January 30, 2006

MEMORANDUM TO: Daniel S. Collins, Acting Chief
Special Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

FROM: William D. Reckley, Senior Project Manager /RA/
Special Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF MEETING HELD ON OCTOBER 27, 2005, BETWEEN THE U.S. NUCLEAR REGULATORY COMMISSION STAFF AND INDUSTRY LICENSING ACTION TASK FORCE

Members of the staff of the U.S. Nuclear Regulatory Commission (NRC) hosted a meeting with representatives of the Nuclear Energy Institute (NEI) and licensees comprising the Licensing Action Task Force (LATF) on October 27, 2005, at NRC Headquarters in Rockville, Maryland. This meeting was open to the public. A list of attendees is provided as Enclosure 1.

A summary of the discussion is provided below:

1. Reorganization of the Office of Nuclear Reactor Regulation (NRR)

The NRR staff briefly discussed the recent reorganization of NRR. An organizational chart (similar to that available on the NRC public web site at www.nrc.gov/reactors/nrr-roster.pdf) was provided to those in attendance.

2. NEI Licensing Forum

The NEI representative, Mike Schoppman, discussed the licensing forum held in Baltimore, Maryland on November 7, 8, and 9, 2005. A program for the forum is provided in Enclosure 2.

3. Licensing Action Request (LAR) Guideline (NEI-06-02) Development

The LATF discussed its development of a guideline for licensing action requests (NEI-06-02). A copy of the draft guideline is provided as Enclosure 3.

4. Generic Issue Management (GIM) Process

The LATF and NRC staff discussed the possible development of processes related to managing/coordinating the activities related to specific licensing actions and generic technical issues. Additional discussions on this topic are expected at the Licensing Forum and future LATF meetings.

5. Operability Determination Process (ODP) Workshop

The LATF stated that its members thought that there had been good and productive interactions between the NRC staff and the LATF leading to the issuance of NRC Regulatory Issue Summary (RIS) 2005-20, "Revision to Guidance Formerly Contained in NRC Generic Letter 91-18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability." Additional discussions and further explanations of the guidance will be discussed at the ODP Workshop on November 9, 2005, as part of the 2005 Licensing Forum. The LATF and NRC staff discussed the possibility of additional meetings or workshops for NRC regional offices and licensees.

Enclosures:
1. List of Attendees
2. NEI/LATF Handout
3. Draft of NEI-06-02, "Guidelines for Preparing License Amendment Requests"

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5. Operability Determination Process (ODP) Workshop

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LICENSING ACTION TASK FORCE MEETING

October 27, 2005

LIST OF ATTENDEES

NAME	ORGANIZATION
Herb Berkow	NRC/NRR/DLPM
Ho Nieh	NRC/NRR/DLPM
David Terao	NRC/NRR/DLPM
Bill Reckley	NRC/NRR/DLPM
Tom Boyce	NRC/NRR/DIPM
Eric Thomas	NRC/NRR/DIPM
Mike Schoppman	NEI
Jim Fisicaro	Duke Energy
Donald Hoffman	Excel Services
Edward Weinkam	Nuclear Management Company
Mark Flaherty	Constellation
Rick Garner	Progress Energy
Doug McKinney	Southern Nuclear
Don Woodlan	STARS
Glen Morris	TVA - Nuclear
Jerry Holm	Framatome ANP
Charlie Brinkman	Westinghouse
Keith Jury	Exelon
Tomoho Yamada	Japan Nuclear Energy Safety Organization
Deann Raliegh	Scientech
Nancy Chapman	SERCH/Bechtel

Enclosure 1

NRC/NEI Meeting
Licensing Action Task Force
October 27, 2005

I. NRC Reorganization

- LATF alignment with the new NRR organizational structure

II. NEI Licensing Forum

- Program (attached)

- 11/7/05 – Keynote speakers and management plenary
  - ✓ NRR reorganization
  - ✓ Generic communications and backfitting
  - ✓ Process improvement opportunities
  - ✓ NRR report on the evaluation of the operating reactor licensing program

- 11/8/05 – Process-improvement plenary and breakout sessions
  - ✓ NEI 06-02 (licensing guidelines), including the use of precedent and the request-for-additional-information (RAI) process
  - ✓ RAI Team report
  - ✓ RIS 2005-05 on Part 50 and Part 72 criticality analyses
  - ✓ NOED process
  - ✓ Topical report process
  - ✓ Generic issue management (GIM)

- 11/9/05
  - ✓ Operability Determination Process (ODP) Workshop
  - ✓ Regulatory Issue Summary (RIS) 2005-20

Enclosure 2

NRC/NEI Meeting
Licensing Action Task Force
October 27, 2005

NEI 06-02

- ✓ Licensing guidelines for use by operating reactors

- ✓ Draft 3 was released on 10/24/05 for informal comment by the NRC LATF. Major topics are:
  - License Amendment Request (LAR) threshold
  - Use of precedent
  - Standard LAR format and content
  - Interfacing with NRC staff on RAIs
  - Interfacing with the NRC Tech Spec Branch and the industry Tech Spec Task Force

- ✓ Distribute draft 3 at the NEI Licensing Forum

- ✓ Comments from NEI LATF Steering Group are due 12/15/05

- ✓ Distribute draft 4 for industry review and comment on 1/5/06

- ✓ Submit final draft to NRC on 4/1/06

- ✓ Request NRC position on NEI 06-02 by 10/15/06

NRC/NEI Meeting
Licensing Action Task Force
October 27, 2005

GIM Process

- ✓ Distribute outline of NEI position paper at NEI Licensing Forum

- ✓ Discuss the regulatory use of generic information during NRC review of plant-specific LARs

- ✓ Discuss ways to minimize the impact of new generic information on the stability of the current licensing basis (CLB)

- ✓ Discuss process-improvement opportunities for incorporating generic information:
  - criteria
  - thresholds
  - documentation
  - applicability of other processes and regulations (e.g., corrective action process; 10CFR50 Appendix B QA criteria; FSAR update; etc.)
  - consolidated line item improvement process (CLIIP)
  - backfitting implications
  - relevant licensing board decisions

- ✓ NEI publish a position paper by 1/15/06

NRC/NEI Meeting
Licensing Action Task Force
October 27, 2005

ODP Workshop

- ✓ Joint NRC/NEI Implementation Workshop

- ✓ RIS 2005-20
  - ➢ Inspection Manual Chapter 9900, "Operability Determinations and Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety"

- ✓ NEI – Welcome & objectives of the workshop

- ✓ NRC – Overview of RIS
  - ➢ intent
  - ➢ changes/clarifications

- ✓ NRC – Communications going forward

- ✓ NEI – Objectives of NEI participation in public meetings

- ✓ NRC – Overview of the ODP

- ✓ NEI – Scope and examples
  - ➢ Operability/Functional hierarchy
  - ➢ Discussion of Specified Functions (SFs in the CLB)
  - ➢ Discussion of Specified Safety Functions (SSFs as a subset of SFs)

- ✓ All Workshop Participants - Open discussion

- ✓ NRC/NEI – Conclusions/Wrap-up

LICENSING FORUM 2005

November 7-9, 2005 ∫ Marriott Inner Harbor at Camden Yards ∫
Baltimore, Maryland

Program

Monday, November 7

11:00 – 5:00 Registration
Grand Ballroom – Pre-Foyer

1:00 – 2:30 MANAGEMENT PLENARY
Grand Ballroom (ABC East)
Introduction and Keynote Speakers

NEI Keynote
Introduction and Overview of Forum 2005
Steve Floyd – Vice President, Regulatory Affairs - NEI

NRC Keynote

- Jim Dyer – Director, NRC Office of Nuclear Reactor Regulation (NRR)

Industry Keynote

- Mike Wallace – President, Constellation Generation Group

2:30 – 3:00 Break

3:00 – 5:00 MANAGEMENT PLENARY (continued)
Grand Ballroom (ABC East)

Topics

1. Generic Communications and Backfitting
   - Brian Sheron, Associate Director for Engineering and Safety Systems (NRR)
   - Alex Marion, Director – Engineering (NEI)
2. Project Management and Special Projects
   - Bruce Boger, Associate Director for Operating Reactor Oversight and Licensing (NRR)
   - Cathy Haney, Director – Division of Operating Reactor Licensing

5:00 Adjourn

5:30 – 7:00 NEI reception
Chesapeake Room

Tuesday, November 8

7:30 – 5:00 Registration
Grand Ballroom – Pre-Foyer
Continental breakfast available (7:30-8:30)

8:30 – 10:00 ISSUES PLENARY
Grand Ballroom (ABC East)

Topics:
1. NEI Guideline 06-02 (LAR process)
2. NRC/NEI RAI team report

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3. NRC Performance Assessment and Metrics

10:00 – 10:30 Break

10:30 – 12:00 ISSUES PLENARY (continued)
Grand Ballroom (ABC East)

Topics:
4. NOED Process
5. Topical Report process
6. Generic Issue Management (GIM) process
   [setpoints; control room habitability; accident source term; 50.46 reports, sump performance, RCS leakage, reportability issues, etc.]

12:00 – 1:30 Lunch (White Cap Tavern)

1:30 – 3:00 Issues Breakout 1

Grand Ballroom A – NEI Guideline 06-02
Grand Ballroom B – GIM Process

3:00 – 3:30 Break

3:30 – 5:00 Issues Breakout 2

Repeat Breakout 1

5:00 Adjourn

Wednesday, November 9

Operability Determination Process (ODP) Workshop

7:30 –3:00 Registration
Grand Ballroom – Pre-Foyer
Continental breakfast available (7:30-8:30)

8:30 – 10:00 ODP Plenary
Grand Ballroom (ABC East)

Topics:
1. Welcome & objectives of the Workshop
2. NRC overview of RIS 2005-20
3. NRC communications & plans going forward

10:00 – 10:30 Break

10:30 – 12:00 ODP Plenary (continued)
Grand Ballroom (ABC East)

Topics:
4. NEI objectives
5. NRC overview of the ODP
6. NEI views on scope & examples

12:00 – 1:30 Lunch (White Cap Tavern)

1:30 – 3:00 ODP Plenary (continued)
Grand Ballroom (ABC East)

7. Open discussion
8. Conclusion/Wrap-up

3:00 Adjourn

NEI 06-02

GUIDELINES FOR PREPARING LICENSE AMENDMENT REQUESTS

2006

Enclosure 3

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Acknowledgements

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

NEI Licensing Action Task Force – Steering Group
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Charles Brinkman, Westinghouse
Jerry Burford, Entergy South
Patricia Campbell, Morgan Lewis & Bockius
Joe Conen, DTE Energy (BWROG)
James Fisicaro, Duke Energy
Mark Flaherty, Constellation
Rick Garner, Progress Energy
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Daniel Stenger, Ballard Spahr & Nuclear Regulatory Services Group
George Stramback, General Electric
Gary Vine, Electric Power Research Institute
Ed Weinkam, Nuclear Management Corp.
Don Woodlan, Strategic Teaming And Resource Sharing (STARS)
Dale Wuokko, First Energy

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 _____.

Guidelines for Preparing
License Amendment Requests (LARs)

TABLE OF CONTENTS

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[1] 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[2] 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."[3]

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.[4] 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[5] 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:

9. the Operating License (OL), including appendices (e.g., Technical Specifications), must be revised to permit implementation of the modification, or

10. 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[6] 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[7] to assist licensees in implementing the revised rule. That same

month NRC published Regulatory Guide 1.187,[8] 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)[9] 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.[10]

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:

1. Amendments to the Operating License or Technical Specifications pursuant to 10 CFR 50.90.
2. Changes to documents controlled by Technical Specifications, such as the Offsite Dose Calculation Manual (ODCM).

3. Changes controlled by 10 CFR 50.54 change processes (i.e., quality assurance program, security contingency plan, and emergency plan).
4. 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.[11]

5. Changes to the standard fire protection license condition (Generic Letter 86-10).
6. 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[12]
- File a plant-specific backfit claim pursuant to 10 CFR 50.109.[13]

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:

1. Commercial information services
2. Nuclear industry sources
   - NEI
   - Regional utility groups
   - Communication among licensees
   - Cooperative arrangements
     - STARS
     - USA
3. 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-101defines precedent licensing actions as those with a similar proposed change and regulatory basis for the SE [page 2.3],[14] 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[15] 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:

- The precedent must be appropriate for the intended amendment.
- The precedent must meet current regulations and NRR guidance.
- Include the following factors when they compare possible precedent with the LAR:
  a. physical characteristics
  b. design basis
  c. risk-significance
  d. [others???]
- NRR needs to obtain concurrence from the Technical Specification Branch that the proposed precedent is appropriate.
- When referring to another submittal or a Tech Spec Task Force (TSTF) Traveler[16] 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.

- Communicate with the utility whose submittal you plan to use as precedent to ensure the systems in each plant are similar.
- 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.
- 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.
- 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.
- 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.[17] Accordingly, the first substantive step in the planning stage of processing a license amendment is for the Staff to "identify, assess, and review" precedent.[18] 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.[19] 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.[20]

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.[21]

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.[22] 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:

1. insufficient guidance to licensees on submittal quality
2. not understanding NRC reviewer expectations or review needs
3. lack of standards on the amount of background information that should be submitted
4. lack of standards on submittal scope and level of detail
5. lack of standards on the applicability of the current licensing basis
6. complex first-of-a-kind submittals
7. a shift in regulatory focus due to operating events
8. an increase in multiple rounds of RAIs
9. duplicate questions
10. questions that overlook information present in the License Amendment Request (LAR)
11. inefficiencies due to changing reviewers
12. reviewer s unfamiliar with NRR operating instruction LIC-101
13. 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, you 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 licensees 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

A.1 Introduction

There are over 300 generic changes to the Improved Standard Technical Specifications (ISTS) NUREGs that have been approved by the NRC since Revision 0. The majority of these changes have been approved after most plants converted to the ITS. There have been hundreds of license amendment requests (LARs) adopting Travelers. Some LARs adopt one Traveler while others adopt multiple Travelers.

A.2 Problem Statement

The format, content, and level of detail of LARs adopting Travelers, and especially those adopting multiple Travelers, have varied considerably as has the NRC's process for reviewing those changes. As a result, some licensees are preparing amendments that are overly detailed (compared to other NRC-approved LARs), resulting in LARs that are difficult for the licensee to prepare and difficult for the NRC to review. Given that the NRC has already reviewed and approved a Traveler, it should be a straightforward process for the NRC to review and approve a LAR based on a Traveler, but it is not. Frequently, license amendments based on Travelers are sent to the NRC Technical Branches for review, ignoring the previous approval. In some cases, the NRC Technical Branches have not approved or modified approved Travelers.

A.3 Examples

Multiple TSTF adoption LARs range from the brief to the detailed. An example of a brief LAR is the Duane Arnold Energy Center submittal on January 28, 2004 and approved on May 12, 2005. An example of a detailed LAR is the Cooper Nuclear Station submittal dated April 13, 2005. This LAR is still under NRC review.

A.4 Proposed Action Plan

A.4.1 Recommendations

A.4.1.1 - Single Traveler Adoptions

Establish an expected level of detail for a LAR adopting a Traveler. The format should be consistent with the NEI Standard LAR Format. The expected level of detail should consider:

- The justification presented in the Traveler and accepted by the NRC should not be repeated in the LAR. Doing so is confusing as the NRC must carefully compare the restated justification in the LAR to the Traveler justification to ensure there are no changes.

- For Travelers with numbers starting with TSTF-400, the NRC prepared Safety Evaluations for approved Travelers. For those Travelers, it is not necessary for the LAR to provide the date of the NRC approval or examples of other plants that have adopted the Traveler. If necessary, the TSTF can provide the NRC with a comprehensive list of NRC approval dates for Travelers starting with TSTF-400.

- For Travelers with numbers less than TSTF-400, the NRC did not prepare Safety Evaluations for approved Travelers. In most cases, the NRC provided a letter stating the Traveler was approved but in some cases Travelers were approved in meetings and no letter was written. For those Travelers, the LAR should provide the NRC approval date and an example of another plant that has adopted the Traveler, including the approval date and amendment number. The TSTF will develop a list of plant-specific approvals for these Travelers and make it available to licensees and the NRC. If the Traveler has been previously approved, restating the justification is not necessary. If there is no previous plant-specific approval, the LAR should state so and provide a justification for the change. This justification should be consistent with the justification provided in the Traveler, but may be more detailed if necessary. The justification provided in early Travelers is typically not sufficiently detailed to meet current industry or NRC expectations.

- The LAR should address the following:

  - Provide the Traveler number, approved Revision, and title;

  - Provide a brief discussion of the change to the plant-specific TS;

  - Describe differences between the affected plant-specific TS and the ISTS marked up in the Traveler.

  - Describe any differences between the Traveler justification and the plant-specific justification. If none, state so. Do not repeat the justification unless necessary to describe differences between the plant-specific application and the Traveler;

  - Describe and agree to any commitments. Some Travelers require commitments from the licensee; and

  - List the affected plant-specific TS pages.

A.4.1.2 - Multiple Traveler Adoptions

Establish a standard format and level of detail required for a LAR adopting multiple Travelers. The format should be consistent with the NEI Standard LAR Format. The level of detail discussion for LARs based on a single Traveler applies to LARs adopting multiple Travelers. In addition, the following should be included:

- The discussion of the Travelers should be in an Appendix to the letter with the discussion of each Traveler beginning on a new page. The discussion of each Traveler should address the points given in Section A.4.1.1.

- Licensees have the option of following the discussion of the Traveler with the markup of the affected TS pages or of having all of the markup pages in a single location (this is preferable if several Travelers affect the same TS pages). If the pages are in a single location, each change should be annotated in the right-hand margin with the corresponding Traveler number.

- Licensees have the option of providing a No Significant Hazards Considerations (NSHC) for each Traveler, a single NSHC for all of the changes, or a number of generic NSHCs for each type of change (Administrative, Less Restrictive, More Restrictive, and Relocation) similar to the format used for ITS Conversions. See NEI 96-06, "Improved Technical Specifications Conversion Guidance."

- An alternative format for adoption of a large number of Travelers is to markup the plant TS similar to an ITS conversion. Individual changes would be identified as Administrative, Less Restrictive, More Restrictive, or Relocations. Discussions of Change would be written for each change. The Discussions of Change may reference the Traveler if the plant TS and the ISTS were the same. A more detailed discussion would be included if the change is not a direct application of a Traveler. A single NSHC would be written for the Administrative, More Restrictive, and Relocated items and individual NSHCs would be written for each type of Less Restrictive Change. See NEI 96-06 for further guidance.

A.4.1.3 NRC Review Process

NRC will consider revising NRR Office Instruction LIC-101, "License Amendment Review Procedures," and other NRC guidance, as necessary, to state that LARs adopting Travelers will be reviewed by the Project Manager and the Technical Specification Section, but not by a Technical Branch unless the licensees vary from the approved justification of the Traveler. In such cases, the Technical Branch may review the deviation, but not the overall basis for the approved Traveler.

A.4.2 Schedule

LARs adopting individual Travelers are submitted frequently. Many plants are developing or planning LARs adopting tens - or even a hundred - Travelers. Additional guidance can be developed and implemented as needed.

A.5 References

1. NEI 96-06, "Improved Standard Technical Specifications Conversion Guidance."

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

B.1 Introduction

The TSTF, in consultation with the originating and applicable Owners Groups, develops generic changes to the Improved Standard Technical Specifications (ISTS). If a change is determined to be technically acceptable, generic, and sufficiently cost-beneficial to offset the expected NRC review fees, it is submitted to the NRC for review. (Note that a limited number of Travelers are exempted from NRC review fees because they support NRC generic initiatives.) After the Traveler is approved by the NRC, it is given an "-A" postscript (e.g., TSTF-445-A) and posted on the TSTF web site(http://www.excelservices.com).

If a Traveler is determined to be technically acceptable and generic, but not sufficiently cost-beneficial to warrant the Owners Group paying NRC review fees, it is approved by the TSTF, given a "-T" (for "template") postscript (e.g., TSTF-445-T) and posted on the EXCEL web site for use by licensees as a template for plant-specific license amendments. The Owners Group and TSTF review and approval ensures the change follows the format and usage rules of the ISTS and applies the change consistently to the ISTS for all applicable plant designs.

B.2 Problem Statement

It would be advantageous for both the industry and the NRC for there to be a mechanism by which licensees will submit plant-specific license amendment requests (LARs) based on "T" Travelers and which will result in NRC generic approval of the Traveler without incurring significant additional review fees to the licensee. The plant-specific amendments will be considered lead plant submittals and the NRC will write a Safety Evaluation sufficiently generic to serve as the approval of the Traveler.

B.3 Examples

Specific examples can be obtained by contacting the Tech Spec Task Force (tstf@excelservices.com).

B.4 Action Plan

B.4.1 Recommendations

2. A licensee basing a plant-specific LAR on a "T" Traveler will prominently state that the amendment is based on a TSTF-approved Traveler and give the Traveler number and title. The licensee will state that their submittal should be considered a lead-plant submittal for the Traveler. It is recommended that the generic Traveler be included as an attachment to the LAR. The licensee's LAR will highlight and justify any differences

between their request and the Traveler. The licensee will copy the TSTF on their submittal letter.

3. As with any lead plant submittal, the licensee recognizes that there may be an increase in the NRC review fees for the LAR due to the need to consider the generic aspects of the Traveler. If a plant submits a plant specific LAR and will not pay review fees for the referenced "T" Traveler, this becomes a plant specific LAR and the NRC's Safety Evaluation does not approve the "T" Traveler.

4. NRC requests for additional information (RAIs) and licensee responses that affect the generic Traveler will be coordinated with the TSTF to ensure the resulting changes continue to follow the ISTS format and usage guidelines and are appropriate for all applicable plant designs. The TSTF will revise the "T" Traveler as necessary to reflect any changes.

5. The NRC review will consider the generic change in addition to the plant specific change. The NRC Safety Evaluation will state that the Safety Evaluation approves the plant-specific amendment and provides generic approval for the Traveler.

6. Upon approval of the lead plant submittal, the NRC will send a letter to the TSTF in parallel with the amendment approval sent to the licensee. This letter documents the generic approval of the Traveler.

7. The TSTF will change the Traveler from a "T" Traveler to an "A" Traveler and post the approved Traveler, Safety Evaluation, and NRC letter on the EXCEL web site.

B.4.2 Schedule

The first LAR using this process has been submitted, and implementation is proceeding to facilitate on-going submittals.

B.5 References

None.

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

C.1 Introduction

Seventy-three (73) of the 103 nuclear units in the U.S. have converted or are converting to the Improved Standard Technical Specifications (ISTS). The remaining 30 units have either committed to convert or are considering conversion. A typical ISTS conversion LAR takes from 12 to 16 months to develop and comprises well over 5000 pages. The industry described the format and content of a LAR to convert to the ISTS in NEI 96-06, "Improved Standard Technical Specifications Conversion Guidance."

C.2 Problem Statement

The NRC has never formalized their review process for LARs that convert to the ISTS. NRC review times have varied from 6 months to over 2 years. The number of RAIs received, and the quality of those RAIs, has varied substantially. As a result, it is difficult for licensees to plan the challenging task of implementing an ISTS conversion LAR with any certainty as it is unknown how long the review will take or what new issues may be identified.

A recurring issue with ISTS conversions is so-called "Beyond Scope Items" (BSIs). A BSI is loosely defined as any proposed change in an ISTS conversion LAR that does not exist in the plant's current TS or in the ISTS. All conversions contain some BSIs that result from design differences between the plant and the generic plant design assumed in the ISTS NUREG for that NSSS. These changes are referred to the NRC technical branches for review. These changes take longer to review and frequently disrupt the NRC review schedule and the licensee's implementation schedule. However, there is no set definition of a BSI and the NRC often classifies necessary changes as BSIs which can a significant, detrimental effect on the review and implementation schedule and divert NRC and licensee resources.

The Industry and the NRC have developed informal procedures for expediting the NRC's review of an ISTS conversion LAR that involves the use of a publicly accessible, web-based question and answer board. This eliminates the delays inherent in exchanges by mail and allows rapid exchange of questions and answers. Following NRC review of the LAR and after agreement on the resolution of NRC questions, a single supplement to the LAR is submitted providing any necessary revisions. Use of this process has shortened the NRC's review time from 18 months to 8 months. This process was used on the D. C. Cook ISTS conversion review and, after incorporation of lessons learned, is now being used on the Beaver Valley and Monticello ISTS conversion review. However, this approach is a based on an informal agreement with the current NRC management.

NRC Procedure LIC-101, "License Amendment Review Procedures," contains a Section 8 that describes the Consolidated Line Item Improvement Process (CLIIP). However, the process for reviewing an ISTS conversion LAR is informal and based on agreements with individuals within the NRC and, as such, is subject to change without notice. A change in the NRC review process can upset an implementation

schedule that involves the revision and implementation of thousands of plant procedures and training for hundreds of individuals.

C.3 Examples

Specific examples can be obtained by contacting the Tech Spec Task Force (tstf@excelservices.com).

C.4 Action Plan

C.4.1 Recommendations

Coordinate with the NRC staff to develop regulatory guidance that describes conversion to the ISTS The guidance should include:

- NRC Conversion Project Manager responsibilities
- NRC plant Project Manager responsibilities
- NRC reviewer qualification and training
- Definition of "Beyond Scope Issues"
- Management of "Beyond Scope Issues"
- Meetings with the licensee
- Communications with the licensee
- Establishment and tracking of the review schedule
- Schedule adherence
- Use of a question and answer web board
- Replacement of bracketed values in the ISTS with plant-specific values
- Issuance of formal RAIs
- Review of licensee supplements
- Development of the NRC Safety Evaluation
- The process for licensees to appeal NRC decisions during the NRC review

C.5 References

1. NEI 96-06, "Improved Standard Technical Specifications Conversion Guidance."

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

D.1 Introduction

The nuclear industry is run using procedures. Procedures cover every significant activity at a nuclear power plant and there are rigorous processes for altering those procedures. 10 CFR 50, Appendix B, Criteria V states, "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished." However, this is not true for the Nuclear Regulatory Commission. Their activities are constrained at a very high level by laws and regulations, but day-to-day activities are described in guidelines that do not have to be followed. Individual NRC employees have wide latitude to determine how they will perform their work.

D.2 Objective

An important industry objective is greater certainty in the LAR approval process. For example, although NRC has published internal LAR review guidance in Office Instruction LIC-101, reviewers are neither required to follow the guidance nor notify NRR management when they deviate from the guidance. The lack of certainty associated with reviewer habits, the RAI process, and the use of precedent destabilizes the LAR Process.

D.3 Examples

Specific examples can be obtained by contacting the Tech Spec Task Force (tstf@excelservices.com).

D.4 Action Plan

D.4.1 Recommendations

The NRC should create procedures that govern how work is performed. Compliance with those procedures by NRC employees should be a job performance measure. Deviations from the procedures should require prior justification, review, and approval by appropriate NRC management.

The NRC should differentiate between process requirements described in procedures, and standard practices described in lower-level desktop guides

D.4.2 Schedule

The schedule for this activity should parallel those in Appendices A-C.

D.5 References

1. NRR Office Instruction LIC-101, "License Amendment Review Procedures."

Appendix E

Standard Format for Operating License Amendment Requests from Commercial Reactor Licensees

ENDNOTES

[1] 50.90
[2] 50.59
[3] 50.59(a)(1)
[4] 50.59(c)(4)
[5] 5059
[6] Rulemaking, 10 CFR 50.59, "Changes, tests, and experiments," 64FR53613, October 4, 1999.
[7] NEI 96-07, revision 1, "Guidelines for 10 CFR 50.59 Implementation," November 2000.
[8] RG 1.187 November 2000
[9] 50.71(e)
[10] NEI 98-03
[11]NEI 99-04
[12] NUREG/BR-0058
[13] 50.109
[14] LIC-101, page 2.3
[15] dictionary
[16] TSTF Traveler definition
[17] "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
[18] LIC-101, Appendix B at § 2.0, step 3
[19] LIC-101, Appendix B at § 2.3
[20] LIC-101, Appendix B, § 4.3
[21] LIC-101, Appendix B, § 4.2
[22] NEI 2002 WP on standard format