change approval is the DCN, Attachment D. This form summarizes the changes and the justification for making these changes. It identifies if there are Credited Engineering Controls or Accelerator Safety Envelope implications or if a PE certified SSCS is impacted. It also contains the approval signatures of committee members and the PE, if required.

5.15. CCC Review(s)

Design change reviews and authorization shall be made utilizing a tailored approach depending on the significance of the SSCS being changed and the type of change being made. For proposed changes to Grade 1 SSCSs, the CCC shall meet collectively. For changes to Grade 2-4 SSCSs, proposed changes may be reviewed individually; however, it should be recognized that group interactions often provide a more thorough review and should be considered whenever possible. The Grades which require CCC review are shown in Attachment C. Locations in the timeline for CCC Reviews are show on the Flowcharts, Attachments A and B.

The requirements on which to base these reviews include:

- Design of SNS equipment shall be based on sound engineering / scientific principles and appropriate standards
- Appropriate technical design reviews of the change are successfully completed
- All issues uncovered during the technical reviews are sufficiently addressed
- All affected Facilities and groups concur with the change
- Appropriate documentation is completed
- Status of test plans and procedures is satisfactory
- Adequate installation and fallback plans are provided
- Special hazards, considerations and accommodations required for installation and testing are addressed
- Training requirements are addressed
- Disposition of existing in-service and spare parts affected by the change is addressed
- Requirements for additional spare parts are addressed
- Maintenance activities are addressed

5.16. **Design Change Implementation**

5.16.1. Implementation begins with the fabrication/procurement/ work planning steps, which generally include the preparation of the fabrication, procurement, or other purchasing documents.

a. Prepare appropriate fabrication, procurement, and purchasing documents.
b. Compile all design documents prepared in the design phase.
c. Provide procurement resources with documentation.
d. Request bids/quotes, etc., as appropriate.
e. Evaluate bids.
f. Award contract for fabrication/procurement.
g. Make or order components; begin purchases; award subcontracts; or in general take steps to start turning drawings and specifications into tangible objects or system installations.
h. Acquire the necessary material and resources to perform the work. This step can involve a procurement solicitation process to obtain outside vendors or contractors to provide the material, equipment, and labor to complete the task.
i. Provide oversight of the fabrication or procurement activities (e.g., generate nonconformance reports, deviation requests, nonconformance resolutions, receipt inspections, vendor submittals, etc.).

5.16.2. Tracking the SSCS: Prior to Pre-Installation Testing, changes in equipment shall be recorded in the SNS Maintenance Management System (INFOR-DataStream) and changed software shall be loaded into the appropriate software repository

5.16.3. Pre-Installation Testing: An appropriate test plan must accompany each Design Change. The test plan shall be executed by a combination of the System Engineer, the Operations Engineer and others who they deem necessary. After the successful execution of the test plan, the plan shall be signed off by the System Engineer and the Operations Engineer. For Grade 1 and 2 SSCSs an additional CCC review must take place after the test plan has been completed and prior to installation.

5.16.4. Installation: Once the Pre-Installation tests have been successfully completed and reviewed by the CCC, the SSCS may be installed. Installation proceeds under the supervision of the Operations Engineer. At this time, the Operations Engineer assumes responsibility for operating the SSCS. At this time a level of documentation consistent with operation of the SSCS must be available.

5.16.5. Acceptance Testing and Integration: Once the SSCS has been successfully installed, it must be tested and integrated horizontally and vertically, with the Integrated Control System in the Central Control Room, if applicable. The

SSCS must be accompanied by sufficient documentation at this stage to enable testing and assure performance.

5.16.6. Acceptance, release for use and Final Documentation: At the end of the Implementation process, the SSCS is Accepted and turned over to the proper s organization via a System Turnover form. This final step includes completion of the SSCS' documentation.

6. Closeout Phase

6.1. The design change process is not complete until all closeout activities have been completed. It is imperative that the closeout capture key data collected during the design and implementation phases. These data are necessary for safe and reliable operation, maintenance, and future modification of the changed systems. These data serve as a historical record and reference for guiding similar design change activities in the future. Therefore, lessons learned should be included in the closeout documentation. The requirements for closeout completion are listed in the following sections.

6.2. PERFORM CLOSEOUT ACTIVITIES

6.2.1. Revise design documentation as necessary to indicate the final design. Affected documents may include requirements (if they changed during the course of the process), specifications, drawings, fabrication and installation procedures, and test procedures.

6.2.2. Gather all design review data for retention. These include review charges, presentations, reviewer recommendations, and responses to the recommendations.

6.2.3. Gather all procurement and fabrication data for retention. These may include vendor proposals, purchase orders, invoices, quality assurance documents, deviation reports, material certifications, photographs, and vendor test procedures and results

6.2.4. Document all *as-built* deviations from the design.

6.2.5. Document significant lessons learned during the Design and Implementation phases. Specific attention should be focused on those lessons related to personnel safety and technical performance of the changed or affected systems.

6.2.6. Close work packages used in the Implementation Phase.

6.2.7. Finalize operating manuals, service and troubleshooting manuals, and any other documentation that will guide operation and maintenance of the changed

6.2.8. Revise existing manuals as needed. Ensure that all of the above-mentioned data are archived in the document control center for future reference

6.3. CLOSEOUT APPROVAL AND COMPLETION

6.3.1. The responsible engineer shall ensure that all closeout activities are complete. Closeout criteria shall be documented. It is recommended that a checklist be used for documenting closeout criteria.

6.3.2. The responsible engineer shall inform their group leader of closeout completion by means of the completed and signed closeout document, including closeout criteria.

6.3.3. The group leader shall confirm that closeout is complete and sign the closeout document indicating closeout approval.

6.3.4. Closeout documentation shall be filed along with the design change process documentation in the Document Control System.

7. Design Change Documentation

7.1.1. For equipment, the normal documentation of a design change is a revised set of drawings that fully detail the change in design of the SSCS. For some Grades of change, the revised drawing with the change described in the revision block will be the only documentation. For more complex changes, the DCN form will be referenced in the drawing revision blocks and maintained in the design files for the equipment.

7.1.2. Formal design documents including specifications, calculations and drawings shall be updated to incorporate the changes of the DCN as soon as practical.

7.1.3. Software changes shall be self-documented in the body of the software itself.

Note
Design changes are also made through the Supplier Deviation Request (SDR) process and the Nonconformance Reporting (NCR) process. Both of these processes have their own approval systems established by formal procedures. Deviation Request changes may be desired to be incorporated into the design of the SSCS. Nonconformances should never be made a part of the design. These design changes need to be made a part of the design documentation to ensure that the "As-Built" configuration is known as a basis for future SSCS design changes.

7.2. RECORDS

- Final Design Package
- Nonconformance Reports
- Design Change Notices
- Design Change Requests
- Conceptual Design Review documentation
- Preliminary Design Review documentation
- Final Design Review documentation
- Design Closeout documentation

8. References

- NScD-ENG-PR-01 Engineering Design Change Process in the Neutron Sciences Directorate
- ORNL Quality Assurance Program
- SBMS Subject Area – System Engineering (For Guidance)
- SBMS Subject Area - Design
- SNS-QA-P01, SNS Quality Assurance Manual

- SNS-OPM 2.B-10, Conducting Unreviewed Safety Issue Determinations
- NFDD-ENG-001, Drawing Preparation / Control Process
- NFDD-ENG-003, Mechanical Design Development
- NFDD-ENG-005, SNS Digital Signatures

9. Attachments

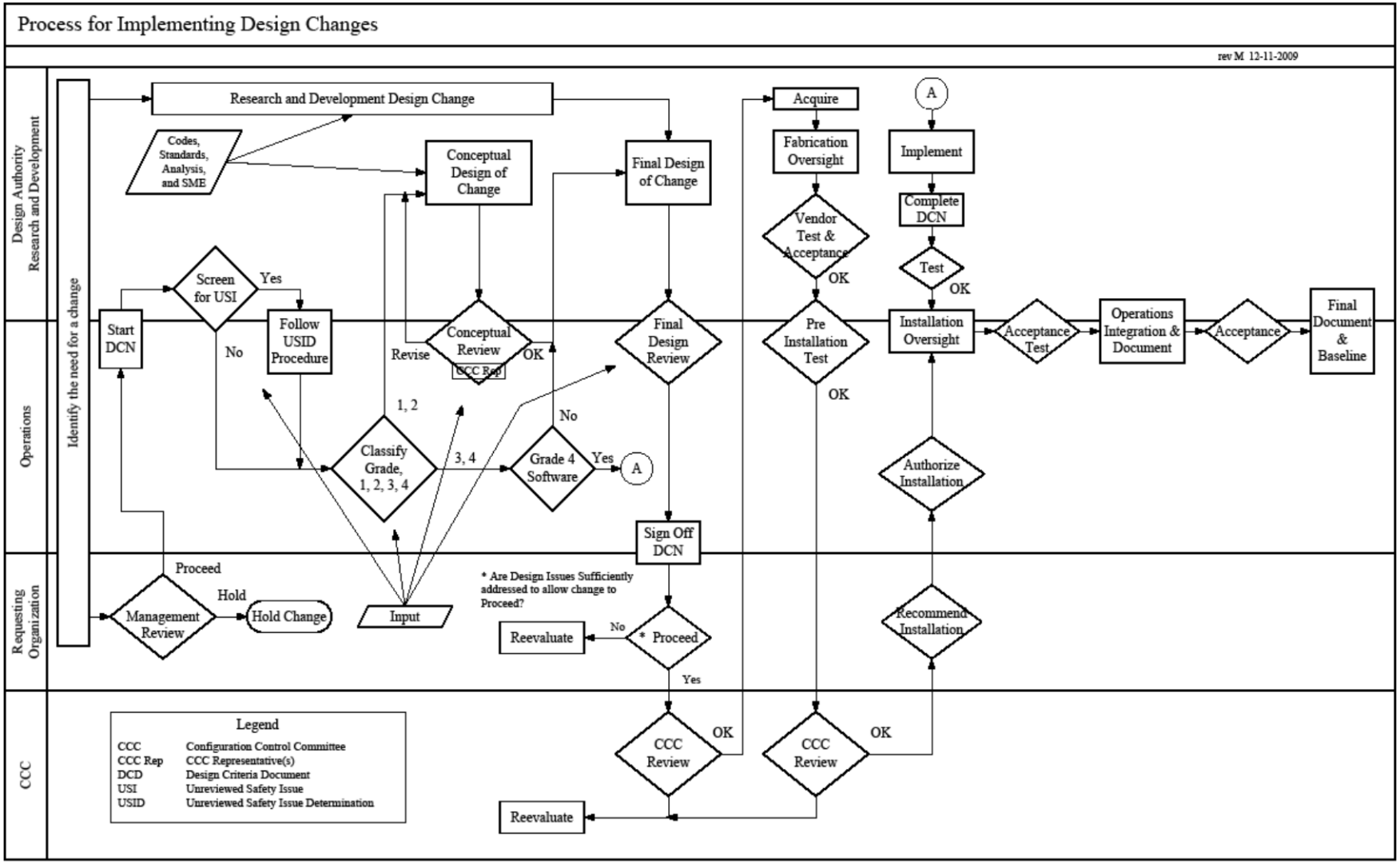
9.1. Standard Design Change Process Flow Chart
9.2. Time Critical Design Change Process Flow Chart
9.3. Change Control Review & Approvals
9.4. Design Change Notice Form

10. Change Revision Log

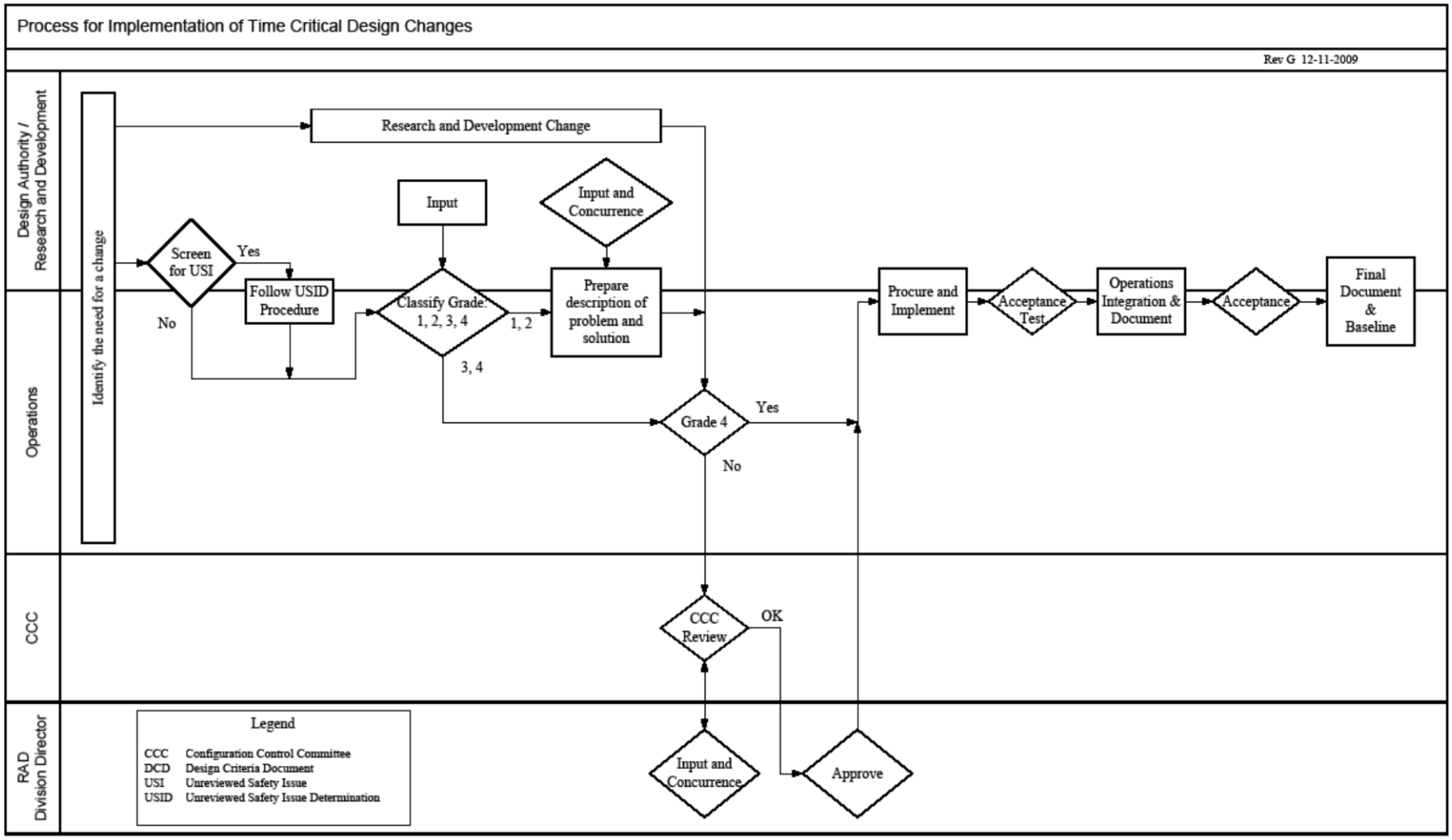
Revision 2

- Procedure now specific only to the Research Accelerator Division, and not to the entire Neutron Scattering Division
- Additions from new procedure NScD-ENG-PR-001 **Engineering Design Change Process in the Neutron Sciences Directorate**

Attachment A
Standard Design Change Process Flow Chart



Attachment B
Time Critical Design Change Process Flow Chart



Attachment C
Change Control Review & Approvals

Grade 1: Affects Safety Systems, Credited Engineered Controls (CEC), Accelerator Safety Envelope (ASE) provisions, and equipment important to personnel safety, equipment whose failure could render the facility inoperable for an extended period of time, or with requirements imposed a higher organizational authority.

Grade 2: Affects Structures, Systems, Components and Software (SSCS) or involves interfaces with other organizations or other facilities, equipment whose failure could render the facility inoperable.

Grade 3: Affects multiple SSCSs within the same facility or has significant potential cost and/or schedule impacts.

Grade 4: Affects only one SSCS without significant cost and/or potential schedule impacts.

Note: In the context of applying the above grading scheme, the term "Facility" is extended down to include individual functional entities such as: an individual beam line; the beam switch yard; the cooling tower; the proton accumulator ring; or the Central Helium Liquefier.

Type of Change	**Equipment / Software/Drawing Grade**			
	Grade 1	Grade 2	Grade 3	Grade 4
	Approval Authority			
"a" **Change of Fit And / Or Function**	System Engineer Team Leader Group Leader QAR & SMEs CCC Operations Engineer	System Engineer Team Leader Group Leader QAR & SMEs CCC Operations Engineer	System Engineer Team Leader QAR & SMEs CCC Operations Engineer	System Engineer SMEs CCC Operations Engineer
"b" **Change of Form**	System Engineer Team Leader Group Leader QAR & SMEs CCC Operations Engineer	System Engineer Team Leader QAR & SMEs CCC Operations Engineer	System Engineer SMEs CCC Operations Engineer	System Engineer Operations Engineer
"c" **Change of Doc.**	System Engineer Team Leader QAR & SMEs CCC Operations Engineer	Design Engineer SMEs System Engineer	System Engineer	System Engineer

Attachment D

Design Change Notice Form

<table>
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DESIGN CHANGE NOTICE</td><td colspan="2">Page Of</td></tr>
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<tr><td colspan="2">Date:</td></tr>
<tr><td rowspan="2">CHANGE PACKAGE TITLE:</td><td>Dwg. No.:</td><td>Sheet No.:</td><td>Rev.:</td></tr>
<tr><td>Spec. No.:</td><td>Section No.:</td><td>Rev. :</td></tr>
<tr><td>SSCS:</td><td>Equip. Grade:</td><td colspan="2">PE Certification Required: [☐] Yes [☐] No</td></tr>
<tr><td colspan="2">USID: [☐] Yes [☐] No Number:</td><td colspan="2">Credited Engineered Control: [☐] Yes [☐] No</td></tr>
<tr><td colspan="4">Reason for Change:</td></tr>
<tr><td colspan="4">Other Documents Affected by this Change:</td></tr>
<tr><td colspan="4">Description of Change: (Provide written description and/or sketch as required.)</td></tr>
<tr><td colspan="2">Prepared by:</td><td colspan="2">System Engineer:</td></tr>
<tr><td colspan="2">System Engineer:</td><td colspan="2">Group Leader:</td></tr>
<tr><td colspan="2">Area Physicist</td><td colspan="2">Team Leader:</td></tr>
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