

NEI HANDOUT

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LAR Team Report

Status of NEI 06-02, Revision 1, "*LAR Guidelines.*"

Modules:

1. Terms & Definitions (attached)
2. Acceptance Review Process (pending industry feedback on initial implementation of LIC-109)
3. Use of Precedent (submit 9/15/08)
4. RAI Process (submit 9/15/08)
5. Exigent/Emergency Tech Specs (submit 10/15/08)
6. First-of-a-Kind LARs (submit 10/15/08)
7. TSTF Interface (submit 11/15/08)
8. Electronic Information Exchange (submit 11/15/08)
9. Consistency with NRR Office Instructions (submit 12/15/08 with draft Rev. 1)
10. Consistency with NEI Guidelines (submit 12/15/08 with draft Rev. 1)

TERMS & DEFINITIONS MODULE

1. ACCEPTANCE REVIEW PROCESS

When the holder of a Part 50 license to operate a commercial nuclear power plant submits an LAR, the NRC staff conducts an "acceptance review" in accordance with NRR Office Instruction LIC-109, "Acceptance Review Procedures." The purpose of the acceptance review is to determine if the LAR appears to contain sufficient technical information for the NRC staff to complete a detailed technical review and render a timely regulatory assessment of the proposed action. The term "non-acceptance" (rather than the term "denial") is used to describe an LAR that has not passed the acceptance-review test. An LAR that has not been accepted may be resubmitted if it is supplemented to address the reasons for the NRC staff's non-acceptance. In the case of non-acceptance, a "no significant hazards consideration determination" (NSHCD) is not issued and there are no subsequent hearing rights.

2. APPLICABLE STAFF POSITION

An "applicable staff position" (ASP) is a written NRC statement that documents one or more approaches acceptable to the NRC staff for addressing a regulatory issue or complying with a regulatory requirement. *[Additional text and examples are under development.]*

3. CONSOLIDATED LINE ITEM IMPROVEMENT PROCESS

The "consolidated line item improvement process" (CLIIP) is an NRC review process designed to facilitate plant-specific adoption of individual sections of the improved Standard Technical Specifications for power reactors (NUREG series 1430 – 1434). The process is based on the NRC staff's preparation of a generic "model safety evaluation" (MSE) that is subject to formal public notice and comment. The initial impetus for an MSE is normally a request from the industry's Technical Specification Task Force (TSTF), but may also come from other industry or public groups or from within the NRC staff. An MSE defines the technical and administrative boundary conditions that a licensee must satisfy in order to adopt a particular change. Licensees can request to adopt the CLIIP by demonstrating conformance with the boundary conditions rather than repeating the entire technical analysis that provided the basis for the MSE.

The purpose of the CLIIP is to streamline the license amendment review process involving TSTF changes applicable to multiple plants. By using a standardized process such as the CLIIP, the burden on an individual licensee would be reduced by saving resources in preparing license amendment applications and, at the same time, the NRC staff review process would become more efficient. The main participants in the process are the TSTF, the NRC staff, and licensees eligible to implement approved CLIIPs. In addition, all NRC stakeholders are provided an opportunity to comment on proposed CLIIPs before NRC acceptance and to participate in the licensing process for each subsequent license amendment application. (References: LIC 101, Section 8; RIS 2000-06)

4. CURRENT LICENSING BASIS (CLB)

The "current licensing basis" (CLB) is not defined in 10 CFR 50. However, the following is a practical definition of the CLB that is derived from 10 CFR 54. The CLB for an operating commercial reactor is comprised of:

- (a) The set of NRC regulations applicable to a specific plant that are docketed and in effect (e.g., 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto).
- (b) The set of written licensee commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. This includes commitments contained in docketed licensing correspondence (e.g., licensee event reports and responses to NRC bulletins, generic letters, and enforcement actions) and NRC safety evaluations.
- (c) The plant-specific "design bases" information defined in 10 CFR 50.2 and documented in the plant-specific final safety analysis report (FSAR) as updated in accordance with 10 CFR 50.71(e).

(References: 10 CFR 54.3; LIC-101)

5. DENIAL

The term "LAR denial" applies after an LAR has been accepted by NRC for review. In accordance with 10 CFR 2.108, NRC may deny an LAR if the applicant fails to respond to a request for additional information (RAI) within thirty (30) days from the date of the request, or within such other time as may be specified. Notices of LAR denials are posted in the Federal Register. LARs that have been denied cannot be resubmitted without substantial revision to address the reason(s) for denial. Also, a hearing may be requested because a "no significant hazards consideration determination" will have been published by the NRC following initial acceptance of the LAR for staff review.

6. DESIGN BASIS

The plant-specific "design basis" is the set of information that identifies the specific functions to be performed by a facility's structures, systems, or components (SSCs), and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. (References: 10 CFR 50.2, NEI 97-04: Regulatory Guide 1.186)

7. DETERMINISTIC

The term "deterministic" is used to differentiate prescriptive requirements from those that are "risk informed." The NRC initially developed many of its regulations without considering numerical estimates of risk. They are "deterministic" in the sense that they set strict limits or prescribe discrete outcomes. Deterministic requirements are established based on experience, test results, and expert judgment considering factors such as design margin, defense-in-depth, and accident prevention or mitigation.

8. DURABLE GUIDANCE

The term “durable guidance” refers to a type of regulatory document that is used to disseminate an “applicable staff position.” A regulatory guidance document is durable if changes to the document are controlled by an administrative approval process that includes an opportunity for the public to comment on proposed changes. For example, Regulatory Guides and the Standard Review Plan are durable guidance documents. *[Additional effort is needed to develop a complete list of durable guidance documents.]*

9. EXIGENT/EMERGENCY LAR

Under certain conditions, the NRC may classify an LAR as an “exigent LAR” or an “emergency LAR” and dispense with certain steps in the public notice and comment process because timely action is necessary to preclude adverse consequences. (References: 10 CFR 50.91(a)(5) and 10 CFR 50.91(a)(6))

10. LICENSING ACTION FINDING

The term “licensing action finding” refers to the NRC staff’s explanation and bases, documented in a written safety evaluation in response to a request for licensing action, for concluding that (1) there is (or is not) reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) such activities will (or would not) be conducted in compliance with the Commission’s regulations, and (3) the issuance of the amendments will not (or would) be inimical to the common defense and security or to the health and safety of the public.

11. FIRST-OF-A-KIND

The term “first-of-a-kind” (FOAK) applies to LARs that involve new or more complex technology, a greater scope of applicability, or a greater organizational complexity than previously reviewed by the NRC staff. There is no close existing analogue or body of precedent that staff can use to aid the regulatory review of an FOAK LAR.

12. FLEET LAR

The term “fleet LAR” refers to an LAR that is submitted by an operating company on behalf of several nuclear units (i.e., more than one Docket).

13. GENERIC ISSUE

A "generic issue" is a well defined, discrete, technical or security issue with the following attributes:

- (a) The issue could affect public health and safety, the common defense and security, or the environment.
- (b) The issue applies to two or more facilities, licensees, certificate holders, or holders of other regulatory approvals.
- (c) The issue is not being addressed by an existing program or process.
- (d) The issue cannot be readily addressed by existing regulations, policies, guidance, or voluntary industry initiatives.
- (e) The issue cannot be readily addressed by other regulatory programs or processes.
- (f) The risk or safety significance of the issue can be adequately determined

A generic issue may lead to regulatory changes that either enhance safety, or reduce unnecessary regulatory burden. (Reference: NRC website)

14. GENERIC SAFETY ISSUE

A "generic safety issue" is a generic issue that falls into one of five groups defined in NUREG-0933, "A Prioritization of Generic Safety Issues:"

- (a) TMI Action Plan items (NUREG-0660 and NUREG-0737).
- (b) Task Action Plan items (NUREG-0371 and NUREG-0471, as well as all Unresolved Safety Issues (USIs) not originally identified in those two documents).
- (c) New generic issues identified from various sources.
- (d) Human factors issues (NUREG-0985).
- (e) Chernobyl issues (NUREG-1251).

15. LICENSE AMENDMENT REQUEST

A "license amendment request" (LAR) is a formal request from a licensee to amend a Part 50 facility operating license pursuant to 10 CFR 50.90 (application for amendment of license, construction permit, or early site permit), 50.91 (notice for public comment; state consultation), and 50.92 (issuance of amendment).

16. OBLIGATION

The term "obligation" refers to any condition or action that is a legally binding requirement imposed on licensees through applicable rules, regulations, orders, and licenses (including technical specifications and license conditions). Also included are regulations and license conditions that define change-control processes and reporting requirements for licensing-basis documents such as the updated FSAR, quality assurance program, emergency plan, security plan, fire protection program, etc.

17. PRECEDENT

The term "precedent" refers to the set of prior LARs and NRC SEs that licensees may use to help establish the bases for subsequent LARs on the same topic. The use of precedent helps expedite the regulatory review by identifying existing technical and regulatory information that is relevant to a new LAR. The successful use of precedent depends to a large extent on the level of detail provided in the applicant's LAR with respect to similarities and differences between the LAR and the cited precedent.

18. REGULATORY COMMITMENT

A "regulatory commitment" is an explicit statement to take a specific action agreed to, or volunteered by, a Licensee and submitted in writing on the docket to the NRC. (References: NEI 99-04; NRR Office Instruction LIC-100, pp 1.2 - 1.3; LIC-101, section 4.4; LIC-105; RIS 2000-17]

19. REQUEST FOR ADDITIONAL INFORMATION

An NRC "request for information" (RAI) is either an informal (verbal or e-mail) request or a written (letter) request for information needed by the NRC staff to document the basis for the staff's conclusions in the Safety Evaluation for the LAR.

20. RISK-INFORMED

An LAR is "risk-informed" if it applies quantitative or qualitative risk insights and techniques in accordance with applicable regulatory guidance. (Reference: Regulatory Guide 1.174)

21. SAFETY EVALUATION

The results of the NRC staff's evaluation of an LAR are documented in a "safety evaluation" (SE). The SE describes the staff's technical and regulatory evaluation with respect to the impact on public health and safety of operation in the manner proposed in the LAR.

22. TASK INTERFACE AGREEMENT

The term "task interface agreement" (TIA) refers to an internal process used by NRR to respond to requests for technical assistance from an NRC region or another NRC office. A TIA contains questions on subjects involving regulatory or policy interpretations, specific plant events, or inspection findings within the scope of NRR's mission and responsibilities. The requesting organization may use a TIA to obtain information on specific plant licensing basis, applicable staff positions for an issue, regulatory requirements, NRR technical positions, or the safety or risk significance of particular plant configurations or operating practices. The TIA process is designed to ensure that concerns from the regions and other NRC offices are resolved in a timely manner and that the NRR responses are appropriately communicated. The process includes a provision to interact with licensees to ensure clear and accurate information. (Reference: COM-106)

23. TOPICAL REPORT

The term "topical report" refers to a wide variety of stand-alone reports that are submitted for NRC review. Normally these reports contain technical information about a nuclear power plant safety issue, although they can address policy and process issues also. TRs improve the efficiency of the licensing process by allowing the staff to review a proposed methodology, design, operational mode, or other subject that will be used by multiple licensees by referencing the NRC-approved TR. (Reference: LIC-500)

24. WITHDRAWAL

The term "LAR withdrawal" applies at any point after an LAR is submitted, but before the NRC staff has completed its regulatory review. An LAR can be withdrawn without prejudice, i.e., it can be resubmitted at a later date.

Acceptance Review (A/R) - Industry Experience Matrix

#	Chronology	NEI Comments
1	<ul style="list-style-type: none"> • The licensee submitted an LAR to revise an analysis to remove credit for boraflex in spent fuel racks • The licensee received 10 multi-part A/R questions • The licensee provided an LAR supplement • The NRC informed the licensee of pending non-acceptance • The licensee withdrew LAR 	<ul style="list-style-type: none"> • Precedent was researched and cited in the LAR. • The basis for the LAR was a commonly used computer code. • LAR (4/08) came before LIC-109 (5/08) & was not prepared with the A/R process in mind. • The communication of non-acceptance from the NRC staff was informal and without a technical explanation, thus the licensee is left without a clear path forward. • Licensees use precedent, to the extent that precedent exists, to guide LAR content. If the NRC reviewer has other expectations, licensees have only 2 weeks to supplement the LAR. • Licensees will tend to withdraw LARs rather than receive non-acceptance letters because the template letter in LIC-109 has a strong negative connotation. • The language in LIC-109 implies that non-acceptance is caused by unacceptable or unresponsive behavior on the part of the licensee. • NEI recommends that additional guidance be added to LIC-109 to help define what constitutes "sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review." • NEI understands that the A/R comment process is not an RAI process. Nevertheless, A/R comments look and feel like RAIs.
2	<ul style="list-style-type: none"> • The licensee submitted an EPU LAR • The licensee received multiple A/R questions • The licensee provided multiple LAR supplements • The NRC informed the licensee of pending non-acceptance • The licensee withdrew the LAR 	<ul style="list-style-type: none"> • Past EPUs were researched and used to develop the LAR. • ACRS transcripts of past EPUs were researched and used to develop the LAR. • The LAR came before LIC-109 & was not prepared with the A/R process in mind. • The A/R process delegate significant authority to the reviewer. • The NRC staff conditioned its acceptance on the completion of a final EQ analysis before submitting the LAR to avoid multiple rounds of RAIs during the review. It is not the purpose of the A/R process to preclude RAIs, and that should not be a criterion for acceptance. • Based on interactions thus far with NRC staff reviewers, it appears that some reviewers believe that NRC management will not permit them to ask RAIs after they have accepted an LAR for review; in other words, they believe the A/R process represents their only chance to ask RAI-type questions. • NEI recommends follow-up NRC/NEI discussions on how to treat reviewer A/R questions that industry believes go beyond previous SEs. • NEI recommends an NRC/NEI protocol for monitor the A/R process to compile lessons learned. • NEI recommends additional NRC guidance on the objectives of LIC-109.

3	<ul style="list-style-type: none"> The licensee plans to submit an EPU LAR, but is having difficulty with the "no linked" LARs provision in LIC-109. 	<ul style="list-style-type: none"> Past EPUs are being researched and used to develop the LAR. NEI recommends that NRC consider revising its position on linked LARs. EPU projects involve design changes and plant modifications that are linked by necessity. Engineering, procurement, scheduling, outage planning, and implementation are interdependent. The LAR process should recognize and accommodate those dependencies.
4	<ul style="list-style-type: none"> The licensee submitted an LAR to revise the TS for CST volume The licensee received an A/R question requesting a calculation During a subsequent licensee/NRC telecon, the reviewer revised the question, leaving little time for a response. The licensee submitted the requested information in a supplement to the LAR 	<ul style="list-style-type: none"> LIC-109 does not give the reviewer and licensee time to understand one another. This is particularly true for complex submittals. LIC-109 is being implemented without a trial period. Licensees have not had a chance to factor it into their LAR-preparation practices. Reviewers cannot know in advance what questions they will have on something they have not seen, and licensees cannot predict the questions they may receive. But LIC-109 gives only 2 weeks to the reviewer and 2 weeks to the licensee to work everything out. The time-limited nature of LIC-109 will create situations where decisions are made based on NRC performance measures, which may not align with the interests of stakeholders. Regulatory decisions should not be based on LIC-109 until it has been in use for at least 6 months, and NRC and Industry have had a chance to share initial lessons learned.
5	<ul style="list-style-type: none"> The licensee submitted an LAR based on plant-specific use of a Topical Report that does not have generic NRC approval. The reviewer informed the licensee that the LAR will not be accepted unless the licensee justifies use of the TR on a generic basis. 	<ul style="list-style-type: none"> This topic is being addressed by the NEI Topical Report Team.
6	<ul style="list-style-type: none"> The licensee submitted an LAR to correct a non-conservative allowable value in the TS for the degraded voltage trip. The NRC staff advised the licensee that if a setpoint (or allowable value) is in TS, it is by definition associate with a "significant safety function" and is therefore a "limited safety system setting." 	<ul style="list-style-type: none"> The NRC staff and the nuclear industry have a long-standing disagreement on the regulatory requirements associated with setpoints and allowable values. NEI recommends that plant-specific setpoint-related LARs be reviewed consistent with the current licensing basis until the broader issue is resolved and a final NRC position is published.

LICENSING PROCESS EFFECTIVENESS - Continued Process Improvement -

Monday, October 6

7:00 a.m.–8:00 a.m. Registration & continental breakfast

KEYNOTE SPEAKERS

8:00–9:00 a.m.

- Introduction –
 - NRC Keynote –
 - Industry Keynote –
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9:00–9:30 a.m.

Break

PLENARY SESSION The Role of the LATF in Process Improvement

9:30–11:30 a.m.

The moderators will lead a discussion on the role and activities of the NEI Licensing Action Task Force (LATF) in providing industry feedback to NRC about license amendment requests, screening regulatory issues for plant-specific and generic applicability, topical reports, and backfitting.

Moderators:

- *NRC*
- *NEI*

Topics:

1. License Amendment Request (LAR) Process
2. Regulatory Issue Screening Process
3. Topical Reports Process
4. Backfitting Process
5. Operability Determination Process
6. Risk-Informed Regulation
7. Fire Protection Issues
8. Pandemic Planning
9. New Plant Impact on Current Sites
10. Licensing Engineer Pipeline
11. 10 CFR 50.54(q) Issues
12. Pending Generic Communications

Panelists:

- NRC
- NRC
- NEI/LATF
- NEI/LATF

11:30 a.m.–1:00 p.m.

Lunch

BREAKOUT SESSIONS

Breakout 1 1:00-2:30 p.m.

Room A Topic – Topics 1, 2, 3

Panelists:

- NRC
- NEI/LATF

Room B Topic – 4, 5, 6

Panelists:

- NRC
- NEI/LATF

Break 2:30-3:00 p.m.

Breakout 2 3:00-4:30 p.m.

Room A Topic – 4, 5, 6

Panelists:

- NRC
- NEI/LATF

Room A Topic – 1, 2, 3

Panelists:

- NRC
- NEI/LATF

Adjourn 4:30 p.m.

5-7 p.m.

NEI reception

Tuesday, October 7

7:00 a.m.–8:00 a.m. Registration & continental breakfast

BREAKOUT SESSIONS (continued)

Breakout 3 8:00-9:30 a.m.

Room A Topic – 7, 8, 9

Panelists:

- NRC
- NEI/LATF

Room B Topic – 10, 11, 12

Panelists:

- NRC
 - NEI/LATF
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Break 9:30-10:00 a.m.

Breakout 4 10:00-11:30 a.m.

Room A Topic – 10, 11, 12

Panelists:

- NRC
- NEI/LATF

Room B Topic – 7, 8, 9

Panelists:

- NRC
 - NEI/LATF
-

11:30 a.m.–1:00 p.m.

Lunch

CLOSING PLENARY

1:00-2:30 p.m.

Topics:

- **LATF Breakout Sessions – Summary and Follow-up Actions**
- **Acceptance Review Breakout Sessions – Summary and Follow-up Actions**

Panelists:

- NRC
 - NEI/LATF
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2:30 p.m.

Adjourn

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Licensed Power Limit

Current Situation

- NRC Summary of June 12 public meeting
- NEI Position Statement, June 23, 2008

Next Step

- Endorse NEI guidance on thermal power by issuing Rev. 1 to RIS 2007-21. This will supersede the current RIS. In progress and expected to be complete this fall.

Pandemic Planning

Current Situation:

- NEI Pandemic Licensing Plan, Rev. 1, December 17, 2008
- NRC Comments on PLP Rev. 1, May 23, 2008

Next Steps:

- NEI respond to NRC comments
- Schedule NRC/NEI public meeting (~ August 2008)
- NRC/NEI bin requirements:
 - a. NRC believes that NEI's proposal for relief is feasible as stated
 - b. NRC believes that NEI's proposal for relief may be feasible pending further justification and dialogue with NRC
 - c. NRC does not believe that NEI's proposal for relief is feasible
- NEI publish PLP Rev. 2 for NRC endorsement (~ December 2008)

Status Reports

Operability Determination Process (ODP) Team

- Reconvene the LATF ODP Team (August 2008)
- Prepare an NEI letter to NRC to:
 - Document industry experience with RIS 2005-20 and its Inspection Manual Chapter
 - Promote consistent use of the terms Specified Function (SF) and Specified Safety Function (SSF) with the IMC
 - Provide detailed industry comments on IMC Appendix C, "Specific Operability Issues:"
 - C.1 Relationship Between the General Design Criteria and the Technical Specifications
 - C.2 Single Failures
 - C.3 Treatment of Consequential Failures in Operability Determinations
 - C.4 Use of Alternative Analytical Methods in Operability Determinations
 - C.5 Use of Temporary Manual Action in Place of Automatic Action in Support of Operability
 - C.6 Use of Probabilistic Risk Assessment in Operability Decisions
 - C.7 Environmental Qualification
 - C.8 Technical Specification Operability vs. ASME OM Code Criteria
 - C.9 Support System Operability
 - C.10 Piping and Pipe Support Requirements
 - C.11 Flaw Evaluation
 - C.12 Operational Leakage From Code Class 1, 2, 3 Component
 - C.13 Structural Requirements

Regulatory Issue Screening Process (RISP) Team

- August 4, 2008 Licensing Panel at ANS Utility Working Conference at Amelia Island, FL
- September 2008 NEI distribute draft 8 of RISP White Paper for NRC/industry peer review
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Topical Report Team

1. *Completed Public Meetings*
 - a. April 11, 2008
 - b. May 15, 2008
 - c. July 9, 2008

2. *Future Public Meeting*
 - a. August 27, 2008 (tentative)

3. *Topic List*
 - a. TR Value Proposition (Communication Plan)
 - b. Work Management (TR pipeline and relative priorities)
 - c. Standardization (format & content)
 - d. Scoping Issues
 - e. Acceptance Review
 - f. RAI Process
 - g. Safety Evaluations
 - h. Implementation
 - i. Documentation
 - j. Training/Qualification
 - k. Electronic Information Exchange
 - l. Fees
 - m. Appeal Process