NEI 09-03, Draft Revision 0

10 CFR 72 LICENSE AMENDMENT REQUEST GUIDELINES

April 2009

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Nuclear Energy Institute

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April 2009

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ABSTRACT

NEI 09-03 describes a standardized process that certificate holders and the NRC staff may use on a voluntary basis to guide the administrative interface during the LAR process. The objective is to improve the efficiency and effectiveness of the certificate holder's preparation and the NRC staff's review by describing key aspects associated with the preparation and review of LARs, such as the use of precedent, the use of standard format and content guidance for LARs, and the resolution of disagreements that may arise during the process. It is not intended to be a guideline for the technical development, validation, review and approval of LARs. While this document specifically discusses license amendment applications, the information contained within is applicable to applications for an initial CoC.

Several aspects are associated with the certificate holder submittals and NRC staff reviews that are required for an initial application or to amend a Certificate of Compliance (CoC) for a spent fuel storage cask. The aspects addressed in this document are:

1. Initiating the License (Certificate) Amendment Process – a certificate holder initiates the license amendment[1] process (pursuant to 10 CFR 72.244) whenever it determines that a proposed activity (e.g., design modification, procedure change) requires modification of the CoC or associated appendices. The License Amendment Request (LAR) process is initiated by the certificate holder pursuant to the regulations (e.g., 10 CFR 72.244) or by NRC direction (e.g., implementation of a generic requirement).

2. Certificate Holder Interface with NRC – a certificate holder communicates with the NRC staff as necessary to facilitate:
   - Pre-submittal communications and meetings.
   - Work planning and LAR submittal schedule.
   - NRC review (acceptance review, RAIs, meetings).
   - Certificate holder submittals that supplement the initial LAR.
   - Certificate holder review of draft CoC and Safety Evaluation Report (SER).
   - NRC issuance of amended CoC for rulemaking (or rejection, or request for withdrawal).
   - Public notification (Federal Register) of the proposed rulemaking.

3. Documentation – A license amendment request may be approved or rejected by NRC, or withdrawn by the certificate holder. Approved amendments are implemented by the certificate holder. Rejected amendments may be appealed by the certificate holder or resubmitted in revised form. Withdrawn amendments may be tabled by the certificate holder or resubmitted at some future time as a new amendment request. In any case, the outcome should be documented for future reference.

4. Resolution of Disagreements – a certificate holder has recourse to administrative processes to request formal resolution of disagreements with the NRC.

[1] The term "license amendment" is used here for simplicity, recognizing that a CoC, not a license is being amended. The acronym "CAR" is often used in other regulatory processes and can cause confusion if used here.

5. Standard Format for LARs and RAI responses – a certificate holder has the option to prepare a license amendment request and RAI responses using the format and content guidance contained in this document.

6. Use of Precedent – a certificate holder seeking regulatory approval to conduct a proposed activity should identify relevant precedent-setting license amendments on its own dockets or on other dockets to support the acceptability of the proposed activity.

Disclaimer – Discussions of activities in NEI 09-03 are illustrative and are not binding on the certificate holders or NRC staff.

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LICENSE AMENDMENT REQUEST GUIDELINES

1 INTRODUCTION

The holder of a 10 CFR 72 Certificate of Compliance (CoC) for a spent fuel storage cask (the "certificate holder") uses administrative means to manage changes to the design and licensing basis for the cask system. Most changes (e.g., design modifications, procedure changes, program changes, etc.) are controlled by the certificate holder, but NRC review and approval is required to change the terms or conditions of the CoC.

The certificate holder evaluates planned changes to determine whether or not prior NRC approval is necessary to implement the planned changes. In this context, "change" is defined by 10 CFR 72.48 *[Reference 1]* as "a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished." Detailed guidance on the implementation of 10 CFR 72.48 is contained in NEI 96-07 Appendix B *[Reference 2]*, which has been endorsed by NRC in Regulatory Guide 3.72 *[Reference 3]*.

In some cases, regulations other than 10 CFR 72.48 establish the criteria for determining whether NRC review is necessary. For example, 10 CFR 72.7 *[Reference 4]* specifies a process that may be used as an alternative to the license amendment process to apply for an exemption from the requirements of a specific regulation.

If the certificate holder's evaluation concludes that NRC approval must be obtained in the form of an amendment to the CoC, the certificate holder must submit a License Amendment Request (LAR) to the NRC in accordance with 10 CFR 72.244 *[Reference 5]*.

While this document specifically discusses license amendment applications, the information contained within is applicable to applications for an initial CoC.

1.1 TERMS AND DEFINITIONS

COMPLEX LAR *[Reference 6]*

A License Amendment Request that needs technical review by more than three technical disciplines.

CURRENT LICENSING BASIS

The current licensing basis (CLB) is the set of NRC requirements applicable to a specific spent fuel cask design and a certificate holder's written commitments for ensuring compliance with and operation within applicable NRC requirements and the spent fuel cask-specific design basis that are docketed and in effect. The CLB includes the applicable NRC regulations; orders; exemptions; FSAR; CoC and associated appendices (including technical specifications); NRC

SERs; certificate holder's written commitments; and all changes made by the certificate holder without prior NRC approval (e.g. 10 CFR 72.48).

LAR ACCEPTANCE

NRC completes an acceptance review and accepts the License Amendment Request for a detailed technical review.

LAR NON-ACCEPTANCE

NRC completes an acceptance review and rejects the License Amendment Request on the basis that there is insufficient information contained in the LAR for the NRC to perform a detailed technical review.

LAR REJECTION

Following LAR acceptance and technical review (including requests for additional information), the NRC rejects the LAR based on insufficient technical information to support approval.

PRECEDENT

Precedent licensing actions are those with a similar technical and regulatory basis. Section 5 provides additional discussion on precedent.

PRE-APPLICATION MEETING

A pre-application meeting is a meeting between the certificate holder and the NRC to discuss the intended scope and content of the LAR and the estimated submittal date to NRC. This meeting is typically a high-level meeting and would occur in the early stages of LAR preparation (multiple months prior to submittal). Additional pre-application meetings may be held as necessary.

PRE-SUBMITTAL MEETING

A pre-submittal meeting is a meeting between the certificate holder and the NRC to discuss the scope and content of the LAR, submittal date, desired review schedule, and utility need. During this meeting, technical details of the LAR will be discussed as appropriate. This meeting typically occurs when the LAR preparation is almost complete (1-2 months prior to submittal). Additional pre-submittal meetings may be held as necessary.

POST-SUBMITTAL MEETING

A post-submittal meeting is a meeting between the applicant and the NRC to discuss various technical aspects of the recently submitted LAR. This meeting may occur during the NRC acceptance review process. Additional post-submittal meetings may be held as necessary.

REQUEST FOR ADDITIONAL INFORMATION (RAI)

An RAI is an official NRC request, usually in the form of a letter, for additional information from the certificate holder that will form part of the basis for the reviewer's safety evaluation. The information is exchanged through formal correspondence and incorporated into the certificate holder's docket file.

2 THE LAR PROCESS

Figure 2-1 provides a flow diagram of the 10 CFR 72 license amendment process as described in this section. Interface between the certificate holder and the NRC during the LAR process is broken down into distinct phases: pre-submittal, post-submittal and implementation/follow-up. These phases are described below.

The basic steps of an NRC LAR review are work planning, safety and regulatory evaluation, documenting results, and rulemaking. With respect to work planning, the LAR acceptance review and technical review schedule are the aspects of interest to certificate holders. The NRC project manager, with technical branch assistance, if necessary, reviews the LAR for completeness. The requirements and key elements of the acceptance review are described in NRC guidance. With respect to the conduct and documentation of the NRC safety and regulatory evaluations, the steps of interest to certificate holders are the treatment of precedent, the review of certificate holder commitments, and the RAI process. The use of precedent is discussed below in Section 5.

2.1 PRE-SUBMITTAL ACTIVITIES

2.1.1 LAR Initiation

A certificate holder initiates the license amendment process whenever it determines that a proposed activity (e.g., design modification, procedure change) cannot be made without prior NRC approval. The License Amendment Request (LAR) process is initiated by the certificate holder pursuant to the regulations (e.g., 10 CFR 72.244) or by NRC direction (e.g., implementation of a generic requirement).

2.1.2 Pre-Application Interface with NRC

Generally, there is frequent interface between the NRC project manager(s) (PMs) and the certificate holder's licensing department. This usually consists of phone calls, e-mails and letters. Occasionally, the certificate holder may meet with the NRC PM(s) and/or management at NRC headquarters. Certificate holders should strive to keep their NRC PM(s) informed of upcoming LARs in a timely manner so the PM(s) can factor the work into their schedule.

For first-of-a-kind (FOAK) and complex LARs, the certificate holder should consider scheduling a pre-application meeting with the NRC staff prior to commencing significant technical work on the LAR. Pre-application meetings can enhance the certificate holder's understanding of NRC expectations and clarify the certificate holder's objectives and technical approach in preparing the LAR and supporting analyses.

Prior to submitting the LAR to the NRC, the certificate holder should consider scheduling a pre-submittal meeting to inform the NRC staff of the technical details and justification for the LAR, and to communicate the desired schedule, typically based on user need. Depending on the complexity of the LAR, additional pre-submittal meetings may be beneficial after the initial

meeting. These meetings are most effective when the members of the NRC staff that attend the pre-submittal meetings are those identified as the potential reviewers for the LAR. It is also beneficial if representatives of the cask user(s) that plan to use the amended CoC attend pre-submittal meetings with the NRC.

2.1.3 Considerations for LAR Preparation

In an effort to preclude repetitive or administrative RAIs, certificate holders should review RAIs from their and other certificate holder's recent LARs. In addition, the certificate holder should review NRC RIS 2007-09: Examples of Recurring Requests for Additional Information for 10 CFR Part 71 and 72 Applications. To further reduce the chance of administrative RAIs, the certificate holder should consider using a technical editor to review the LAR prior to submittal for typographical errors and inconsistencies within the LAR.

The certificate holder should clearly identify references within the LAR. The certificate holder should also consider identifying, within the LAR, the applicable page, section, table or figure numbers from the reference. In cases where the reference may not be easily located or the reference may be large, the certificate holder should consider providing to the NRC, for information purposes, a copy of the reference or specific sections and/or pages from the reference.

2.2 POST-SUBMITTAL INTERFACE

Once an LAR has been submitted to the NRC document control desk, it is advisable for the certificate holder to follow up with an e-mail or phone call to assure receipt of the LAR by the NRC PM. The LAR may also be sent directly to the NRC PM simultaneously.

The NRC review process for the LAR begins with the acceptance review, as shown in Figure 2-1. Upon receipt of the LAR, the NRC project manager, with technical branch assistance if necessary, reviews the LAR to determine whether it appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review. Generally, the NRC will complete the acceptance review within 30 to 60 days of their receipt of the LAR.

If NRC determines that the LAR is not acceptable, they may provide the certificate holder with an opportunity to provide supplemental information. However, if the NRC finds that the deficiencies are too significant, they may terminate the review and return the LAR to the certificate holder with a letter that identifies the deficiencies and the reasons that the review has been terminated.

When the NRC determines that the LAR passes the acceptance review, they notify the certificate holder of the result and the schedule for the NRC technical review and issuance of the draft amendment to the CoC and associated draft SER. The NRC will usually assume one RAI in the review schedule. The NRC will not typically include a schedule for the rulemaking period for CoC amendments.

A post-submittal meeting, with the assigned reviewers, may be beneficial during the NRC acceptance review period to provide background information and to discuss the resolution of issues identified during the pre-application meetings, pre-submittal meetings and acceptance review period.

2.3 REQUESTS FOR ADDITIONAL INFORMATION (RAIS)

After the NRC has accepted the LAR, the NRC will perform a detailed technical review. The basic steps in the NRC technical review process are shown in Figure 2-1 and described in this section. The time required for the NRC to complete the technical review of the LAR is affected by many factors, such as the quality and completeness of the LAR, whether or not the LAR is complex, effective communication between the certificate holder and the NRC, and availability and continuity of NRC technical review staff. However, the general expectation is that the LAR will contain sufficient information for an NRC reviewer cognizant in the technical discipline to complete their review without the need to request additional information from the certificate holder. To achieve this objective, the certificate holder is encouraged to communicate early and often with the NRC in order to develop better mutual understanding of the LAR scope and complexity, as well as the information needed to complete the technical review.

2.3.1 Overview of RAI Process

As stated previously, the objective of submitting a high-quality LAR is that it will contain sufficient information for the NRC to complete its review without requesting additional information. The NRC uses the RAI process when staff believes that sufficient information necessary to support the regulatory review of the LAR is not included in the LAR, is not contained in any other docketed correspondence, or cannot reasonably be inferred from other sources of information readily accessible by the NRC staff. In addition, the NRC staff reviewer may request additional information to evaluate input variables or assumptions significant to safety; applicability or bounding nature of third-party analyses or data correlations; differences between the LAR and relevant NRC guidance documents, e.g., Standard Review Plan, Regulatory Guides, etc.

Frequent and early communication between the NRC PM, the NRC technical staff, and the certificate holder can minimize the need for RAIs.

2.3.2 Factors that can affect the RAI process:

The nature and duration of the NRC staff review depends on the following factors:

- Submittal quality
- Submittal complexity
- First-of-a-kind request
- New or updated technology or methodology
- Margin to design limits
- Access to background information
- Mutual understanding of submittal objectives and expectations
- NRC review personnel changes

- Use of standardization
- Management oversight
- Use of precedent

2.3.3 Steps in the RAI Process

Typically the following steps would be followed in the RAI process:

1. During the technical review, the NRC staff develops clarifying questions. NRC reviewers have the option to categorize individual questions in accordance with Appendix B. The informal use of this standard set of categories can help clarify the regulatory basis for each question and aid the certificate holder in preparing the response.
2. After NRC management review, the NRC sends the clarifying questions to the certificate holder via e-mail or fax. These clarifying questions are typically grouped by discipline (e.g. structural, thermal, etc.) before being transmitted to the certificate holder. However, multiple disciplines do not necessarily have to be included in the transmittal.
3. Typically within a week of receiving the clarifying questions, the NRC and the certificate holder convene a teleconference to discuss the questions. Prior to the teleconference, the certificate holder may categorize the questions in accordance with Appendix B. The goals of the teleconference should be:
   - Ensure mutual understanding of what is being requested.
   - Compare the NRC categorization of the questions with the certificate holder's categorization (optional).
   - Eliminate questions for which information has already been provided by the certificate holder.
   - Eliminate questions for which the NRC agrees the information is not needed to conduct the review or the answer is simple and can be provided on the teleconference.
   - Identify questions for follow-up action.
4. After the teleconference, the certificate holder documents the results, including the clarifying questions, and transmits to the NRC, typically, within 1 to 2 weeks after the teleconference.
5. The NRC dockets the results of the teleconference.
6. After the NRC completes the technical review for all disciplines, including review of the answers to the clarifying questions, an RAI may be issued, by letter, to the certificate holder.
7. The certificate holder may request a meeting with NRC to obtain further clarification on the RAI and/or to discuss a proposed resolution.
8. The certificate holder responds in writing to the RAI in the requested timeframe.

If the LAR is not complex, Steps 1 through 5 may be eliminated at the discretion of NRC.

2.3.4 Subsequent RAI

If an RAI is submitted to the certificate holder, it should contain all questions resulting from a comprehensive review of the application so that a second RAI, if necessary, would only focus on the responses to the original RAI and their adequacy. In other words, the second RAI would be

limited to clarifications or follow-up from the first RAI. If there are no questions on the design resulting in changes to the CoC or associated appendices, there should be no need for a second RAI.

2.3.5 Post-RAI Interface

The NRC may contact the certificate holder with additional clarifying questions during the final stages of the NRC review and SER development. Teleconferences may be held to discuss these clarifications. Based on the teleconference, the certificate holder will appropriately respond (e.g., providing FSAR or CoC markups, commitments to make future changes) in writing.

The NRC will forward the draft CoC, associated appendices, and SER to the certificate holder for review prior to submittal to the rulemaking branch within NRC. Upon receipt of the draft documents, the licensee should review them for completeness and accuracy. If incorrect or incomplete information is identified in any of the documents, the licensee should document the concerns and promptly inform the NRC PM. For errors that conflict with the amendment request, the licensee should request a revised SER from the NRC.

2.4 ISSUANCE OF AN NRC-APPROVED COC AMENDMENT

Once the NRC has completed the technical review and preliminary SER, the draft CoC amendment and appendices are sent to the rulemaking branch within the NRC for publication of a proposed change to 10 CFR 72.214. After the NRC completes the draft CoC/preliminary SER, the documents are published in the *Federal Register* for comment. The NRC will usually publish both a proposed rule and a direct-final rule concurrently in the *Federal Register* with a 30-day public comment period. If no significant adverse comments are received, the direct-final rule will become effective approximately 75 days after publication in the *Federal Register* as stated in the notice. If significant adverse comments are received, the direct-final rule is rescinded and comments are addressed on the proposed rule. The NRC will respond to the comments in an appropriate time and issue the final rule, typically in about 45 days. During the comment resolution period, the NRC may request additional information from the certificate holder, although this is not typically required.

After the rulemaking is complete, the CoC amendment becomes effective and is available for use by any Part 72 general licensee. The certificate holder updates the FSAR to reflect the changes made in the CoC amendment and submits to the NRC pursuant to 10CFR 72.248. Although not required, the NRC may request an FSAR update sooner than the normal two-year update required by 10 CFR 72.248 after a CoC amendment is approved for completeness. It is also helpful for cask users to have an FSAR revision that matches the CoC amendment they plan to use.

2.5 NRC TREATMENT OF ISSUES AFFECTING MULTIPLE SYSTEMS

In the context of NEI 09-03, an RAI affecting multiple systems is a question posed during the NRC review of an LAR that may be applicable to multiple dockets. The NRC does not impose

staff positions that pertain to multiple systems during the review of an individual LAR unless such imposition is necessary in response to an immediate safety or compliance concern. Absent an immediate concern, conformance with the CLB is a sufficient (and necessary) basis for NRC approval of the LAR.

If a certificate holder receives what it believes is an RAI affecting multiple systems, it should forward the question to the NEI Dry Storage Vendor Task Force (DSVTF). The DSVTF will determine if, in their view, the question does indeed affect multiple systems. Upon this determination, NEI will engage the NRC to determine the applicability of the RAI to other systems. The following are three examples of potential questions that could affect multiple systems:

- A request for the certificate holder to implement an ISG.
- A request for the certificate holder to include additional information in the FSAR that is not related to the LAR.
- A request for the certificate holder to perform additional analyses beyond what is contained in the CLB.

Regardless of NEI's efforts, the certificate holder should respond to the question in the context of their specific CoC and amendment request.

3 DOCUMENTATION OF RESULTS

3.1 LESSONS LEARNED

Periodically, the certificate holders and the NRC should conduct meetings or teleconferences to discuss lessons learned and potential process improvements. The DSVTF should meet with the NRC, when appropriate, to discuss generic lessons learned from recent licensing activities.

3.2 RESOLUTION OF DISAGREEMENTS WITH THE NRC

In some cases, the NRC may respond to the LAR by rejecting it during the acceptance review, requesting additional information during the technical review, or denying it upon completion of the technical review. If a certificate holder disagrees with the NRC position, it has recourse to the following steps.

- Initiate discussions with NRC (teleconference, e-mail).
- If warranted, engage industry, NEI and NRC management in the regulatory dialogue. Consider the following options:
  - Request a meeting with the NRC to discuss the disagreement. Document the expectations, interpretations and factual information discussed during the meeting. Prepare a resolution plan and schedule.
  - Request generic resolution through the DSVTF interface.
- Request interpretation by the NRC Office of the General Counsel (OGC). Official NRC interpretations are limited to those contained in documents reviewed by, or statements made by, OGC.
- Request an NRC regulatory analysis pursuant to NUREG/BR-0058 *[Reference 7]*.
- File a petition for rulemaking, if applicable.
- Request a hearing pursuant to 10 CFR 2 *[Reference 8]*.
- Seek judicial remedy through the courts.

4 STANDARD FORMAT FOR LARS AND RAI RESPONSES

4.1 TEMPLATE FOR THE LAR

Appendix A is an example of a standardized format that certificate holders may use on a voluntary basis to prepare a proposed request for an amendment to the CoC for a spent fuel cask. It provides a standard format for the following:

- Cover letter (required).
- CoC and associated appendices page markups (required).
- Summary of proposed changes (optional)
- FSAR page markups (required).
- Retyped CoC and associated appendices pages (optional).

4.2 IDENTIFICATION OF CHANGES NOT REQUIRING NRC APPROVAL

Certificate holders are required by 10 CFR 72.248 to provide biennial updates of FSARs to the NRC that include changes made under 10 CFR 72.48 without prior NRC approval. However, a certificate holder may need to submit a LAR that includes changes made via 10 CFR 72.48 that did not require prior NRC review, but are needed to support the changes requested by the LAR. In this case, the certificate holder must clearly identify and differentiate those changes that have been made via 10 CFR 72.48 from the changes in the LAR that require NRC review. It is recommended that the certificate holder provide a summary of changes with the LAR, in which changes made under the provisions of 10 CFR 72.48 are identified. If practical, the certificate holder may also consider using a unique change indicator for changes that have been made under 10 CFR 72.48 or are associated with a concurrent LAR.

4.3 RAI RESPONSE FORMAT

A recommended format for the RAI response is to repeat each question from the NRC and then provide the answer. Certificate holders may choose to split up complex RAIs into sub-questions for clarity, without changing the overall RAI numbering scheme the NRC used. If changes to the FSAR or CoC occur as a result of the RAI, these changes should be discussed in the RAI response.

The certificate holder must ensure that each question is addressed in its entirety. Often the NRC poses questions with several parts and/or subparts. The certificate holder must exercise caution to ensure each part of each question is answered.

5 USE OF PRECEDENT

Precedent-setting licensing actions can help reduce the certificate holder's developmental effort, reduce the need for NRC RAIs, lead to a more predictable and abbreviated regulatory review schedule, and improves the consistency among similar licensing actions. However, limitations accompany the use of precedent. The certificate holder has the primary burden to identify relevant LARs, Topical Reports, NRC SERs, or other precedent-setting correspondence or regulatory actions. Differences between the certificate holder's LAR and the referenced precedent(s) must be identified and a disposition provided as either acceptable or not applicable.

The effective use of precedent has three main components:

- Access to NRC-approved, precedent-setting documents.
- Certificate holder submittal of an LAR that provides appropriate justification based on the precedent SER and supporting documents (i.e., applicability, differences, acceptability of differences, etc.).
- Informal agreement with the NRC that the proposed precedent would improve the efficiency of the regulatory review.

5.1 SOURCES OF PRECEDENT

The following are possible sources for identifying NRC-approved precedent-setting amendments, Topical Reports, and NRC SERs:

- Certificate holder experience with similar amendments
- Information search services
- Nuclear industry groups:
    - Nuclear Energy Institute (NEI)
    - Standards organizations
    - Groups formed in response to a particular technical issue
- Electric Power Research Institute (EPRI)
- Government sources:
    - NRC Agency-wide Documents Access and Management System (ADAMS)
    - NRC Public Document Room
    - NRC Web Site
    - Federal Register
- Topical Reports for which NRC has issued generic safety evaluations.

5.2 APPLICABILITY OF PRECEDENT

An LAR that relies on precedent should reference the affected CoC(s) and amendment number(s), and discuss how the precedent applies to the specific circumstances of the proposed amendment. Precedent, by itself, does not demonstrate the acceptability of a proposed amendment, but it does give the NRC information about how the agency has treated similar changes in the past.

5.3 CERTIFICATE HOLDER TREATMENT OF PRECEDENT

The following considerations relate to the identification and use of precedent:

- The use of precedent is voluntary. However, the NRC recognizes that there are significant efficiencies to be gained by using applicable precedent, especially for LARs that are FOAK, technically complex, or based on a generic topical report. Therefore, a useful early step in preparing the LAR is to identify, assess, and review potential precedents.
- Typically, a single precedent is sufficient, although certificate holders may cite multiple precedents.
- The certificate holder has the primary responsibility to identify precedent.
- The NRC may, but is not obligated to, identify potential precedents. If so, it is the certificate holder's obligation to ensure that the proposed precedent is appropriate.
- Regardless of the precedent source, discuss how the precedent applies to the LAR. Look for consistency with respect to:
  - Physical characteristics.
  - Design basis.
  - Risk significance.
  - Scope and depth of technical justification.

- The precedent-seeking certificate holder has the obligation to perform a thorough design/licensing basis comparison to verify that the proposed precedent is appropriate for use in the proposed amendment. Identify and justify all differences between the precedent and the LAR that are relevant to the issue being addressed by the proposed amendment. Even if the LAR closely follows the precedent, associated applications may be sufficiently different that the proposed precedent might not apply either in whole or in part.

- Include a summary of the precedent(s) in the submittal. The summary should include:
  - A discussion of how the precedent(s) applies to the LAR.
  - A discussion of the differences between the certificate holder's application and the precedent certificate holder's application that are relevant to the scope of the LAR.
  - References to all precedent-related documents, e.g., LARs, LAR supplements, RAIs, NRC SERs, etc.

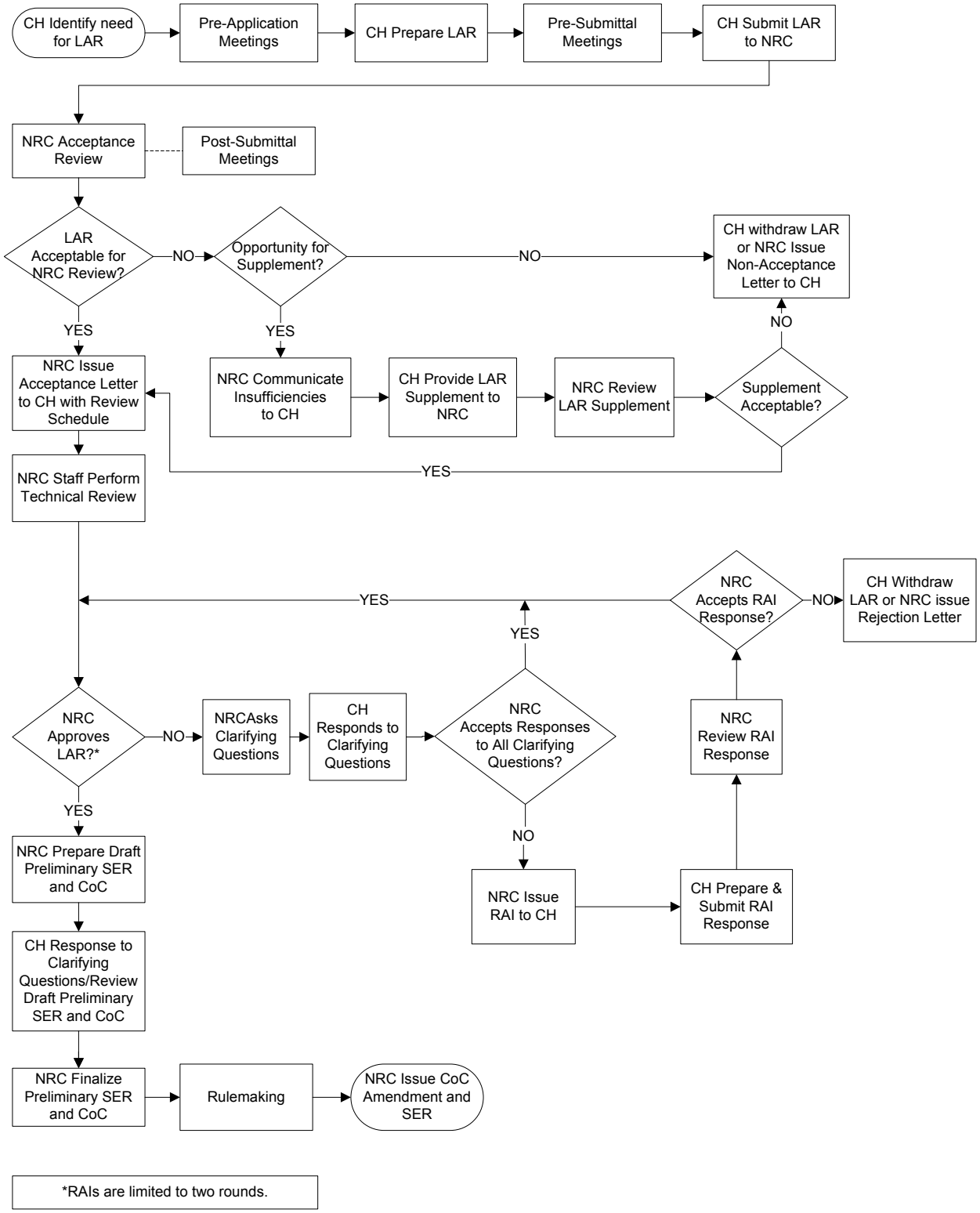
- Communicate the proposed use of precedent to the NRC Project Manager (PM) early in the development of the LAR. NRC PMs can facilitate and expedite the exchange of information with technical reviewers.
- Request pre-submittal discussions with NRC if that would be useful in determining scope, format, and technical content. This step is advisable if the submittal is technically complex or FOAK. The pre-submittal interface could facilitate follow-up action, e.g., expanding the precedent search or resolving NRC staff concerns.
- Provide feedback to NEI regarding precedent experience.

5.4 NRC TREATMENT OF PRECEDENT

Precedent documents can be a valuable input to the NRC work plan and the SER. They can help the PM and technical branches develop a review plan, identify a lead reviewer, avoid duplication of past RAIs, and reduce the overall resources necessary to complete the review.

The proposed precedent is reviewed for applicability, accuracy, and completeness when compared with the incoming LAR. The NRC staff verifies that the precedent is appropriate for use with the LAR and meets current NRC expectations with respect to format, content, guidance, and findings.

FIGURE 2-1
LAR Flow Chart



APPENDIX A
STANDARD FORMAT FOR LARS FROM CERTIFICATE HOLDERS

(*Date*)

U. S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852-2738

Attn.: Document Control Desk

Subject: Request for an Amendment of Certificate of Compliance (CoC) No. *XXXX* for the *Generic* Storage System to Incorporate Changes to the Certificate of Compliance, the Technical Specifications and the Final Safety Analysis Report (FSAR)

Docket No. 72-*XXXX*

References:
1. Certificate of Compliance No. *XXXX*, Amendment *Y*, for the *Generic* Storage System, U.S. Nuclear Regulatory Commission (NRC), (*Date*)

2. Final Safety Analysis Report for the *Generic* Storage System, Revision *X*, (*Certificate Holder*), (*Date*)

(*Certificate Holder*) herewith submits a request for approval of an Amendment to the *Generic* Storage System CoC and Technical Specifications (Reference 1) to incorporate changes based on (*give summary*). In addition, some editorial changes are being requested to improve clarity and consistency within Reference 1 and Reference 2 (*as applicable*).

The list of proposed changes to the *Generic* Storage System Amendment *Y* CoC, Technical Specifications (Reference 1) is provided in Attachment 1and the FSAR (Reference 2) is provided in Attachment 2 to this letter.

The list of changes for the License Drawings is provided in Attachment 3 to this letter.

This submittal includes N copies of the proposed Amendment *Z* CoC, Technical Specifications and Revision (*X.A*) FSAR changed pages. The revised Technical Specification pages incorporate the requested amendment changes noted above. Revision bars in the margin of the affected pages indicate the proposed changes.

In accordance with the (*Certificate Holder*) licensing document control procedures, the proposed FSAR revision is numbered to uniquely identify the applicable changed pages. The revised List of Effective Pages and Pages *aa-a, bb-b* and *cc-c* include 10 CFR 72.48 changes that have been implemented since the updated *Generic* Storage System FSAR, Revision *X* was issued. (*Describe how the 72.48 changes are identified or provide List of 72.48 Changes.*) Upon final approval, the changed pages will be reformatted, assigned the next appropriate revision number and incorporated into an updated revision of the *Generic* Storage System FSAR.

The NRC is requested to complete the review of these proposed changes and issue a draft CoC and Safety Evaluation Report by (*date*). The desired final effective date for this proposed amendment is (*date*). (*Provide justification as necessary.*)

If you have any comments or questions, please contact me at (*telephone number and/or email address*)

Sincerely,

(*Certificate Holder*)

Attachment 1: List of Proposed Changes, CoC No. *XXXX*, Technical Specifications

Attachment 2: List of Proposed Changes, *Generic* Storage System FSAR, Revision (*X.A*)

Attachment 3:List of License Drawing Changes, Generic Storage System FSAR, Revision (*Unique Identifier*)

Enclosures: Changed Pages for the Generic Storage System Final Safety Analysis Report, Revision (*X.A*) (N hard copies) and Proposed Amendment *Z* CoC, Technical Specifications

Attachment 1

List of Proposed Changes

CoC No. *XXXX*, Technical Specifications

List of Proposed Changes to the CoC, Technical Specifications for the *Generic* Storage System

Proposed CoC Change for Amendment No. *Z*

Page a, nth paragraph, nth sentence – Deleted "…"

Proposed Technical Specifications Changes – General

Revised "…".

Proposed Changes in Appendix A, Technical Specifications for the *Generic* Storage System

- Pages A*a-a* & Aa-b – Revised ….
- Page A*a-c* – Deleted "…".
- Page A*a-d* – Added "…"

Proposed Changes in Appendix B, Technical Specifications for the *Generic* Storage System

- Pages B*a-a* & Aa-b – Revised ….
- Page B*a-c* – Deleted "…".
- Page B*a-d* – Added "…"

Attachment 2:

List of Proposed Changes,

Generic Storage System FSAR, Revision (*X.A*)

List of Proposed Changes to the FSAR for the *Generic* Storage System

Proposed *Generic* Storage System FSAR Changes Required to Support the Proposed Tech Spec Changes

List Changes by Chapter/Page/Section/etc.

Attachment 3

List of License Drawing Changes

Generic Storage System FSAR, Revision (*Unique Identifier*)

License Drawing *Number*, Drawing *Title*, Revision No.

Detailed list of changes:

- XXXXXXX
- XXXXXXX
- XXXXXXX
- XXXXXXX
- XXXXXXX
- XXXXXXX

License Drawing *Number*, Drawing *Title*, Revision No.

Detailed list of changes:

APPENDIX B
RAI QUESTION CATEGORIES

The following framework classifies the reasons for RAI questions into four categories. The framework is provided for voluntary use by NRC staff and certificate holders during the RAI process. Certificate holders may find the framework useful when responding to RAI questions, or as a source of lessons learned for improving LAR quality.

1. CATEGORY 1 – the reviewer is requesting additional information because:
   a. the LAR is complex, e.g., new cask design,
   b. the LAR is first-of-a-kind, e.g., based on new technology,
   c. the LAR is affected by an NRC management decision to change regulatory policy,
   d. the LAR proposes the use of new methods/guidance,
   e. the LAR proposes a reduction in safety margin, or
   f. the reviewer has concerns with respect to previously approved methods/guidance.

   Category 1 RAI questions are a necessary and expected part of the LAR process.

2. CATEGORY 2 – the reviewer is requesting additional information to evaluate:
   a. input variables or assumptions,
   b. the methodology used or the results obtained,
   c. the applicability or bounding nature of third-party analyses or data correlations,
   d. the differences between the LAR and relevant NRC guidance documents, e.g., Standard Review Plan (SRP), Regulatory Guides, etc.,
   e. conformance with applicable regulatory requirements,
   f. potentially incorrect information, or
   g. potentially inadequate responses to previous RAI questions.

   Category 2 questions highlight the types of information NRC expects to see in the LAR. Thus, certificate holders can use categorization information to adjust the standard content of LARs to better meet NRC expectations.

3. CATEGORY 3 – the reviewer is requesting additional information which:
   a. is not directly related to the LAR,
   b. is inconsistent with applicable codes, standards, Regulatory Guides, or SRP sections,
   c. does not appear to be needed given the precedent cases discussed in the LAR,
   d. is not safety significant or is not pertinent to the regulatory finding that needs to be made,
   e. should be known to engineers that work in the general technical area addressed by the LAR,
   f. is outside the scope of the current licensing basis,
   g. is a formal commitment as a condition of NRC approval,
   h. is already in the LAR, or
   i. is accessible from readily available sources that were explicitly referenced in the LAR.

   Designating an RAI question as Category 3 does not necessarily mean that it should not be processed as an RAI question. For example, a certificate holder may choose to answer

questions that fall in Categories 3.h and 3.i to assist the reviewer in locating pertinent information.

4. CATEGORY 4 – the RAI question does not fall into one of the other three categories.

APPENDIX C
ACRONYMS

All acronyms should be spelled out the first time they are used. The acronym should then appear in parentheses following the complete spelling (e.g., Unites States Nuclear Regulatory Commission (NRC), Nuclear Energy Institute (NEI), or reactor coolant system (RCS)).

ADAMS	Agency Documents Access and Management System
ASME	American Society of Mechanical Engineers
BWR	Boiling Water Reactor
CFR	Code of Federal Regulations
CLB	Current Licensing Basis
CoC	Certificate of Compliance
EPRI	Electric Power Research Institute
FOAK	First-of-a-Kind
FSAR	Final Safety Analysis Report
ISG	Interim Staff Guidance
LAR	License Amendment Request
NEI	Nuclear Energy Institute
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
OGC	Office of the General Counsel
OL	Operating License
PM	Project Manager
PWR	Pressurized Water Reactor
RAI	Request for Additional Information
RIS	Regulatory Issue Summary
SER	Safety Evaluation Report
SFST	Division of Spent Fuel Storage and Transportation
SOC	Statements of Consideration
SRP	Standard Review Plan
SSC	Structure, System, or Component
TS	Technical Specification
UFSAR	Updated Final Safety Analysis Report
USC	U.S. Code

APPENDIX D
REFERENCES

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[1] 10 CFR 72.48, "Changes, tests and experiments."

[2] NEI 96-07, Appendix B, "Guidelines for 10 CFR 72.48 Implementation," March 2001.

[3] NRC Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments" March 2001.

[4] 10 CFR 72.7, "Specific exemptions."

[5] 10 CFR 72.244, "Application for amendment of a certificate of compliance."

[6] NRC Regulatory Issue Summary 2005-27, Rev.1, "NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review."

[7] NRC NUREG/BR-0058, revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," September 2004.

[8] 10 CFR 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders."