Guidelines for Completing

Engineering Changes

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Record of Revisions

Revision	Pages	Description of Change	Date
01	All	None	05/06
02	All	None	07/07
03	1, 4, 5	None	05/09
04	All	Change to ECR/ECN process and CM forms.	04/10
05	All	Change to Guidelines and 10 CFR 50.59 Screening Criteria. Update revision numbers to 5.	05/10
06	All	Change to ECR/ECN process, guidelines, and forms. Update reflects improvements based on NCNR response to comments received from 2011 Safety Assessment Committee Audit.	09/12

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Engineering Changes

The National Institute of Standards and Technology (NIST) Center for Neutron Research (NCNR) Engineering Change process comprises two steps.

1. Engineering Change Request (ECR) (NCNR-0001-CM).
2. Engineering Change Notice (ECN) (NCNR-0002-CM).

A third form, the "10 CFR 50.59 Evaluation" (NCNR-0003-CM), is designed as a tool to further examine changes identified as having reactor safety significance. This form must be completed if "YES" responses are received to any of the 10 CFR 50.59 Pre-Screening (completed by responsible individual) or Final Level Determination (completed by approval authorities) questions on the ECR.

Also available to be utilized for determining the impact of engineering changes is a "Quality Assurance Checklist," found at the conclusion of the Quality Assurance Program (NBSR-0002-DOC).

This process is intended to be utilized for change management purposes at the NCNR and is not intended to indicate or infer approval or disapproval of projects.

Engineering Change Request (ECR)

An ECR is a proposal. It is prepared with the aim to either fix an existing problem or to implement a new idea.

The Chief, Reactor Engineering is responsible for processing and tracking all ECRs.

There are no restrictions on who can and who cannot prepare an ECR (and associated ECN). The individual preparing the ECR shall be considered a responsible individual. Any individual involved in execution of a change may also be considered a responsible individual.

The ECR is a vehicle by which the responsible individual(s) of a project informs Reactor Operations and Reactor Engineering of a proposed change to permit evaluation of any potential impact(s) on the operation of the reactor.

An ECR clearly states the scope and interest of the proposed change as well as the problem or issue it intends to address.

A proposed change does not necessarily have to involve a physical component (i.e. a pump) in a system (i.e. secondary cooling system) at the NCNR. The proposed change may be focuses on or result in (engineering) documentation to be either altered or newly created. Examples of NCNR engineering documents that – when changed or newly created – constitute an engineering change are:

a) Safety Analysis Report
b) Technical Specifications
c) Process Drawing
d) Electrical Drawing
e) Mechanical Drawing
f) Other Drawings
g) Procedures
h) Manuals
i) Tests

An ECR contains the following:

a) Engineering Change number – assigned from the Engineering Change Index;
b) Title – should describe the change succinctly;
c) Responsible Individual(s) – individual(s) managing the proposed project;
d) System Code – list of currently designated codes available in the front of the index;
e) Systems or equipment to be changed;
f) Purpose;
g) Description Summary – detailed discussion of the change that supports the answers to the questions asked in the 10 CFR 50.59 Pre-Screening;
h) 10 CFR 50.59 Pre-Screening – questions regarding the safety significance of the change; discussed in further detail below;

i) Performance Improvement – discuss why the change is desirable;
j) Engineering Effort (hours) – approximately how many engineering hours is required and by which engineering group (i.e., ROE, RFO);
k) Operations Effort (hours) – approximately how many operations hours is required; and,
l) Cost (dollars, estimate) – approximately cost required to complete the change (should also include contract spending).

10 CFR 50.59 Pre-Screening

The responsible individual(s) managing the proposed project should understand and be able to identify whether possible reactor safety issues may arise during the course of implementing the change. The 10 CFR 50.59 screening section in the ECR is intended to assist in identifying those issues by having the responsible individual(s) answer a series of questions; while the answer may be Yes or No, it must be fully supported by the information in the Description Summary section.

The first question asks the responsible individual(s) to look holistically at the change and identify if the change has the potential to adversely affect a Structure, System, or Component (SSC) as described in the NBSR Final Safety Analysis Report (FSAR). The FSAR, maintained by the Reactor Operations and Engineering group, contains information on the safety-significant SSCs and design functions.

1. Is the activity a modification, addition, or removal (i.e. a change) to the facility described in the FSAR that has the potential to adversely affect:
    a. A design function of a System, Structure, or Component (SSC)?
    b. A method of performing or controlling the design function?
    c. An evaluation (i.e. computational method) for demonstrating that intended design functions will be accomplished?

The second question asks the responsible individual(s) to identify if the change affects (regardless of positive or negative impact) the design basis limit of a fission product barrier. The fission product barriers and design bases are discussed in the FSAR.

2. Is this a change (either positive or negative) to a design basis limit for a fission product barrier? (i.e. cladding, primary coolant boundary or confinement).

If the answer to any of the above questions is yes (and it is not later examined and determined to be no), then the change must be further examined against the criteria in 10 CFR 50.59 during the ECN phase.

Final Level Determination and ECR Approvals

The completed ECR is brought to the Chief, Reactor Operations and Chief, Reactor Engineering, who jointly determine if the proposed change will be pursued. If it is determined that the change will be pursued, a final level determination is then made of the associated ECN (yet to be developed). The ECR must contain sufficient detail in the Description Summary to make this determination. The first step in the final level determination is to answer the two following questions regarding the change:

1. Does the proposed change have any adverse effect on the design function of the SSCs or accident analysis described in the FSAR?
2. Do any sub-activities under the overall proposed change result in adverse effects as described above? If yes, such activities should be evaluated separately if embedded in a larger engineering change.

The answers to these two questions require an in-depth knowledge of the SSC design functions, accident analyses, and integrated plant operations. If necessary, the Chief, Reactor Operations and Chief, Reactor Engineering may consult with other staff in order to provide informed answers to these questions. If the answer to any of the above questions is yes (and it is not later examined and determined to be no), then the change must be further examined against the criteria in 10 CFR 50.59 during the ECN phase.

Then, two level classifications exist. The change will be classified as a Level I ECN (i.e., Minor ECN), if the change:

1. Does not require a 10 CFR 50.59 evaluation.
2. Is limited in scope, budget, and staff resource commitment (both Engineering and Operations).
3. Does not create a hazard that would be severe or catastrophic.

If the change does not meet the above criteria, it becomes a Level II ECN (i.e., Major ECN).

If an ECR is rejected, no ECN will be prepared and the proposed change will not happen. The reason for disapproval is to be documented on the ECR form. If management has determined implementation of the proposed change is a priority, a different technical approach may be required.

Questions from the Chief, Reactor Operations and Chief, Reactor Engineering that are required to be addressed shall be placed in the Comments section on the ECR.

The ECR is filed under the next available number, to be obtained from the Engineering Change Index maintained by the Reactor Engineering Group (A151). Hence, ECRs are numbered sequentially; the ECN numbering system will show gaps where rejected ECRs exist.

Any disagreement concerning ECR approval, outcome of 10 CFR 50.59 screening, and ECN classification is resolved by the Chief, Reactor Operations and Engineering.

Engineering Change Notice (ECN)

An approved ECR constitutes authorization for the development of an ECN.

The Chief, Reactor Engineering is responsible for processing and tracking all ECNs.

The Chief, Reactor Engineering, or designee, shall be responsible for ensuring documents prepared for the ECN, and safety reviews, are maintained. These documents shall be available for independent review and audits.

The Chief, Reactor Engineering may delegate this responsibility as deemed appropriate.

ECNs shall contain enough descriptive information and technical data such that they can be properly understood and evaluated (some of this work may already have been done at the ECR level). This is especially important for ECNs that involve reactor safety-related systems and/or equipment that require SEC review. The following sections of an ECN shall be addressed individually.

Design Description

1. A description of the ECN with sufficient detail included to adequately communicate the change to an individual knowledgeable about the facility. The description should expand upon the information presented in the Description Summary section of the ECR.
2. State the specifications (i.e. power, cooling or space requirements, etc.) that adequately present the technical requirements of the ECN.
3. Add relevant calculations and graphs such as required to review the development of specifications (i.e. pump sizing, structural calculations, etc.).
4. Provide a general discussion of any necessary installation instructions, schematics, or drawings. It may be determined for review of an ECN that specific check-sheets, drawings/sketches, instructions, procedures, training, etc., are also required to permit any reviewers to appropriately evaluate and comment on a proposed change.
5. If the change necessitates operation of a modified system as part of a retest or immediately following a change, provide a set of operating instructions or modified operating instructions that describes how the modified system is to be operated.
6. If required, a Quality Assurance Plan (QAP) outlining the appropriate points of the NBSR Quality Assurance Program should be submitted. The QAP shall also delineate the review and approval requirements. If submitted, approval of the QAP by the Chief, Reactor Engineering is required. In addition, reviews of appropriate design, development, and documentation stages shall be required and monitored by the responsible individual(s).

Safety Considerations, Identification, and/or Analysis

This part shall identify relevant safety questions and show how they were resolved and clearly justify the conclusions that are summarized in the Safety Evaluation in part below. Enough information shall be provided so that reviewers can satisfy themselves that all pertinent safety questions have been properly addressed.

Typical information to be included is provided below.

1. Any reactor safety questions addressed and their resolution.
2. Summary results of calculations and underlying assumptions.
3. Comparison of system or component function and reliability to that being replaced.
4. Quality assurance used in the fabrication (e.g. certified materials, tests, etc). Also describe any tests, measurements, inspections, etc., that are unusual or are to be performed by outside parties to confirm the design following installation of the engineering change.
5. Probable failure scenarios, protective action, and probable consequences.
6. Potential for radiation exposure or radioactive release.
7. Effect of change on other safety systems including common mode failures and consequences.
8. Potential for fire, flooding, explosion, etc. and proposed protective action.

Required Tests, Retests, Surveillances, or Measurements

This part shall provide a general discussion of how it will be verified that the installation was both properly performed and meets the requirements, and that these activities are adequately documented in the ECN. Examples of tests, retests, surveillances, or measurements are: hydrostatic tests, liquid or gas barrier leak test (e.g. from opening a fluid piping system), verification of proper system operation, reactor startup checklist if components on that checklist were affected by maintenance, etc.

Engineering Documentation Impact Matrix

If the change results in a modification to engineering documentation, then these documents must be identified in the impact matrix in the ECN.

The impact matrix is intended to provide a space to list documents to be changed by type, number, and revision. Examples of document types used at the NCNR are: DWG for drawings, PROC for procedures, SAR for safety analysis report, SPEC for specification, BDR for Building Design Requirements, DOC for document, AR for administrative report, CL for checklist, TR for technical report.

Prior to ECN approval, the responsible individual(s) should only complete the portion of the matrix showing the documents that are to be superseded. If a new document is to be created, the matrix should be annotated with the appropriate “Document Type” and, under “Document Number”, write “New <drawing, procedure, specification, document, checklist, report etc.>”.

Once the documents are drafted and assigned document identifiers, the information should be placed in the matrix in the column identifying the superseding documents. When the documents are approved, a copy of the document should be placed in the ECR/ECN file and the approval date in the matrix updated.

Note: While all affected documents should be identified during the design phase, it is possible that this list may grow following approval of the ECN. This impact matrix should be considered a living part of the ECN and can be updated.

Safety Evaluation (and Conclusion)

This should be a brief narrative, based on applicable design, safety considerations, and an engineering analysis of the proposed change. The conclusion should consider the responses for the "10 CFR 50.59 Pre-Screening" section in the ECR, the "10 CFR 50.59 Evaluation" (if applicable), and should discuss the validity of the reasoning presented in the evaluation. The conclusion should clearly state what impact the change has on the continued safe operation of the facility.

Review and ECN Approvals (by level)

The Chief, Reactor Engineering shall be responsible for ensuring the appropriate reviews and approvals for the ECN are conducted.

The responsible individual(s) shall ensure that all required review signatures and approvals are obtained before implementing any portion of the change.

Level I ECN

1. The fully prepared Level I ECN is presented for approval to the Chief, Reactor Operations and Chief, Reactor Engineering.

2. The Chief, Reactor Operations or Chief, Reactor Engineering may require third party review(s). These third party reviewers are identified by the checkboxes in the Review section on page 1 of the ECN.

3. When signed by both Chiefs, the ECN can be executed.

4. At this point it may become apparent that the ECN was wrongfully classified as a Level I ECN. If this is the case, the ECN is reclassified as a Level II ECN and the Level II review process is executed.

Level II ECN

1. The ECN, including any required attachments (i.e. "10 CFR 50.59 Evaluation" form), is sent to the list of reviewers that is indicated on the ECN form. Determining the number of reviewers as well as defining their subject matter expertise is the combined responsibility of the Chief, Reactor Operations and Chief, Reactor Engineering, who will take proposals from the responsible individual(s). The reviewers are asked to reply with their comments (in writing) before a certain cutoff date. Any comments will be provided in memorandum format and attached to the ECN (as documentation of the review). All reviewers have the right to call a review meeting, which will be organized by the responsible individual(s). Any minutes of such a meeting will be attached to the ECN (as documentation of the review).

2. One special reviewer is the SEC. The SEC reviews every change that requires completion of the "10 CFR 50.59 Evaluation" form. Another special reviewer is the Hazard Review Committee (HRC). The HRC reviews every change where it is identified that there could be a severe or catastrophic hazard.

3. The responsible individual(s) for the ECN shall address and resolve all comments (in writing) received from the reviewers. Any responses will be addressed in memorandum format and attached to the ECN (as documentation of the review). If addressing the comments requires a different technical approach, the ECN shall be revised accordingly. If the changes require a re-evaluation of the safety of the proposal, an additional review of the "10CFR 50.59 Evaluation" shall be done.

   Upon completion of the detailed design and resolution of all comments, the final ECN shall be circulated one last time. The reviewers are invited to review all of the changes and sign the final package. If the reviewers signed the package before all of the changes were made, they should opt to provide their initials and the date acknowledging they were made aware of changes after they initially reviewed the ECN package.

4. Obtain the approval and signatures of the Chief, Reactor Operations and Chief, Reactor Engineering as well as the approval and signature of the Chief, Reactor Operations and Engineering. The ECN sent to the Chief, Reactor Operations and Engineering shall be the final version reviewed by the SEC Chairman or the SEC as a committee. No changes shall be made to the final ECN without the written approval of the Chief, Reactor Operations and Engineering. If the changes to the ECN are judged by the Chief, Reactor Operations and Engineering to be safety related, the ECN shall be returned to the Chief, Reactor Engineering to revaluate. Once approved by the Chief, Reactor Operations and Engineering, the ECN shall be sent to the NCNR Director for final approval.

Closeout of the Engineering Change Process

The responsible individual(s) are responsible for updating the Chief, Reactor Engineering, or designee, with information regarding the status of implementing the change.

Any change in status (drawings changed, procedures changed, SAR updated, work completed, tests/measurements completed) shall be promptly communicated and followed up by the appropriate annotation on the original ECN paperwork.

Any implemented change to engineering documentation shall be reflected on the Engineering Documentation Impact Matrix with the superseding document number, revision, and approval date entered. Copies of the approved documentation should be provided for inclusion in the ECN file.

Completion of any of the following will be documented on the original ECN paperwork with the responsible individual(s) initials and date: Work Completed, Test/Measurements Completed, Drawings Changed, Procedures Changed, and SAR Updated.

The Chief, Reactor Engineering shall ensure that the Work Completed, Test/Measurements Completed, Procedures Changed, Drawings Changed, and SAR Updated boxes have been initialed and dated in a timely manner. Once all of the applicable spaces have initials and dates indicating completion, the ECN may be closed out.

The Chief, Reactor Engineering, or designee, shall maintain a tracking system such that the status of all ECNs can be readily displayed. All ‘in-process’ ECNs are readily available for NCNR personnel to view.

10 CFR 50.59 Evaluation[1]

In performing a 10 CFR 50.59 Evaluation of a proposed activity, the evaluator must address the criteria in 10 CFR 50.59 to determine if prior NRC approval is required. Although the conclusion in each criterion may be simply "yes," "no," or "not applicable," there must be an accompanying explanation providing adequate basis for the conclusion. Consistent with the intent of 10 CFR 50.59, these explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognized, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the 10 CFR 50.59 Evaluation could be very brief.

The importance of the documentation is emphasized by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the safety significance and complexity of the activity.

Since an important goal of the 10 CFR 50.59 Evaluation is completeness, the items considered by the evaluator must be clearly stated. When preparing 10 CFR 50.59 evaluations, the evaluator may combine responses to individual criteria or reference other portions of the evaluation.

[1] Nuclear Energy Institute (February 22, 2000). *Guidelines for 10 CFR 50.59 Evaluations (NEI 96-07, Revision 1, Final Draft). Washington, District of Columbia: Nuclear Energy Institute.*

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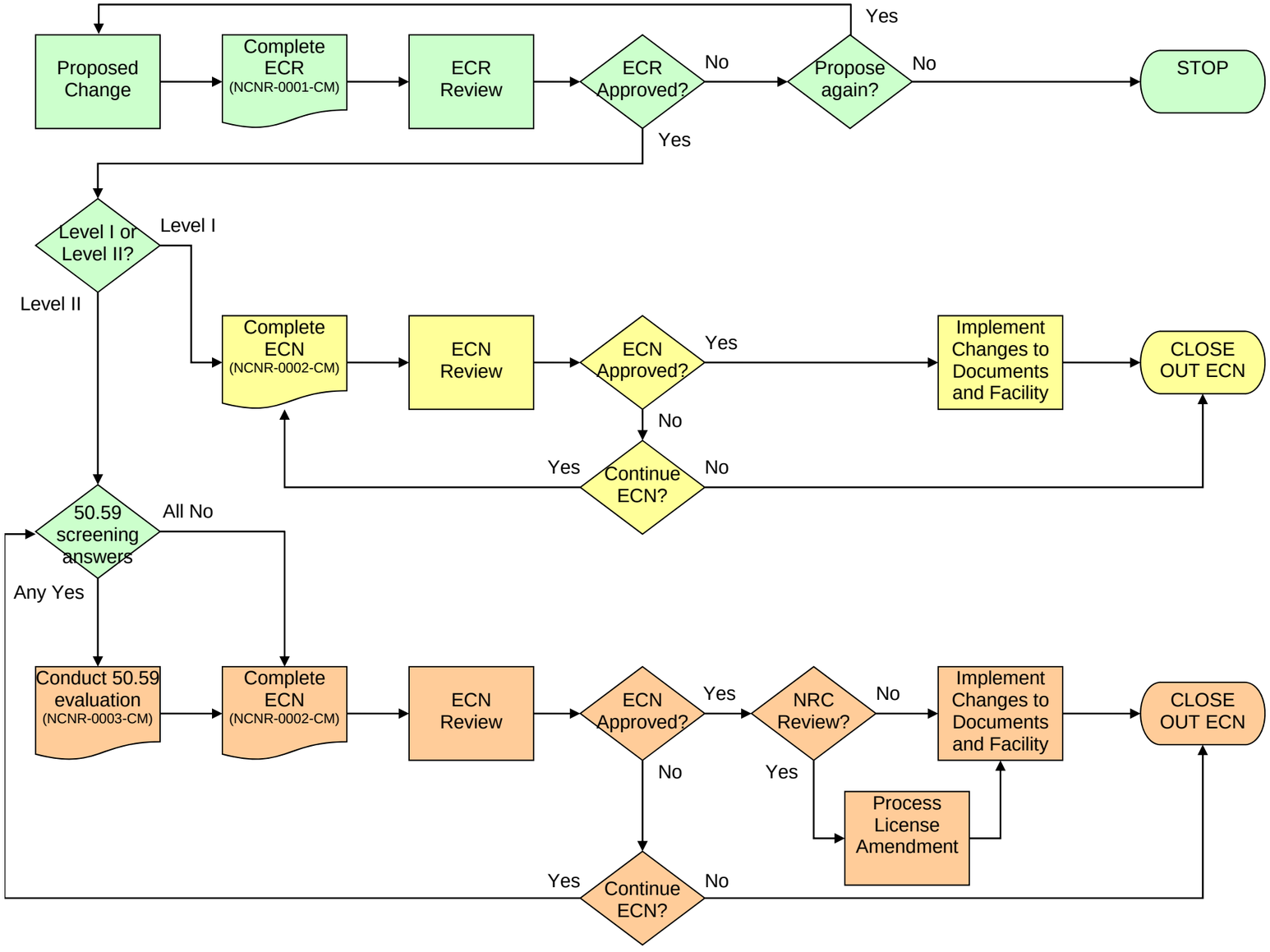

Figure 1 – Engineering Changes Flow Diagram