

# NEI 06-02

## GUIDELINES FOR PREPARING LICENSE AMENDMENT REQUESTS

\_\_\_\_\_ 2006

Guidelines for Preparing  
License Amendment Requests (LARs)

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Guidelines for Preparing  
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## ABSTRACT

Several administrative processes are associated with the licensee submittals and NRC staff reviews that are required to amend the operating license for a commercial nuclear power plant.

The processes are:

1. License Amendment Request (LAR) Threshold – the process used by a licensee to determine the threshold at which a proposed activity (e.g., plant modification, procedure change) must be submitted to the NRC for prior NRC staff approval.
2. Use of Precedent – the process used by a licensee to identify precedent-setting LARs or NRC safety evaluations (SEs) that support the acceptability of a proposed activity.
3. LAR Preparation – the process used by a licensee to prepare a LAR using format/content guidance prepared by the NEI Licensing Action Task Force (LATF).
4. Request for Additional Information (RAI) Process – the process used by the NRC staff to request, and for a licensee to provide, additional information necessary to complete the regulatory review of a LAR.

This Guideline describes a standardized process that licensees may use on a voluntary basis to prepare plant-specific LARs. It has been endorsed by NRC in

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## 1.0 LICENSE AMENDMENT REQUEST (LAR) THRESHOLD

The term “threshold” in this guideline describes the decision point for either (1) submitting a LAR in accordance with 10 CFR 50.90<sup>1</sup> to obtain prior NRC approval of a proposed activity, or (2) using an alternative process to determine that prior NRC approval is not required. To define the threshold, it is necessary to describe the alternatives to the LAR process.

To determine whether an activity requires prior NRC approval, the licensee must evaluate all planned actions associated with the activity that involve a change to the facility. In this context, “change” is defined by 10 CFR 50.59<sup>2</sup> as “a modification or addition to, or removal from, the facility 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.”<sup>3</sup>

The potential impact of changes must be evaluated in accordance with 10 CFR 50.59, or other applicable regulations that “establish more specific criteria for accomplishing such changes.”<sup>4</sup> For example, 10 CFR 50.54(a) and 10 CFR 50.54(q) establish criteria for changing the quality assurance program and the emergency plan, respectively.

### 1.1 10 CFR 50.59 Process

10 CFR 50.59<sup>5</sup> establishes the framework under which a licensee may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval. In summary, a licensee may modify the plant and associated documents (procedures, drawings, updated final safety analysis report, etc.) without prior NRC approval unless:

- the Operating License (OL), including appendices (e.g., Technical Specifications), must be revised to permit implementation of the modification, or
- the modification meets one or more of the criteria in 10 CFR 50.59(c)(2).

10 CFR 50.59 was revised in October 1999<sup>6</sup> to (1) clarify the specific types of changes, tests, and experiments that require an evaluation pursuant to 10 CFR 50.59, and (2) revise the criteria used to determine when prior NRC approval is necessary. The 1999 rulemaking added definitions for terms that had been subject to differing interpretations, and it reorganized the rule language for clarity. In November 2000, the Nuclear Energy Institute (NEI) published revision 1 to NEI Guideline 96-07<sup>7</sup> to assist licensees in implementing the revised rule. That same

month NRC published Regulatory Guide 1.187,<sup>8</sup> which endorses the revised NEI Guideline.

#### 1.1.1 The 10 CFR 50.59 Screening Process

*[add brief description from 96-07]*

#### 1.1.2 The 10 CFR 50.59 Evaluation Process

*[add brief description from 96-07]*

#### 1.1.3 Sources of Information for 10 CFR 50.59 Screening/Evaluation

The primary source of information for performing a 10 CFR 50.59 screening/evaluation is the final safety analysis report (FSAR). The FSAR includes text, tables, figures, and other information that is explicitly "incorporated by reference." *[define IBR]* Simple reference listings within the FSAR and information outside the FSAR that is not incorporated by reference is not subject to the 10 CFR 50.59 process.

10 CFR 50.71(e)<sup>9</sup> requires that the FSAR be updated at least once per refueling cycle. Between formal updates, FSAR pages that have been updated but not submitted to NRC may be relevant to the evaluation of a pending change and should be considered as part of the "updated final safety analysis" (UFSAR) when conducting the 10 CFR 50.59 screening/evaluation process. Guidelines for updating the FSAR are contained in NEI 98-03.<sup>10</sup>

Additional sources of information include the Operating License (OL), the Technical Specifications, the technical specification Bases, and docketed correspondence with the NRC. Additional sources of information are used as necessary to assure that all relevant information is evaluated. The information is reviewed by licensee personnel familiar with the change to help ensure a complete and accurate review.

### 1.2 Other Processes

In addition to 10 CFR 50.59, there are several complementary processes for controlling activities that affect other aspects of the licensing basis, including:

- Amendments to the Operating License or Technical Specifications pursuant to 10 CFR 50.90.
- Changes to documents controlled by Technical Specifications, such as the Offsite Dose Calculation Manual (ODCM).
- Changes controlled by 10 CFR 50.54 change processes (i.e., quality assurance program, security contingency plan, and emergency plan).

- Changes that require an exemption from a regulation in accordance with 10 CFR 50.12.
- Changes to licensee commitments in accordance with NEI 99-04.<sup>11</sup>
- Changes to the standard fire protection license condition (Generic Letter 86-10).
- Maintenance activities, including temporary changes in support of maintenance, in accordance with 10 CFR 50.65.

### 1.3 Resolution of Disagreements

The “statements of consideration” (SOC) that accompany the publication of a new or revised regulation typically include background information to help readers interpret the regulation. However, interpretations evolve over time to accommodate new technical information, operating experience, inspection experience, changes in personnel, unfamiliarity with precedent, and other factors. The two main topics subject to interpretation within the context of 10 CFR 50.59 are the use of PRA and the use of new or revised methods of evaluating postulated accidents.

If a member of the NRC staff stipulates that a proposed activity by a licensee requires prior NRC approval by means of a license amendment, but the licensee disagrees, the licensee has recourse to the following options to ensure that prior NRC approval is either consistent with 10 CFR 50.59 (i.e., is not a new or different interpretation) or is otherwise justified:

- Request a public meeting with NRC to resolve the disagreement.
- Request resolution through the NRC/NEI LATF interface.
- Request an official 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<sup>12</sup>
- File a plant-specific backfit claim pursuant to 10 CFR 50.109.<sup>13</sup>

## 2.0 USE OF PRECEDENT

License amendment requests (LARs) are often based on precedent. Licensees use precedent to reduce regulatory review costs and obtain predictable review schedules.

The effective use of precedent has three main components:

1. Licensee and NRC access to precedent-setting documents,
2. a LAR that clearly shows the applicability of the proposed precedent, including all differences between the precedent and the LAR and why the differences are acceptable, and
3. NRC acceptance of the proposed precedent as the basis for an expedited regulatory review.

### 2.1 Sources of Precedent

Precedent-setting LARs and NRC Safety Evaluations (SEs) can be located through:

- Commercial information services
- Nuclear industry sources
  - NEI
  - Regional utility groups
  - Communication among licensees
  - Cooperative arrangements
    - STARS
    - USA
- Government sources
  - NRC Agency Documents Access and Management Systems – ADAMS (electronic)
  - NRC Public Document Room (paper)
  - Federal Register

Licensees do not have access to precedent databases available to the Staff. Likewise, the Staff may not be aware of commercial databases available to licensees. [how to factor in the draft NEI data base of LAR/RAI/SE information for calendar years 2000 – 2005?]

### 2.2 Applicability of Precedent

LIC-101 defines precedent licensing actions as those with a similar proposed change and regulatory basis for the SE [page 2.3],<sup>14</sup> such that searching for, identifying, and using precedents in the review process maximizes staff efficiency, minimizes the need to issue requests for additional information, and ensures consistency of licensing actions.” LIC-101 later notes that the PM [NRC project manager has a responsibility to review the

precedent for accuracy, applicability, and completeness against the details of the submittal and the plant.

However, the lack of additional detailed guidance results in inconsistent regulatory reviews of proposed precedents. As a consequence, potentially applicable precedent may be overlooked by both licensees and the NRC Staff, or even if identified, may be discounted as marginally useful.

### 2.3 Licensee Guidance

The dictionary<sup>15</sup> defines “precedent” as “an earlier occurrence of something similar.” When a licensee submits a LAR, there should be NRC/licensee dialogue to identify precedent. Licensees have the primary responsibility for identifying precedent as part of the initial development of a license amendment request. Current licensee practices are described in an NEI White Paper entitled “Standard Format for Operating License Amendment Requests from Commercial Reactor Licensees,” Revision 1 (contained herein as Appendix C). Section 7 (References) states:

If precedent can be identified, the licensee should reference the affected power plant(s) and amendment number(s), and briefly discuss how the precedent applies to the specific circumstances of the proposed amendment. If there are any differences between identified precedent and the proposed amendment, the licensee should explain the differences and describe their impact on the acceptability of the proposed amendment. Precedent, by itself, does not demonstrate the acceptability of a proposed amendment, but it does give the NRC staff information about how they have treated similar changes in the past. This may simplify the NRC staff's review.

The following considerations and cautions apply to the proposed use of precedent:

- (1) The precedent must be appropriate for the intended amendment.
- (2) The precedent must meet current regulations and NRR guidance.
- (3) Include the following factors when they compare possible precedent with the LAR:
  - a. physical characteristics
  - b. design basis
  - c. risk-significance
  - d. *[others???*]
- (4) NRR needs to obtain concurrence from the Technical Specification Branch that the proposed precedent is appropriate.
- (5) When referring to another submittal or a Tech Spec Task Force (TSTF) Traveler<sup>16</sup> as precedent, it is important to note all differences between the document that is defined as the precedent and the LAR. On the surface the requests may be similar but the associated systems may not be.

- (6) Communicate with the utility whose submittal you plan to use as precedent to ensure the systems in each plant are similar.
- (7) If using an NRC approved submittal and the submittal included any RAIs, consider listing the RAIs in a separate attachment rather than in the body of the submittal. This might help the NRC and might also eliminate any additional RAIs.
- (8) Although it is more efficient for the NRC to use precedent and they are required to look for precedent, it is the utility's responsibility to attempt to identify any precedent first. If the utility does not identify precedent and the NRC does, the utility has to ensure the precedent is appropriate.
- (9) NRC and the licensee should communicate the results of precedent search with one another, including a preliminary evaluation of whether the precedent is supporting or non-supporting.
- (10) Communicating about precedent early in the review process would permit the licensee to take appropriate action, e.g., expand the precedent search, withdraw the amendment request, challenge Staff preliminary conclusions regarding non-supporting precedent, or resolve Staff concerns.

#### 2.4 NRC Treatment of Precedent

Guidelines for Staff review of license amendment requests are contained in NRR Office Instruction LIC-101, which describes the basic framework for processing license amendment applications. The primary objectives of LIC-101 are (1) consistent processing of license amendments, and (2) technical consistency between similar amendments. An important part in meeting the objectives is the appropriate use of precedent set by prior, similar licensing actions.

The NRC recognizes that there are significant efficiencies to be gained by using precedent.<sup>17</sup> Accordingly, the first substantive step in the planning stage of processing a license amendment is for the Staff to "identify, assess, and review" precedent.<sup>18</sup> LIC-101 directs the Staff to continue to search for precedent until it is satisfied that either one or more precedents have been identified or that no appropriate precedent exists.<sup>19</sup> The mechanisms that LIC-101 suggests the Staff may use in its search for precedent include:

- License amendment application or licensee's response to Project Manager's request for information on precedent
- Informal discussions among Staff
- Relevant Staff guidance
- An Intranet "homepage" internal to NRC
- Designated software applications (i.e., ADAMS and TRIM)
- Standard Technical Specifications
- Federal Register notices

The precedent identified as a result of the Staff's search is an input to the amendment review work plan and, later, to the NRC Safety Evaluation. In the planning stage, the availability of precedent is a factor to be considered in allocating the responsibility for developing the work plan between the Project Manager and the appropriate Technical Branch. In addition, estimations of Staff resources required for amendment review are based on the degree of similarity between the amendment request and any precedent. The availability of precedent helps determine the appropriate individual to act as lead reviewer. LIC-101 specifically directs the Staff to give proper consideration to precedent when developing requests for additional information (RAIs) to avoid unnecessary requests.<sup>20</sup>

LIC-101 provides that precedent must be reviewed for accuracy, applicability, and completeness against the details of a license amendment submittal and the particular plant. The responsible reviewer must ensure that the precedent: (1) is appropriate for use with the intended amendment, and (2) meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to industry, and technical content.<sup>21</sup>

### 3.0 STANDARD FORMAT FOR LICENSE AMENDMENT REQUESTS

Many licensees have incorporated the standard format for LARs that is contained in an NEI White Paper distributed for voluntary use in October 2002.<sup>22</sup> The White Paper is included in this Guideline as Appendix E.

**{update the white paper and incorporate it into this Guideline}**

## 4.0 REQUEST FOR ADDITIONAL INFORMATION (RAI) PROCESS

The RAI process is a necessary part of the LAR process. However, consistency and discipline in formulating LARs and RAIs are also necessary to minimize the need for followup resources to request and provide information beyond that provided in the initial LAR.

### 4.1 RAI Process Description

*[need lead-in text]*

- RAI process is an essential part of the LA review and approval process
- RAIs allow the NRC Staff an efficient and effective means of obtaining the information needed to prepare LA safety evaluations (SEs) and approve the LAs
- Not all LARs need RAIs for the NRC to complete its review and approval. CLIIPs and travelers are examples of some LARs that might be approved without any RAIs needed.
- RAIs allow the licensee to assemble and submit the additional needed information so that it is done on the needed time frame and minimal cost
- If RAIs are asked unnecessarily, the process becomes inefficient and ineffective. LA approvals are delayed. NRC resources are wasted. The cost for the licensee goes up.
- RAIs can generally be placed in three categories:
  1. Information that should have been anticipated and included in the original LAR
  2. Requests that are not essential to the review and approval of the LAR per the regulations and the licensees licensing basis
  3. Requests that are needed for the review and approval of the LAR but would not reasonably have been anticipated by the licensee
- Category 1 LARs can be minimized by following the guidance with respect to LAR format and precedent as presented elsewhere in this guidance.
- Category 2 RAIs can be minimized by reviewing the proposed RAIs with the NRR project manager and confirming the purpose of each RAI and how the RAI applies to this docket.
- Category 3 RAIs, in general, can not be entirely prevented.

### 4.2 RAI Trends

The number of RAIs per year has been trending upward for the past several years. It would be helpful to understand the cause(s) of the trend because NRC and industry could use that information to improve the efficient and effective use of resources.

Potential causal factors for the increasing trend in the quantity of RAIs:

- insufficient guidance to licensees on submittal quality
- not understanding NRC reviewer expectations or review needs
- lack of standards on the amount of background information that should be submitted
- lack of standards on submittal scope and level of detail
- lack of standards on the applicability of the current licensing basis
- complex first-of-a-kind submittals
- a shift in regulatory focus due to operating events
- an increase in multiple rounds of RAIs
- duplicate questions
- questions that overlook information present in the License Amendment Request (LAR)
- inefficiencies due to changing reviewers
- reviewer s unfamiliar with NRR operating instruction LIC-101
- a change in NRC management oversight of the RAI process

#### 4.3 Good Practices

The following good practices can minimize or eliminate RAIs:

- Follow the LAR format in this guidance
- Write the descriptions in the LAR as if you were writing an NRC SE for the LAR
- Follow the guidance for using precedent as provided in this guidance. The better the precedent and the better it is tied to the LAR, the fewer RAIs
- Review previous LARs which are similar and the RAIs for those LARs – and then enhancing the LAR to resolve those RAIs in the LAR.
- Use the binning process with the NRR PM and the branch reviewers. Identify deficiencies in the way you prepare LARs from the binning process and enhance future LARs based upon this information. Ensure that weaknesses in the RAIs is fed back to the NRR PM and NEI for their use to enhance the NRC's performance.
- After a LA is approved and implemented, have a lessons learned or debrief meeting to look for ways to improve the process (by either the licensee or the NRC).
- For complex or "ground breaking" LARs, consider a pre-submittal meeting with the NRR PM and appropriate branches. Such meeting can greatly enhance understanding by the NRC of the objectives of the LAR and enhance the licensees understanding of the NRC's focus. The cost of the meeting may be clearly overshadowed by the speed of approval and the reduced review costs.
- Take advantage of the "RAI Conference Calls" in which the licensee discusses draft or new RAIs with the NRR PM and the applicable reviewers. Be sure that you have sufficient clarity at the end of the call to

answer the RAIs in a way that provides the information needed by the reviewer.

- If you are comfortable doing so, answer the RAIs without forcing the NRC to ask them formally. You pay for the cost of writing, reviewing and sending the formal letters.
- Consult with the peers in your industry. It is unlikely that you are the first one to make a change and even if you are, your peers may have good ideas that can save you time and money.
- Use a clear format to respond to questions. A recommended format is to repeat the question in its entirety and then to provide the licensee's response. If it is appropriate to make a change to the LAR, provide a sufficient portion such that the change and its context are clear.

***[need to merge the following into Good Practices]***

- a. Licensees provide NEI, and NRC reviewers provide NRC management, with specific RAI experience for use in NRC/NEI LATF dialogue.
- b. NRC/NEI LATF trend RAIs and evaluate results (includes data collection).
- c. NRC/NEI explore opportunities for expanding the use of the consolidated line item improvement process (CLIIP) to reduce the need for RAIs.
- d. NRC/NEI LATF develop long-term action plan for improving the RAI process.
- e. Licensee near-term actions:
  - (i) Upon receipt of an RAI letter, conduct a prompt "acceptance review" of each question.
  - (ii) For each question that does not pass the acceptance review, document the basis for that determination.
  - (iii) For each question that passes the acceptance review, prepare a firm schedule for submitting a response to NRC.
  - (iv) Schedule a telecon with NRC to discuss all RAI questions.
- f. NRC near-term actions:
  - (i) Technical branch chiefs review all draft and formal RAIs before they are transmitted to the licensee.
  - (ii) Section chiefs in the Division of Licensing Project Management review all draft and formal RAIs before they are transmitted to the licensee.
  - (iii) NRC issue internal memoranda directing staff to existing RAI guidance in NRR Operating Instructions.

**Appendix A**  
**Plant-Specific Adoption of Travelers**



**Appendix B**  
**Obtaining NRC Generic Approval of "T" Travelers**  
**Using a Lead Plant Submittal**

**Appendix C**  
**Standardization of NRC Review of Conversions**  
**to the Improved Standard Technical Specifications**

**Appendix D**  
**Update of NRC Procedures and Guidance to Provide Efficient Reviews**  
**and Utilization of Precedents, Including Approved Traveler**



**Appendix E**

**Standard Format for  
Operating License Amendment Requests from  
Commercial Reactor Licensees**

## ENDNOTES

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<sup>1</sup> 50.90

<sup>2</sup> 50.59

<sup>3</sup> 50.59(a)(1)

<sup>4</sup> 50.59(c)(4)

<sup>5</sup> 5059

<sup>6</sup> Rulemaking, 10 CFR 50.59, "Changes, tests, and experiments," 64FR53613, October 4, 1999.

<sup>7</sup> NEI 96-07, revision 1, "Guidelines for 10 CFR 50.59 Implementation," November 2000.

<sup>8</sup> RG 1.187 November 2000

<sup>9</sup> 50.71(e)

<sup>10</sup> NEI 98-03

<sup>11</sup> NEI 99-04

<sup>12</sup> NUREG/BR-0058

<sup>13</sup> 50.109

<sup>14</sup> LIC-101, page 2.3

<sup>15</sup> dictionary

<sup>16</sup> TSTF Traveler definition

<sup>17</sup> "Searching for, identifying, and using precedents in the review process maximizes staff efficiency, minimizes the need to issue requests for additional information, and ensures consistency of licensing actions." LIC-101, Appendix B at § 2.3

<sup>18</sup> LIC-101, Appendix B at § 2.0, step 3

<sup>19</sup> LIC-101, Appendix B at § 2.3

<sup>20</sup> LIC-101, Appendix B, § 4.3

<sup>21</sup> LIC-101, Appendix B, § 4.2

<sup>22</sup> NEI 2002 WP on standard format