



NEI Licensing Action Task Force Handout for Meeting with NRC Staff July 25, 2007

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 - A. Action Item List
 - B. GIM White Paper (draft Revision 5)
 - C. Licensing Forum Preliminary Program
 - D. Comments on LIC-500

10 CFR 50.59

Implementation Guidance

- Supplement NEI 96-07 Revision 1
- Update the examples
- Guidance on 50.59 screening
- First draft – October 1, 2007

Generic Issue Management (GIM) Process

- White Paper, draft Revision 5 (Attachment B)
 - To initiate NRC/Industry dialogue
 - To fully implement a comprehensive process
 - To identify, manage, and document generic issues
 - From plant-specific inspections and licensing-action reviews
- Work in progress
- The paper is sufficiently mature to share with NRC staff
- Request a meeting to discuss staff comments on the white paper

License Amendment Request (LAR) Guidelines

- NEI 06-02, Revision 2
 - 1st draft – October 1, 2007
 - New/revised topics
 - Treatment of Tech Spec Bases
 - Use of precedent
 - RAI process
 - First-of-a-kind (FOAK) – using inputs from digital I&C task working group
 - Public notice & comment
 - Consolidated line item improvement process (CLIIP)
 - No-Significant-Hazards-Consideration (NSHC) determination
 - List attributes of:
 - Updating plant-specific analyses and licensing bases
 - LAR completeness
 - Level of detail (safety & compliance)

NEI Licensing Forum 2007

- Westin Hotel, Arlington, VA
- October 15-16, 2007
- Preliminary Program (Attachment C)
 - Generic Issue Management
 - Role of the CRGR
 - Topical Report Process
 - NRC Strategic Plan for FY 2008
 - Resource Management (forecasting and scheduling)
 - Licensing Metrics
 - Operability Determination Process
 - Codes & Standards Development
 - NRC Headquarters/Region Interface
 - LAR Process
 - NRC Licensing Process Improvements
 - Pandemic Licensing Plan

Operability Determination Process

- NEI submit comments on ODP inspection manual chapter (~9/15/07)
 - Treatment of inspection “guidance” as “policy”
 - Scope of “operability” compared to “functionality”
 - Scope of “specified function” compared to “specified safety function”
 - Inservice Inspection (ISI) “action range”
 - Treatment of Class 2&3 operational leakage
 - NRC interim guidance – June 22, 2007
 - NRC/NEI meeting – August 30, 2007
 - Comments on Appendices
 - Documentation (scope and retrievability)
- Recommend public working meetings to discuss potential changes

Topical Report Process

- Comments on LIC-500 (Attachment D)
- The NEI TR Team is preparing a process-improvement white paper
 - Use of NRC-approved generic TR as plant-specific precedent
 - Scope of applicability of SE (limitations and conditions reduce the effectiveness of the TR process)
 - Predictability of outcomes
 - Thresholds
 - Burden of proof
 - Training
 - Process mapping
 - Re-review by LAR
 - Workshops
 - Examples
 - Etc.

Task Interface Agreement (TIA) Process

- The TIA process continues to be a “black box” to licensees
- Licensees are not informed or given an opportunity to participate (in accordance with COM-106 Revision 1)
- Is COM-106 Revision 2 a public document?

LATF ACTION ITEMS

NEI Action Items from NRC/NEI meetings

NEI-YR-QTR-#	TOPIC	OVERSIGHT	ACTION	DUE DATE
NEI-07-Q1-01	Resource Management: NEI, Exelon, and Entergy meet with NRC to discuss typical licensee practices when planning and budgeting for future licensing submittals	LAR Team	Schoppman Contact Dan Frumkin (NRR) to schedule a public meeting.	TBD
NEI-07-Q1-02	Issue Management: WHITE PAPER (coordinate with Houghton)	GIM Team	NEI submit draft WP to NRC: a. Status reports at NRC/NEI LATF meetings b. NEI submit WP	a. 07/25/07 b. 8/15/07
NEI-07-Q1-03	Pandemic Licensing Plan: a. TELECON - discuss date/agenda for a meeting to hear Initial NRC comments on the NEI pandemic white paper submitted on January 17, 2007. b. Submit WP Revision 1 incorporating NRC comments	Pandemic Team	a. Schoppman call Peters to discuss meeting agenda and possible dates Public meeting held on 3/23/07. NEI is revising the WP. COMPLETE b. Schoppman coordinate with Pandemic Team to set date for submitting Rev 1.	a. COMPLETE b. TBD
NEI-07-Q1-04	Topical Report Process: (1) NEI LETTER - comments on LIC-500 (2) MEETING - schedule next NRC/NEI meeting on TR process improvement	Topical Report Team	a. NEI submit comments on LIC 500 b. Schoppman contact Tayna Mensah to schedule a meeting	a. 7/25/07 b. TBD
NEI-07-Q1-05	First-of-a-Kind White Paper: WHITE PAPER	FOAK Team	NEI submit draft WP to NRC	TBD
NEI-07-Q1-06	LATF Interface with NRC: NRR "CHARTER"	LATF Steering Group	Provide comments on NRR's draft charter entitled, "NRR's Interactions with NEI LATF"	COMPLETE
NEI-07-Q2-07	Agenda for NEI Licensing Forum a. Draft agenda b. Final draft agenda	NEI	a. Schoppman provide 1 st draft to Lubinski b. NRC/NEI concur on final draft Note: NEI has NRC comments on 1 st draft.	a. COMPLETE b. 8/1/07

LATF ACTION ITEMS

NRC Action Items from NRC/NEI meetings

NEI-YR-QTR-#	TOPIC	OVERSIGHT	ACTION	DUE DATE
NRC-07-Q1-01	Develop a "charter" to describe the NRC Interface with the NEI LATF	NRR DORL	Status Report	COMPLETE
NRC-07-Q1-02	Consider using the quarterly LATF meetings to advise industry of pending generic communications.	NRR DPR	NRC consider re-posting a page on the NRC website; possibly under "Operating Reactor Licensee Toolkit" http://www.nrc.gov/reactors/operating/op-reactor-toolkit.html Status report at July LATF meeting	7/25/07
NRC-07-Q1-03	Consider performing a self-assessment of the NRC acceptance review process.	NRR DORL	Status Report	7/25/07
NRC-07-Q1-04	Consider ways to provide electronic copies of approved amendments.	NRR DORL	Pilot underway with Exelon. Continue status reports at LATF quarterly meetings. Communicate final results of pilot 11/07.	November 2007
NRC-07-Q1-05	Consider requesting stakeholder comments on the next revision of LIC-101	NRR DORL	NRC will entertain industry comments on LIC-101 Rev 4 after it is published.	COMPLETE
NRC-07-Q1-06	Give feedback to LATF on endorsement options available for NEI 06-02	NRR DORL	Status Report	Feb 2008
NRC-07-Q1-07	Give update on NRR licensing metrics	NRR DORL	Lubinski status report at 5/23/07 meeting.	COMPLETE
NRC-07-Q1-08	Confirm date of next quarterly meeting	NRR DORL	Frumkin now coordinating for NRC; confirm next meeting scheduled 7/25/07.	COMPLETE
NRC-07-Q2-09	Operability determinations for operational leakage	NRR DORL	Identify POC for inspector guidance (Ted Sullivan)	COMPLETE
NRC-07-Q2-10	NUREG-1022 revision	NRR DORL	NRC to determine if this will be revised and get POC and status.	7/25/07

NEI White Paper

Generic Issue Management

***Identifying and Managing Generic Regulatory Issues Derived
From Plant-Specific Licensing Reviews and Inspections***

_____ **2007**

Acknowledgements

NEI acknowledges the assistance of the Licensing Action Task Force (LATF) Steering Group and its GIM Team in preparing this White Paper.

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ABSTRACT

Regulatory stability and predictability are key enablers of operating decisions for current plants and business decisions for new plants. The interactions through which the NRC and the industry identify, debate, and resolve generic issues are important contributors to either increasing or decreasing stability and predictability. The objective of this white paper is to discuss how NRC and industry can better align expectations about the applicability of preliminary generic information during plant-specific NRC licensing reviews and inspections. Common definitions and expectations are essential for regulatory stability and predictability.

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1.0 INTRODUCTION

One of the most important factors in achieving a predictable, efficient licensing process is the concept of the "current licensing basis," or CLB. The commercial nuclear industry relies on the stability of the plant-specific CLB to optimize plans and budgets for future operations and maintenance. Thus, the frequency and magnitude of challenges to the adequacy of the CLB, and the process for resolving challenges that do occur are important enablers of safe and efficient nuclear operations.

In recent years, licensees have seen an increasing number of NRC challenges to the adequacy of plant-specific CLBs during NRC inspections and licensing-action reviews (see Appendix A). Licensee evaluations of safety and compliance have not been sufficient to preclude NRC-initiated changes to the CLBs of affected plants. In most cases, the issues are not limited to one or two plants. When a significant number of operating plants are affected, NEI believes that NRC should bundle the set of plant-specific issues into one generic issue and, absent demonstrable safety significance, conduct a front-loaded technical review to establish standardized guidelines for implementation by affected plants.

In terms of resource management and operational needs, a generic issue (i.e., an issue that affects a significant subset of plants in the same or similar way) is resolved most efficiently, predictably, and transparently by a regulatory review that produces a resolution path that can be implemented by affected plants in the same or similar way at the same time.

The purpose of this white paper is to initiate a dialogue between the NRC staff and the commercial nuclear industry about the need to fully implement a comprehensive regulatory process that can identify, manage, and document the resolution of generic issues that arise from plant-specific inspections and licensing-action reviews.

2.0 PROBLEM STATEMENT

The NRC and the nuclear industry do not have complementary processes for identifying, resolving, and implementing changes derived from generic issues. As a result, there are variations in the way NRC and licensees treat potential generic issues, which can detract from efforts to manage safety.

This paper describes the current situation from the industry point of view. The concerns, which affect applicants for new plants as well as operating plant licensees, are summarized in this section, with details in Appendix A.

2.1. Licensing actions that apply generic information to expand plant-specific CLBs:

- (1) Control room habitability.
- (2) Safety-related instrument setpoints.
- (3) Conditioning LAR approval for a plant with custom technical specifications on the adoption of Standard Technical Specifications for the structure, system, or component in question.
- (4) Using an LAR review to challenge previously accepted evaluation model assumptions.

- 2.2. Inspections that apply generic information to expand plant-specific CLBs:
- (1) Challenging a generic design basis (e.g., tornado missiles).
 - (2) Generic URIs during team inspections (e.g., component design basis inspections).
 - (3) Using the significance determination process (SDP) to generate requests for information.
 - (4) Challenging definitions (e.g., RCPB leakage).
 - (5) Challenging industry interpretations (e.g., operability determinations).
- 2.3. Generic communication initiatives that change or add regulatory expectations:
- (1) Material control and accounting (Bulletin 2005-01).
 - (2) Fire protection manual actions.
 - (3) Scope of fitness for duty testing (RIS 2005-08).
 - (4) Steam generator CLIIP implementation date (GL 2006-01).
 - (5) Grid reliability.
- 2.4. NRC Staff treatment of guidance as agency policy that must be followed:
- (1) Operational leakage from ASME Class 2 and 3 components.
- 2.5. New or different interpretations as the basis for inspection findings and licensing decisions:
- (1) 10 CFR 50.46 reporting (changes/errors in LOCA models).
 - (2) 10 CFR 50.59 threshold for prior NRC review of method changes.
 - (3) Applicability of the "single failure criterion" in Tech Spec action statements.
 - (4) 10 CFR 50.72 and 50.73 reportability requirements.
 - (5) Issues that emerge from plant-specific implementation of model safety evaluations for generic Tech Spec changes issued pursuant to the consolidated line item improvement process (CLIIP)
 - (6) Operability determinations for SSCs outside the scope of Tech Specs.
- 2.6. Missed opportunities to reduce unnecessary regulatory burden:
- (1) Digital instrumentation and control.
 - (2) Use of risk techniques to evaluate inspection unresolved items (URIs).
 - (3) Review 10 CFR 50.55a to identify administrative requirements that do not have a safety benefit commensurate with their cost.
- 2.7. Consistency of NRC requirements, expectations, and guidance:
- (1) Risk management in the context of the maintenance rule (10 CFR 50.65(a)(4)).
 - (2) The regulatory treatment of RCS leakage.
 - (3) Spent fuel storage criticality requirements (RIS 2005-05).
- 2.8. NRC regulatory positions without benefit of stakeholder comments:
- (1) Processing task interface agreements.
 - (2) Use of the Inspection Manual to redefine "performance deficiency."
 - (3) Retracting the approval of one vendor's flow measurement device.
 - (4) Rejecting NRC-approved TSTF Travelers as the basis for a plant-specific amendment.
 - (5) Changes to inspection procedures that apply new requirements or change prior inspection standards (e.g., IP 71114.03, "Emergency Response Organization Staffing and Augmentation," October 27, 2006).

3.0 PROPOSED REGULATORY PROCESS

3.1 Overview

This section describes NEI's proposed process for identifying and managing plant-specific licensing and compliance issues that have generic implications. It defines several key terms and concepts, discusses alternative ways to manage generic information, and describes the relationship between generic issues and the plant-specific licensing basis.

Absent an immediate plant-specific safety or compliance concern, the process is an acceptable means for applying generic resolutions to plant-specific situations. Criteria, thresholds, and documentation guidelines would be developed to describe the use of generic information during inspections and licensing actions.

NEI recommends that the NRC/NEI LATF interface be used to prepare guidelines that address the following key attributes of generic information management:

- (1) Establishing a safety threshold as a first step.
- (2) Participation by all stakeholders.
- (3) Identification of sources of new information (e.g., operating experience, research).
- (4) Identification of relevant underlying regulatory requirements.
- (5) Prompt coordination of NRC and industry activities.
- (6) Information quality guidelines.
- (7) Rigorous definition of key terms and concepts.
- (8) Working meetings to establish timely consensus positions.
- (9) Milestone scheduling.
- (10) Management oversight.
- (11) Accessible documentation of precedent.
- (12) Maximize process efficiency and effectiveness.
- (13) Recognition of the CLB as the plant-specific regulatory baseline.
- (14) One issue – One review – One resolution

3.2 Key Terms and Concepts

The precise definition of the following key terms and concepts is central to the success of the proposed GIM process.

3.2.1 Current Licensing Basis

The term "current licensing basis" (CLB) is defined in 10 CFR 54.3¹ as the "set of NRC requirements applicable to a specific plant and a licensee's written 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."

¹ U.S. NRC, Code of Federal Regulations, Title 10, Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," Section 54.3, "Definitions."

A documented, accessible, well-managed CLB is the foundation of regulatory stability. It is a licensee's baseline for evaluating all aspects of plant design and operation, and it is central to the NRC's management and control of regulatory requirements and interpretations for each licensee.

3.2.2 Compliance

The term "compliance" means that a structure, system, or component (SSC) satisfies all requirements of applicable rules, regulations, orders, and licenses (including Technical Specifications). Compliance is based on the intent of the requirement at the time of its promulgation. The NRC typically documents the intent of a requirement in a Federal Register notice, and licensees typically incorporate implementing language into the CLB by updating the Final Safety Analysis Report (FSAR) or other licensee-controlled document. NRC regulations (10 CFR 50.59 and 10 CFR 50.109), supplemented by NRC and licensee procedures, control the imposition of new or different interpretations.

With respect to generic compliance compared to plant-specific compliance, the NRC should not impose resolution of an emergent generic issue on an individual licensee unless there is an immediate safety issue. The matter should be resolved through the generic issue process, not the LAR process. No LARs should be delayed and no licensee should be obliged to adopt unusual conditions (i.e., conditions inconsistent with the CLB and precedents established by other licensees) to obtain regulatory approval of a proposed LAR. Resolution should be the same for all licensees to which the issue applies.

3.2.3 Operating Authority

The Perry decision² describes a threshold for regulatory approval based on whether, in the staff's opinion, a licensee's actions "exceed the operating authority already granted under the licensee's license." A too-narrow interpretation of "operating authority" pre-empts licensees from using the 10 CFR 50.59 change-control process to make changes without prior NRC approval. Both industry and the NRC would benefit from additional guidance on the concept of operating authority.

3.2.4 Precedent

Licensees use the concept of precedent (e.g., LARs, RAIs, and NRC safety evaluations for plants of the same or similar design) to reduce the time needed to prepare an LAR, to minimize the likelihood of RAIs, and to achieve a more predictable regulatory review schedule. NEI 06-02³ contains NEI guidance on the identification and use of precedent.

There is no regulatory process for determining whether a licensing document will be accepted as precedent by the NRC staff, nor is there a repository of precedent-setting documents that licensees could use as a resource when preparing submittals or that NRC could use to standardize reviews.

² U.S. NRC, Memorandum and Order, CLI-96-13, December 6, 1999.

³ Nuclear Energy Institute, NEI 06-02, "License Amendment Request Guidelines," December 2006.

3.2.5 Reviewer Findings

Before approving a plant-specific licensing action, the NRC reviewer must make a regulatory "finding." However, reviewers are not obliged to articulate the finding that must be made.

NEI believes that NRC should advise all parties to a licensing action of the findings necessary to approve the action. The better the licensing community understands the agency's obligations, the better it can provide the necessary information to help satisfy those obligations.

3.2.6 Regulatory Analysis

The NRC has long-standing guidance on the performance of regulatory analyses to ensure that it makes sound decisions regarding actions needed to protect the health and safety of the public or the common defense and security. Regulatory analyses are required for all regulatory actions that involve backfitting.

NEI believes that a significant improvement in the efficiency and effectiveness of the overall licensing process would be achieved by simplifying the NRC's regulatory analysis guidance and applying it to a broader scope of licensing documents and activities. NEI is prepared to participate in a public process to simplify the regulatory analysis guidance.

3.2.7 Backfitting

The Commission recognized the importance of backfitting controls in 1985 when it approved a change to 10 CFR 50.109 that established administrative standards for NRC imposition of new regulations or new interpretations of existing regulations. The 1985 rule defined the term "backfitting" as the "modification of or addition to systems, structures, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position ..."

The concept of backfitting is closely related to the concept of the CLB. For example, it is NEI's position that the use by NRC inspectors and reviewers of new information or new interpretations to seek an expanded scope for licensee commitments and submittals that are based on the CLB should be subject to backfitting controls. Similarly, NRC should not use generic communications, requests-for-additional-information (RAIs), or inspection activities to solicit commitments that go beyond the CLB.

The 10 CFR 50.90 license amendment process requires that NRC assure technical compatibility of the proposed change with the licensing and design bases. If there is no incompatibility, i.e., no unacceptable inconsistency between a license amendment request and the licensing or design basis, NRC should not impose additional requirements that are based on new generic information without first performing a regulatory analysis. Further, the incompatibility must be "unacceptable," i.e., more than just a good idea or just "related to" the LAR. The imposition of more restrictive requirements should be limited to proposed license amendments that cannot be sustained without conditioning approval on related

changes to the licensing basis and/or the design basis. The burden to justify imposing requirements that are more restrictive falls on the NRC, not the licensee.⁴

3.3 Implementation Alternatives

A concerted effort by all stakeholders is needed to address the concerns described in this white paper. NEI proposes that NRC and the commercial nuclear licensing community hold a series of public meetings and workshops to develop a GIM process that would guide the NRC staff and licensees in identifying, evaluating, and documenting the appropriate use of generic information derived from plant-specific inspections and licensing-action reviews.

One or more of the following options could be used to document and communicate process improvements derived from the GIM dialogue:

- (1) NRC Office Instructions or Management Directives
- (2) NRC Inspection Manual changes
- (3) NRC policy statements
- (4) NRC generic communication (Bulletin, Generic Letter, RIS)
- (5) Licensee procedures
- (6) Industry white papers, guidelines, and initiatives

3.3.1 Generic Safety Issue (GSI)

If the data are insufficient to establish an issue that requires action and there is no immediate safety concern, the issue should be considered for resolution via the Generic Safety Issue process. Issues in the Generic Safety Issue process should be revisited periodically to confirm that there is still not an immediate safety issue as new data or information is developed. Final resolution of the Generic Safety Issue will be similar to the other options in this section.

3.3.2 Generic Communication

Generic communication may be used to communicate information and gather information. Generic communications should not be used to impose backfits (unless a backfit is justified by a cost benefit analysis and risk/safety considerations indicate that the backfit is needed). Generic communication should not imply that a current licensing basis is not acceptable or that compliance with new guidance is required without completing the backfit analysis. When gathering data, the NRC must confirm that the burden imposed on the industry to gather the data is justified (i.e., the generic communication should estimate the extent of the burden and at least qualitatively justify imposing that burden).

3.3.3 Voluntary Industry Initiative

When deemed appropriate based on the projected risk and safety considerations, the industry may choose to adopt an initiative to address the issue. The initiative may be in the form of a self-imposed backfit or a new activity. Such initiatives may take different forms

⁴ U.S. NRC, Atomic Safety and Licensing Board, Memorandum and Order, ASLBP No. 04-832-02-OLA, November 22, 2004.

such as the NEI Initiative. Such initiatives have the same regulatory impact as a commitment to the NRC by each of the licensees within the scope of the initiative.

3.3.4 Risk-Informed, Performance-Based Solution

All solutions should be based on risk and safety considerations. In some cases, deterministic bases may be used because it satisfies the risk and safety considerations and the costs are justified. In other cases, the deterministic solution may not be justified and such cases a Risk-Informed, Performance-Base Solution should be pursued per 10 CFR and regulatory guidance.

3.3.5 Rulemaking

When risk and safety considerations indicate that the current licensing bases and current operations of the plant do not need to be changed, but compliance in accordance with current regulatory requirements is in doubt, rulemaking should be initiated to revise the regulations and remove the compliance questions.

3.3.6 Backfit

Backfits should not be imposed unless dictated by safety considerations. All backfits should be supported by an analysis which shows that the cost of the backfit is commensurate with the improvement in safety. When the backfit is not justified, rulemaking should be considered. Licensees may choose to adopt a backfit, in which case the cost analysis would not be necessary.

3.3.7 Use-As-Is

In some cases, resolution may be that no action is required if safety considerations do not justify a backfit and compliance is not in question. Such solutions should be documented, with no additional action required.

Appendix A - Examples

[Under development]

NEI Licensing Forum
October 15-16, 2007
Westin Hotel, Arlington, VA

LICENSING PROCESS EFFECTIVENESS
- Continued Process Improvement -

Monday, October 15

Room _____
7:00 a.m.–8:00 a.m.

Registration & continental breakfast

KEYNOTE SPEAKERS

Room _____
8:00–9:00 a.m.

- *Introduction – NEI*
- *NRC Keynote*
- *NEI Keynote*

9:00–9:30 a.m. --

Break

PLENARY on GENERIC ISSUES

Room _____
9:30–11:30 a.m.

Topics:

1. NEI Generic Issues Management (GIM) Team – NRC and NEI speakers
2. Role of the CRGR – NRC speaker
3. NEI Topical Report (TR) Team – Industry speaker

Moderators:

- *NRC*
- *NEI*

Panelists:

- *NRC (2)*
- *NEI/Industry (2)*

Room _____
11:30 a.m.–1:00 p.m.

Lunch

PLENARY on NRC MANAGEMENT ISSUES

1:00–4:30 p.m.

Break from 2:30–3:00 p.m.

1. NRC Strategic Plan for FY 2008 – NRC and Industry speakers
2. Resource management (licensee forecasts; NRC milestone schedules) – NRC and Industry speakers
3. Licensing metrics – NRC and Industry speakers

Moderators:

- *NRC*
- *NEI*

Panelists:

- *NRC (3)*
- *NEI/Industry (3)*

4:30 p.m.

Adjourn for the day

Room _____
5-7 p.m.

• NEI reception

Tuesday, October 16

Room _____

7:00-8:00 a.m. –

Registration & continental breakfast

Room _____

8:00-8:30 a.m. –

Introduction/Recap of First Day

PLENARY on LICENSING PROGRAMS

Room _____

8:30-11:30 a.m.

Break from 9:30-10:00 a.m.

Topics:

1. Operability Determination Process (ODP) – NRC and Industry speakers
2. Codes and standards development – NRC and Industry speakers
3. NRC Headquarters/Region interface – NRC and Industry speakers

Moderators:

- *NRC*
- *NEI*

Panelists:

- *NRC (3)*
- *NEI (3)*

Room _____

11:30 a.m.-1:00 p.m.

Lunch

PLENARY on LICENSING ACTIONS

1:00-4:30 p.m.

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

1. License Amendment Request (LAR) Process – NRC and Industry speakers
2. Licensing Process Improvements – NRC and Industry speakers
3. Pandemic Licensing Plan – NRC and Industry speakers

Moderators:

- *NRC*
- *NEI*

Panelists:

- *NRC (3)*
- *NEI (3)*

4:30 p.m.

Forum Adjourned

NEI LATF Comments on LIC-500, Rev. 3, June 24, 2005
 "Processing Requests for Reviews of Topical Reports"

#	Section	Comment
1	Title	Recommend changing the title to "Topical Report Process."
2	1 – Policy	The link to http://www.nrc.gov/what-we-do/regulatory/licensing/topical-reports.html should be http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html .
3	2 - Objective	Recommend adding the following: "The objective of the topical report process is, in part, to add value by improving the efficiency of other licensing processes, for example, the process for reviewing license amendment requests from commercial operating reactor licensees. Therefore, topical reports should be reviewed with the intent of maximizing their scope of applicability consistent with current standards for licensing actions, compliance with applicable regulations, and reasonable assurance that the health and safety of the public will not be adversely affected."
4	4.1 – Overview of the TR Process	Same as comment 2.
5	4.2 – TR Review Process Steps	Items 4 and 7 under Time Period Column specify "within X working days" but do not specify the starting point as other time periods are specified in the column. • Item 4 add "...of receipt from Work Planning Center." • Item 7 add "...of receipt of TR."
6	4.2 – TR Review Process Steps	Item 13 specifies a time period of "Within 10 working days for proprietary information, and within additional 10 working days for factual errors or clarity issues." However, it is not clear why there is a difference in the time periods, and the difference could lead to the NRC project manager having to handle comments twice. Recommend 20 working days for commenting on both proprietary information and factual/clarity issues.
7	4.2.1 – Pre-submittal Meeting	Recommend adding following paragraph to end of this section: "The staff should prepare a meeting summary to document input provided by, and agreements reached with, the applicant. This is to ensure consistency of staff expectations in case different reviewers or managers are assigned during the course of the topical report review."

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#	Section	Comment
8	4.2.3 – Work Plan	<p>The last paragraph currently reads:</p> <p>"If approval of the TR requires a change to the standard TSs then the Technical Specifications Section should be contacted to determine if the change is significant enough to warrant a technical specification task force (TSTF) submittal by the Nuclear Energy Institute (NEI). The TSTF process is the method that the staff and industry (through NEI) use to maintain standard TSs. For an owners group to change its standard TSs, the owners group submits a proposed TSTF to NEI which submits the TSTF to the NRC for review and approval."</p> <p>Recommend updating this paragraph to reflect a change in responsibility for the TSTF. The TSTF is a joint activity of the BWROG and the PWROG and is no longer an NEI task force. Recommend revising the paragraph as follows:</p> <p>"If approval of the TR requires a change to the standard TSs then the Technical Specifications Section should be contacted to determine if the change is significant enough to warrant a Technical Specification Task Force (TSTF) submittal. The TSTF is a joint owners group activity of the BWROG and the PWROG. The TSTF and the staff maintain standard TSs using the TSTF Traveler process. For an owners group to change its standard TSs, the owners group submits a proposed TSTF Traveler to the TSTF, which then finalizes and submits the Traveler to the NRC for review and approval."</p> <p>The NRC TS Branch and the TSTF are working together to develop a process for coordinating TRs and TSTF Travelers.</p>
9	4.2.4 – Acceptance Review	<p>The second paragraph, last sentence, currently reads:</p> <p>"Once agreed upon, the report-specific review schedule will be considered a "commitment" by the staff and the applicant."</p> <p>It is not clear what is meant by the word "commitment" in this context. It does not fit the definition of a regulatory commitment defined in NEI-99-04, and the nature of the staff commitment is not clear. Recommend rewording the sentence as follows:</p> <p>"Once agreed upon, the staff and the applicant will take reasonable steps to meet the schedule and the parties notify one another as soon as practicable if schedule adjustments are necessary."</p>

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#	Section	Comment
10	4.2.5 – Proprietary Determination	<p>The first paragraph, fifth and sixth sentences, currently read: "If the staff determines that some or all the information designated by the applicant as proprietary is not proprietary, the PM should contact the applicant to try to resolve the issue. The staff should not continue with the review if there is a disagreement about the information designated as proprietary."</p> <p>Recommend deleting the sixth sentence. A technical review need not be stopped by disagreements about information designated as proprietary. Fragmented reviews are an inefficient use of resources. Disagreements should be resolved by management oversight while minimizing the affect on the technical review.</p>
11	4.2.6 – RAIs	<p>Recommend a review to ensure consistent RAI language between LIC-101, LIC-500, and NEI 06-02. NEI is preparing NEI 06-01 Revision 1 for submittal to NRC in late 2007.</p>
12	New 4.3 – Safety Evaluation Content	<p>A Safety Evaluation (SE) for a topical report should be written with the LAR process in mind. This will assist licensees when they draft LARs and NRC staff when they review LARs that are based on a TR. The SE should define, as explicitly and broadly as possible, the applicability of a generic TR to help licensees and reviewers manage the scope of plant-specific reviews. NRC safety evaluations should be as explicit as possible in stating how they can be used as references in subsequent LARs so that staff resources aren't spent re-reviewing in the LAR what has already been approved in the topical report SE. Licensees need to know what information is necessary in the LAR to show applicability of the TR and what additional plant-specific information is needed by the reviewer. Also, for added efficiency, it would be helpful if safety evaluations of topical reports included guidance for implementation under 10 CFR 50.59.</p> <p>To assist NRC reviewers of LARs that reference an approved TR, we recommend that topical report SEs address the following topics:</p> <ul style="list-style-type: none"> • Reasonable assurance (i.e., attributes of the "finding" that the LAR reviewer needs to make). • Flexibility of limitations and conditions (i.e., to expand the plant population that can reference the TR). • 10 CFR 50.59 (i.e., the extent to which the TR can be implemented without additional review). • Precedent (i.e., the extent to which an SE builds on past SEs). • Generic applicability (i.e., explicit statement of the scope of generic applicability and what needs to be addressed on a plant-specific basis by licensees that seek to use the TR). <p>This will help licensees provide the necessary information in LARs that reference approved TRs to preclude unnecessary questions that go beyond the scope of the TR and its NRC SE.</p>

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13	New 4.4 – Metrics	<p>Our understanding is that the metric for completion of a Topical Report review is 96% in 1 year and 100% in 2 years (from issuance of the acceptance review letter), to be consistent with the LAR metric. The purpose of the metric is to:</p> <ul style="list-style-type: none"> • Facilitate prompt adoption of standard methods • Avoid inefficiencies due to changing reviewers • Free NRC resources for other work <p>Aggressive metrics can help drive process changes and improve efficiency. For example, aggressive goals were established for license-renewal reviews and the necessary processes were built to meet those goals. However, metrics should not drive regulatory decision-making about whether to stop a review. Staff should not deny a request or ask for withdrawal because a timeliness goal is approaching. Metrics should be flexible to accommodate reasonable outlier situations (complexity, first-of-a-kind, new information, significant change in need date, etc.).</p>
14	New 4.5 – Use of CLIIP	<p>Recommend that NRC work with industry to identify ways to apply the consolidated line item improvement process (CLIIP) to topical reports. The CLIIP is based on front-loading the technical review to establish licensing boundary conditions that can be administratively implemented by NRC Project Managers. A CLIIP includes the generic boiler-plate language for plant-specific submittals. They establish model SE boundary conditions and generally include a template that permits a licensee to "fill in the blanks" to show how the boundary conditions will be satisfied. Submittals to adopt a CLIIP must address criteria for licensee-specific use.</p>
15	New 4.6 – Dispute Resolution	<p>Recommend that NRC work with stakeholders to develop a process for dispositioning disagreements between NRC and industry about the TR process and its implementation. Proposed discussion topics are:</p> <ul style="list-style-type: none"> • Defining and documenting a disagreement • Peer review • Participants (applicant, reviewers, responsible managers, etc.) • Independence • Appeals • Arbitration • Responsible NRC manager • References
16	5.3 - Responsible Manager 6 – Performance Measures	<p>Both of these sections refer to performance measures for the Topical Report Program contained in the NRR Operating Plan. Please advise where we can locate the Operating Plan on the NRC website, in ADAMS, or in some other location.</p>

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17	General Comment	LIC-500 Revision 3 gives its ADAMS Accession Number (ACN) as ML051800651. However, neither a search on this ACN nor a search on "LIC-500" leads to the document. Searching for LIC-500 in ADAMS provides Revision 1 and Revision 2, but not Revision 3. It appears that Revision 3 is not posted in ADAMS.
18	General Comment	<p>Communications</p> <ul style="list-style-type: none"> • Consider post-submittal meetings when appropriate to keep expectations aligned, especially if personnel change. • Use milestone scheduling, and have periodic communications on whether the review is on track to meet the milestone schedule. • Provide advance communication about pending RAI or denial letters.
19	General Comment	Add cross references to other Office Instructions, such as LIC-101, etc. At some point this may include NRC-endorsed industry guidance documents.
20	General Comment	<p>The scope and implementation of the Topical Report (TR) process is very important to the safe operation of nuclear power plants. The industry believes that the process is fundamentally sound, but that it is not being implemented efficiently and effectively. Industry would like to work with NRC toward:</p> <ul style="list-style-type: none"> • criteria for consistent expectations, processing, and timely review and approval of TRs and subsequent licensing actions, • increasing opportunities to use TRs, • minimizing limitations and conditions in SEs, • applying the consolidated line item improvement process to the implementation of TRs, • minimize changing reviewers, • using precedent reviews as the starting point for subsequent reviews, • using pilot plants on a case-by-case basis to assist the regulatory review of a TR, • facilitating generic endorsement of new technical information & methods, and • standardizing industry implementation by multiple plants that intend to use the generic precedent established by the TR.