

From: Jack Cushing

To: Les Cupidon

Date: 8/12/03 5:37PM

Subject: Attached is the electronic/ADAMS version of the ISG process

Les

I wil get the slides to you by the end of the week. I will drop off the hard copies tonight.

Jack

Mr. Alex Marion
Nuclear Energy Institute
1776 I Street, NW., Suite 400
Washington, DC 20006-3708

Mr. David Lochbaum
Union of Concerned Scientists
1707 H Street, NW
Suite 600
Washington, DC 20006-3919

SUBJECT: THE INTERIM STAFF GUIDANCE PROCESS

Dear Messrs. Marion and Lochbaum:

The staff stated, when it issued the interim staff guidance (ISG) to applicants for license renewal, that it would provide guidance on implementation of ISGs to licensees holding a renewed license. The staff, in Attachment 1, provides that guidance to licensees holding a renewed license as well as to applicants for license renewal. In addition, the staff describes the process for a stakeholder to request a management review of an approved ISG.

The staff issued a draft of the ISG process on July 30, 2002. On September 25, 2002, the staff issued a draft of the "appeals process." The name of this process has been changed to "management review," and it has been included as part of the ISG process. By letters dated October 29, 2002, and November 12, 2002, NEI provided their comments on the ISG process and the management review process. NEI's comments and the staff's responses are discussed in Attachment 2.

The ISG process captures lessons learned from license renewal reviews and communicates them to the stakeholders. The process includes interaction with stakeholders during the development of the ISG to receive and address their comments. If the ISG is approved, then an applicant for a renewed license needs to address the issue.

Once an ISG is approved it will be incorporated into the next revision of the license renewal guidance (LRG) documents. The three guidance documents are NUREG-1801, "Generic Aging Lessons Learned (GALL) Report," NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR), Regulatory Guide 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses." The NRC has endorsed Nuclear Energy Institute, NEI 95-10, Revision 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule," and NEI has indicated that it will update this guidance in accordance with new staff positions.

The ISG process provides management review and control of new staff positions related to license renewal. ISGs only apply to applicants for license renewal and licensees holding renewed licenses. Any stakeholder may request a management review of an approved ISG. However, the approved ISG remains in effect while under management review.

For licensees holding a renewed license, the license renewal regulations in 10 CFR 54.37 (b) require:

After the renewed license is issued, the FSAR update required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with §54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in §54.4(b) will be effectively maintained during the period of extended operation.

Therefore, for ISGs involving newly identified systems, structures and components that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the LRG documents are updated, the staff will wait until the ISGs have been incorporated into the LRG documents before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. After the LRG documents have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

Changes were made to the ISG process as a result of your comments and further staff review. Should you have questions, please contact Mr. Jack Cushing of my staff at (301) 415-1424.

Sincerely,

David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Project No. 690

Attachments: 1. Process for Interim Staff Guidance Development and Implementation
2. NRC response to NEI's Comments on ISG Process

cc w/att.: See next page

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David B. Matthews, Director
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OFFICIAL RECORD COPY

DISTRIBUTION: Letter to A. Marion & D. Lochbaum Re: ISG, Dated:

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Project No. 690

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Process for Interim Staff Guidance Development and Implementation

Process for Interim Staff Guidance Development

1.0 POLICY

Part 54 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 54), hereafter referred to as "the rule," governs the issuance of renewed operating licenses for nuclear power plants. To facilitate the implementation of the rule and the review and inspection of programs and activities associated with a license renewal application (LRA), the staff has developed license renewal guidance (LRG) documents.

The LRG documents are:

- NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR)
- NUREG-1801, "Generic Aging Lessons Learned (GALL) Report"
- Regulatory Guide (RG) 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses"

In addition, the Nuclear Energy Institute (NEI) developed the following document that is endorsed in RG 1.188:

- NEI 95-10, Revision (Rev.) 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule"

The SRP-LR provides guidance to NRC staff reviewers in the Office of Nuclear Reactor Regulation (NRR). These reviewers perform safety reviews of applications to renew nuclear power plant licenses in accordance with the license renewal rule. The principal purposes of the SRP-LR are to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate applicant programs and activities for the period of extended operation. The SRP-LR is also intended to make information about regulatory matters widely available, to enhance communication with interested members of the public and the nuclear power industry, and to improve the public's understanding of the staff review process. Each of the individual SRP-LR sections addresses (1) who performs the review, (2) the matters that are reviewed, (3) the basis for review, (4) the way the review is accomplished, and (5) the conclusions that are sought.

The SRP-LR references the GALL report (which evaluates existing programs), generically, to document (1) the conditions under which existing programs are considered adequate to manage identified aging effects without change and (2) the conditions under which existing programs should be augmented for this purpose. The GALL report should be treated as an approved topical report (as explained in NUREG-1739).

The purpose of RG 1.188 is to provide guidance to an applicant on the information to be submitted in an application for renewal of a nuclear power plant operating license in a uniform format that is acceptable to the NRC staff for structuring and presenting this information. It also endorses NEI 95-10, Rev. 3, as an acceptable method for implementing the requirements of the license renewal rule.

NEI 95-10 was developed by the NEI License Renewal Implementation Guideline Task Force and the NEI License Renewal Working Group for the implementation of the license renewal rule.

The license renewal program is a living program. The staff, industry, and other interested stakeholders gain experience and develop lessons learned with each renewed license. The lessons learned address the NRC's performance goals of maintaining safety, improving effectiveness and efficiency, reducing regulatory burden, and increasing public confidence. The lessons learned are captured in interim staff guidance (ISG) for use by the staff and interested stakeholders until the LRG documents are revised.

2.0 OBJECTIVES

This instruction ensures that proposed changes to the LRG documents are properly evaluated, documented, and implemented. Further, this instruction establishes the responsibilities and authorities for the NRR staff in identifying changes to the LRG using the ISG process.

This instruction provides NRR staff with the basic framework for processing ISGs. The goals of this instruction include the following:

- To ensure the continued health and safety of the public
- To improve public confidence in the license renewal process
- To implement a documented and controlled license renewal review process, so as to reduce unnecessary regulatory burden
- To maintain a consistent, effective, and efficient review process

3.0 BACKGROUND

The LRG documents have been developed to enhance the license renewal process. It is expected that, as lessons are learned during LRA reviews, these guidance documents may need to be modified to capture new insights or address emergent issues. This process serves to expeditiously address specific areas in the LRG documents that need to be revised and to serve as a bridge until the entire document can be revised.

Public involvement is an important part of this process. The process, as described in Section 4.0 of this document, gives the public opportunities to obtain information and to comment on the proposed ISG. ISG's will be discussed in public meetings. The staff will respond in writing to any written comments. The public will also be able to comment when the LRG documents are revised to include the ISGs. A management review process is available for any stakeholder who may disagree with the position described in an ISG. The management review process is described in section 4.2.6 of this document. The NRC will make ISGs available to the public by publishing them on the NRC web site, in ADAMS, and by holding public meetings, as appropriate.

4.0 ISG PROCESS

4.1 Overview

The staff, industry, or interested members of the public may comment or propose changes to information provided in an LRG document. Some comments may warrant the staff's developing and issuing an ISG prior to the next update of the LRG documents. Each ISG will be incorporated into the periodic updates of the LRG documents. For comments that do not result in an ISG, the ISG coordinator will evaluate the comments to determine if they should be addressed in the next revision of the LRG documents.

Failure to follow the ISG process might adversely affect the stability and predictability of the license renewal program. During the course of an LRA review, the staff may discover an issue that would expand the scope of the issues being addressed under the LRG documents. The staff should not ask an applicant to address the new issue through a request for additional information (RAI) until an approved ISG has been issued. The ISGs have schedule implications for current and future applicants for license renewal and licensees holding a renewed license may be required to address the ISG in their next FSAR update. Therefore, the structured approach described in this instruction should be followed.

The process is administered and controlled by the License Renewal Section in the License Renewal and Environmental Impacts Program (RLEP), Division of Regulatory Improvement Programs (DRIP), NRR. Expected primary contributors to the process are NRR, and the Office of Nuclear Regulatory Research (RES).

The ISG coordinator and ISG lead project manager (PM) play vital roles in the overall review process. They are responsible for screening, documenting, planning, tracking, coordinating, and implementing resolutions of license renewal proposed ISGs. Technical reviewers will be assigned to support the development of each ISG.

The staff evaluating ISGs should be familiar with the following documents:

- 10 CFR Part 54 and the associated statements of consideration (60 FR 22461 as amended by 61 FR 65175 and 64 FR 72002)
- RG 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses"
- NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR)
- NUREG-1801, "Generic Aging Lessons Learned (GALL) Report"
- NEI 95-10, Revision 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule"

In using these guidance documents, the staff, industry, or member of the public may discover guidance that is unclear, incorrect, or incomplete, or may find that new guidance is warranted. Comments can be provided to the ISG coordinator orally, by e-mail, or by letter. The ISG coordinator will document the comment. Oral comments made during a meeting will be reflected in the meeting summary. Disposition of such oral comments will either be reflected in the meeting summary, a proposed ISG, or a written response to the commenter.

Once documented, the issue will be controlled by this process to ensure timely resolution. At any step during the process, a proposed ISG can be modified or determined to be unnecessary. If a proposed ISG is determined to be unnecessary, the staff will document the closure of the issue in a letter to the interested stakeholders and the originator. If an ISG is approved, it will be published and placed on the NRC web site as an approved ISG. The ISG will be incorporated into the next revision of the LRG documents. Appendix B to this instruction provides a flow chart of the process.

4.2 Processing License Renewal Proposed ISGs

The basic activities are as follows:

- Section 4.2.1 - Screen Comments
- Section 4.2.2 - Develop an Evaluation Plan
- Section 4.2.3 - Evaluation and Transmittal of Proposed ISG
- Section 4.2.4 - Resolution of Comments on the ISG
- Section 4.2.5 - Implementation of the Approved ISG
- Section 4.2.6 - Management Review of an Approved ISG

These basic activities are described in the sections below.

4.2.1 Screen Comments

The process starts when the NRC staff, industry, or members of the public submit a comment to the ISG coordinator on the LRG documents. Stakeholder requests are expected to be brought to the NRC's attention via letter, telephone call, or e-mail. Once RLEP is notified, the issue will be referred to the ISG coordinator for review. The ISG coordinator screens, tracks, and documents the comments.

The ISG coordinator will screen the comments to determine if development of an ISG is warranted. Development of an ISG is not necessary if adequate staff guidance is already available. No ISG is developed if the comments are determined to be purely editorial comments. These editorial comments improve the readability and consistency of the documents and would not cause a current or future applicant to revise their LRA. The ISG coordinator will ensure the comments are evaluated for inclusion in the next revision of the LRG documents. The originator will be informed of the resolution.

An ISG will be developed if the comment would result in a staff position or guidance that needs to be communicated to external stakeholders, such as current or future applicants, so that they can address it in their LRAs. The staff will commence developing the ISG in accordance with the guidance contained in this document. The ISG coordinator's actions for this section are discussed below.

ISG Coordinator Actions

Once a proposed ISG is received, the ISG coordinator will:

- Screen the proposed ISG to determine whether interim staff guidance is necessary. The ISG coordinator may involve technical branches from other NRR divisions or NRC offices during the evaluation of the issue.
- Request that the originator forward the basis for the proposed ISG in writing. The basis should include the need and the underlying regulatory requirement that the proposed ISG would address. The originator should, but is not required to, provide a markup of the LRG to communicate their proposed resolution. External stakeholders should be encouraged to submit their comments in a letter or e-mail to the RLEP program director (PD-RLEP). If needed, the ISG coordinator will arrange a conference call or public meeting to discuss the ISG.
- Ensure that a written response has been provided to the originator within 30 days following receipt of the proposed ISG. The response should indicate how the issue was previously resolved or the current status of the review. The final resolution should be provided to all interested stakeholders.
- Track the status of the ISG

4.2.2 Develop an Evaluation Plan

Planning the processing of a proposed ISG is a critical step in ensuring that the review is completed in a timely and effective manner. The plan is intended to define the scope of the review, the resources needed for the review, and the schedule for resolution.

Developing the evaluation plan involves the following activities:

- The ISG coordinator should determine the schedule for completing initial review and discuss this determination with the RLEP license renewal section chief for confirmation.
- The ISG coordinator should discuss the schedule for completing the initial review with the originator.
- The RLEP license renewal section chief will assign an ISG lead PM for each proposed ISG to develop a proposed resolution.

- Upon acceptance of a proposed ISG, the ISG lead PM will obtain a technical assignment control (TAC) number, if necessary. This provides a means of tracking the resources expended and the work activities on each review. Separate TAC numbers are appropriate if significant resources (i.e., more than eight hours) are expected to be expended for a particular issue.
- The ISG lead PM will assess the proposed ISG to define the scope, resources, and schedule for resolution. This should include a discussion with the technical branch to determine the type of ISG (i.e., clarification or compliance).
- The ISG lead PM will be responsible for coordinating the activities documented in the evaluation plan, monitoring the progress of these activities, and reporting the status of the review to the ISG coordinator for tracking by RLEP.
- The ISG lead PM will be responsible for obtaining clarification of the input from the originator or stakeholder. It is expected that the input will be clearly written with a proposed resolution for the identified concern. The input should, but is not required to include a markup of the guidance document that warrants modification.
- The ISG coordinator will track and monitor the proposed ISG's progress toward resolution.

4.2.3 Evaluation and Transmittal of Proposed ISGs

4.2.3.1 Evaluation of Proposed ISGs

There are two types of ISGs, (1) clarification ISGs and (2) compliance ISGs. Clarification ISGs provide additional guidance to applicants that the staff or stakeholders feel is necessary to reduce unnecessary requests for additional information (RAI). Clarification ISGs do not create new staff positions that have not been addressed by previous applicants. Clarification ISGs can inform applicants that more information is needed on an issue already addressed in the LRG documents. Clarifications ISGs do not apply to licensees holding a renewed license. Compliance ISGs involve compliance with the regulations and therefore do apply to licensees holding a renewed license.

The memorandum transmitting the proposed ISG from the branch chief of the technical branch to the PD-RLEP will specify if the ISG is a clarification or compliance ISG. The transmittal memorandum for clarification ISGs may be signed by the branch chief. The transmittal memorandum for compliance ISGs will contain a documented evaluation. The technical branch division director's concurrence in the memorandum is necessary.

The ISG lead PM will coordinate the review and the proposed resolution. OGC review of a proposed ISG is necessary. The ISG lead PM assigned to resolve the proposed ISG is also responsible for coordinating the staff's evaluation with all involved branches and offices.

Proposed ISGs involving multiple branches and/or offices may result in scheduling and resource conflicts or staff disagreements on the proposed resolution of the issue. The ISG lead

PM is responsible for notifying management and the ISG coordinator of these conflicts and for coordinating discussions that lead to a consensus staff position.

Some proposed ISGs may involve policy issues that warrant Commission involvement. These issues can be identified at any time in the planning and evaluation process and need to be discussed with the PD-RLEP as soon as the potential for a Commission-level issue is identified. RLEP will document the proposed ISG, the proposed options, and a staff recommendation before presenting the proposed ISG to management for submittal to the Commission. Upon receipt of the Commission's directions on the ISG, the staff will take the appropriate action implementing the Commission's decision.

4.2.3.2 Transmittal of Proposed ISGs

Once a proposed ISG is developed, it will be documented and transmitted to the originator and stakeholders for feedback. The following provides guidance for the format and content that should be used for all ISGs:

Issue Heading:

A short summary or description of the issue (one or two sentences). [Keyword searches in ADAMS could be generated from the summary, so it is beneficial to be specific.]

Staff Position:

This section describes the proposed ISG and the proposed resolution.

Rationale:

This section should provide a description of the issue in sufficient detail, such that an informed reader can understand the issue, its basis, significance, applicability (e.g., generic, BWRs only), and ramifications. The staff will document its analysis of the proposed ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.

References:

List references mentioned in the ISG text. These could include the ASME and ANSI Codes, NUREGs, other ISGs, Part 54 subsections, and Regulatory Guides.

Attachments:

This section contains the staff's markup of existing or new guidance that implements or incorporates the staff's proposed resolution of the issue (including the SRP-LR, GALL, RG 1.188, and/or NEI 95-10) and should normally be provided for all changes.

4.2.4 Resolution of Comments on the ISG

It is the ISG lead PM's responsibility to prepare a letter to solicit comments on the proposed resolution of the issue. The letter should be addressed to NEI and to the Union of Concerned Scientists (UCS), as the coordinator for public interest groups. Current license renewal applicants, other stakeholders on the license renewal service list, and the originator will be sent a copy of the letter. Typically, the letter should be reviewed by the technical branch supporting the ISG, OGC, and PD-RLEP. Review and concurrence should ensure the quality and consistency of the proposed resolution of the issue. The division director of DRIP will normally sign all proposed resolution letters, unless otherwise specified by NRR Office Instruction ADM-200, "Delegation of Signature Authority." Typically, the letter will request comments on the proposed ISG within a 60-day period. For complex issues, a longer comment period may be considered.

Comments should be provided in writing to the PD-RLEP within the comment period. A public meeting or conference call (minutes to be published in ADAMS) may be conducted to clarify the concern. The staff will communicate with the stakeholders to clarify, and if possible, resolve their comments.

Once the staff has made its determination, the proposed ISG will be considered resolved. The final resolution could be approval or a determination that the proposed ISG is unnecessary. The staff will post the approved ISG on the NRC License Renewal web page for staff and industry use. The resolution letter will also be available in ADAMS. At this point, the approved ISG will have a number designation and an implementation date. The ISG can then be referenced in an applicant's LRA or as part of the LRA regulatory review process. The ISG will be incorporated into the next revision of the LRG documents. If a stakeholder does not agree with the approved ISG then the stakeholder may request management to review the decision following the procedure in Section 4.2.6.

4.2.5 Implementation of the Approved ISG

Implementation of compliance ISGs affects both future and current applicants. Future applicants will address the ISG in their LRA. Current applicants will address the approved ISG by responding to an RAI, by addressing an open item in the draft SER, or by supplementing their application.

For licensees holding a renewed license, the license renewal regulation in 10 CFR 54.37(b) require:

After the renewed license is issued, the FSAR update required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with §54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in §54.4(b) will be effectively maintained during the period of extended operation.

Therefore, for ISGs involving newly identified systems, structures and components that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the LRGs are updated, the staff will wait until the ISGs have been incorporated into the LRGs before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. After the LRGs have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

4.2.6 Management review of an Approved ISG

The management review process is designed for stakeholders to request NRC management to review an approved ISG. An ISG under management review is still in effect and applicants are expected to follow the ISG. If the management review process results in the ISG being modified or rescinded, then the staff will inform the stakeholders and update the web site. If the request for management review is made by an applicant for license renewal, the staff review of the application will continue during the management review process, unless the applicant submits a written request to the PD-RLEP that the review, or a portion thereof, be placed on hold, pending the final management review decision. Fees for the management review will be assessed in accordance with 10 CFR Part 170.

Any stakeholder (the public, a industry group, or an applicant) can request a management review of the generic aspects of an ISG. Only the applicant can request a management review of an ISG as it applies to its application. All management review meetings will be public meetings. The process is initiated by a stakeholder submitting a written request to the PD-RLEP. The PD-RLEP will serve as the first-level decision-maker in the management review process. Upon acceptance of a request for management review, the ISG coordinator will acknowledge receipt in writing to the stakeholder who submitted the request, with copies to NEI, UCS, and the license renewal service list. Receipt of the request will also be reflected on the license renewal website. These actions will serve to notify stakeholders of the request, and provide them with an opportunity to comment on the issue raised.

If first-level management has issued a determination in response to a request for management review, a stakeholder may seek division level review by submitting a written request to the Director, DRIP, who will serve as the second-level decision-maker. A further request for management review would be initiated by submitting a written request to the Director, NRR, who will serve as the third and final level decision maker. The ISG coordinator will inform NEI, UCS, and any other stakeholder who previously provided comments on the matter of each of the above requests, and request their comments on the matter.

First Level Management Review- Program Director License Renewal and Environmental Impacts

As described above, a stakeholder initiates management review by submitting a written request to the PD-RLEP. The written request will contain a briefing paper describing the position taken and the basis for the position. The issue statement should have a clearly defined scope and should reference the applicable section(s) of the regulation that provides the requirements for the issue being submitted for management review. The basis should reference any supporting documents. The stakeholder should include a draft of proposed changes to the guidance documents that would be needed. The request should also include a proposed date for the management review meeting.

Upon receipt of the request for management review, PD-RLEP will forward the request to the relevant staff who will review the request and determine if the stakeholder has clearly identified the issue. PD-RLEP will then determine whether the issue warrants consideration. PD-RLEP may decide that a request for management review cannot be granted because insufficient documentation was submitted with the request. Within 10 days of receipt of the management review request, PD-RLEP will provide a written response to the originator, indicating if it was accepted for management review and identifying the ISG lead project manager, who will provide administrative oversight and support during the management review process. The ISG lead project manager will notify stakeholders of the acceptance of the request, as described above. If PD-RLEP's denies the request for management review, then the response should contain the basis for the decision.

The staff will prepare a briefing paper describing the staff's position and the basis for the position. The staff should start preparing the briefing paper as soon as they know the management review will be undertaken. The issue statement should have a clearly defined scope and should reference the applicable section(s) of the regulation that provides the requirements for the issue being reviewed. The basis should reference any supporting documents. The staff and the stakeholders on the license renewal service list will receive copies of the briefing papers. Any other stakeholders wishing to comment on the matter should do so by the date indicated in the acceptance letter.

The management review meeting should occur as soon as is practicable, but no later than 20 days after receipt of the management review request. The management review meeting is a public meeting and would be noticed on the NRC web site 10 days prior to the meeting.

If the management review was requested by an applicant and deals specifically with their LRA, then the public meeting will be a category 1 public meeting. The public will be invited to observe. The NRC staff will be available to answer questions before the meeting is adjourned.

If the management review does not address a specific LRA, then the public meeting will be a category 2 public meeting. The public is invited to discuss the regulatory issues with the NRC at designated points during the meeting. At the meeting, the stakeholder who requested management review will present his or her position. The NRC staff will respond, and comments will be received from other stakeholders. The stakeholder requesting review will then be afforded an opportunity to address the staff's response and any other comments received.

The PD-RLEP will, within 10 days of the conclusion of the meeting, issue a written statement of its findings, which will include the basis for the decision. Should the issue be further reviewed, the report will be included in the written request to the decision maker at the next level. The total time for a level 1 review is 30 days.

Second Level Management Review- Director, Division of Regulatory Improvement Programs

If any stakeholder decides to continue to the division director level, a written request must be submitted to the ISG lead project manager no more than 10 days after the issuance of the decision from the previous level. The written request will include the report from the previous decision level and all other supporting documentation. The level 2 public meeting will be held within 25 days of receipt of the request for review to the division director. Stakeholders who commented during the lower level review will be informed of the meeting and afforded an opportunity to comment on the matter. Following the meeting, the division director will within 10 days of the conclusion of the meeting, issue a written statement of the division director's findings, which will include the basis for the decision. Should the issue proceed to the next level, the report will be included in the written request to the decision-maker. The total time for a level 2 review is 45 days.

Third Level Management Review - Director, Office of Nuclear Reactor Regulation

If any stakeholder decides to continue to the office director level, a written request for review by the Director of NRR, must be submitted to the ISG lead project manager no more than 10 days after the issuance of the decision from the previous level. The written request will include the report from the previous decision level and all other supporting documentation. The level 3 public meeting will be held within 25 days of receipt of the request for review to the office director. Stakeholders who commented during the lower level review will be informed of the meeting and afforded an opportunity to comment on the matter. Following the meeting, the office director will, within 10 days of the conclusion of the meeting, issue a written statement of the office director's findings, which will include the basis for the decision. The staff will incorporate any changes resulting from the management review and as necessary revise the ISG. The total time for a level 3 review is 45 days.

Summary of Management Review Process

As described above, the first level of management review, including issuance of the final report, would be completed no more than 30 days from receipt of the request. Each successive level of review is scheduled for 45 days. The length of time the review process would take depends on the number of levels to which the stakeholder requests review. The review process can be as short as 30 days or as long as 120 days, if reviewed through the Director of Nuclear Reactor Regulation. After the final management review, the staff will as necessary revise the ISG and publish the revision on the NRC website and send copies to all stakeholders who commented on the ISG as well as license renewal service list.

5.0 RESPONSIBILITIES AND AUTHORITIES

All NRC staff members who participate in the review and inspection of license renewal programs and activities are responsible for reading, understanding, and applying the guidance in this instruction.

5.1 Roles and Responsibilities for the Review of ISGs

A. GENERAL

Division of Regulatory Improvement Programs

The DRIP director is responsible for the overall development and implementation of the license renewal program and license renewal activities.

License Renewal and Environmental Impacts Program

The PD-RLEP is responsible for oversight of license renewal activities, process development activities, overall regulatory compliance, and implementation of the license renewal program.

The RLEP license renewal section chief is responsible for the general oversight and implementation of license renewal work planning activities. The RLEP license renewal section chief will provide direction and assistance in the development and approval of evaluation plans to ensure effective allocation of resources, responsiveness, and quality of work. The RLEP license renewal section chief assigns the ISG coordinator, ISG lead PM and the project managers to work with the technical staff to develop the ISGs.

The ISG coordinator is responsible for the initial review of the proposed ISG. The ISG coordinator is also responsible for the tracking of the proposed ISG through to resolution, for maintaining the list for tracking licensees holding renewed licenses and for sending out the letters to the licensees to ensure their FSARs are updated to include the compliance ISGs.

The ISG lead PM is responsible for clarifying the issue with the originator, drafting or revising the assigned proposed ISG, obtaining a TAC number, working with the cognizant staff to address the issue, resolving any comments received during the ISG review process, and processing the draft or revised ISG through the various levels of review both inside and outside of RLEP. The ISG lead PM will be the point of contact for the management review process for their assigned ISG.

Technical Branches

The technical branches evaluate the technical aspects of the proposed ISG. Staff involved with the review should be familiar with the requirements of the rule; the guidance provided in the statements of consideration that accompanied the rule, the staff SRP-LR, the GALL report, and RG 1.188; and the industry guidance in NEI 95-10. The technical branches are responsible for developing the documented evaluations for compliance ISGs.

NRR Management

Division directors, program directors, and the regions will assist in resolving concerns relating to the ISG, including schedules, resources, priorities, technical issues and management review.

The Office of the General Counsel

Reviews the ISG from a regulatory and legal perspective.

Offices/Divisions/Branches

Other offices, divisions, and branches are responsible for reviewing and concurring consistent with the established schedule.

6.0 PERFORMANCE MEASURES

The ISG coordinator should provide an annual status update to the RLEP program director. The performance measures provide the following goals:

1. Provide a response to the originator on the status and potential resolution approach within 30 days of initial contact with RLEP.
2. Issue 90 percent of the proposed ISGs for comment within 180 days of initial contact with RLEP.
3. Issue 90 percent of the final ISG positions within 120 days of the end of the comment period provided in the comment letters.
4. Issue 100 percent of the final ISG positions within two years.

7.0 PRIMARY CONTACT

Jack Cushing, NRR/DRIP/RLEP, (301) 415-1424, JXC9@NRC.GOV

8.0 RESPONSIBLE ORGANIZATION

NRR/DRIP/RLEP

9.0 EFFECTIVE DATE

August 15, 2003

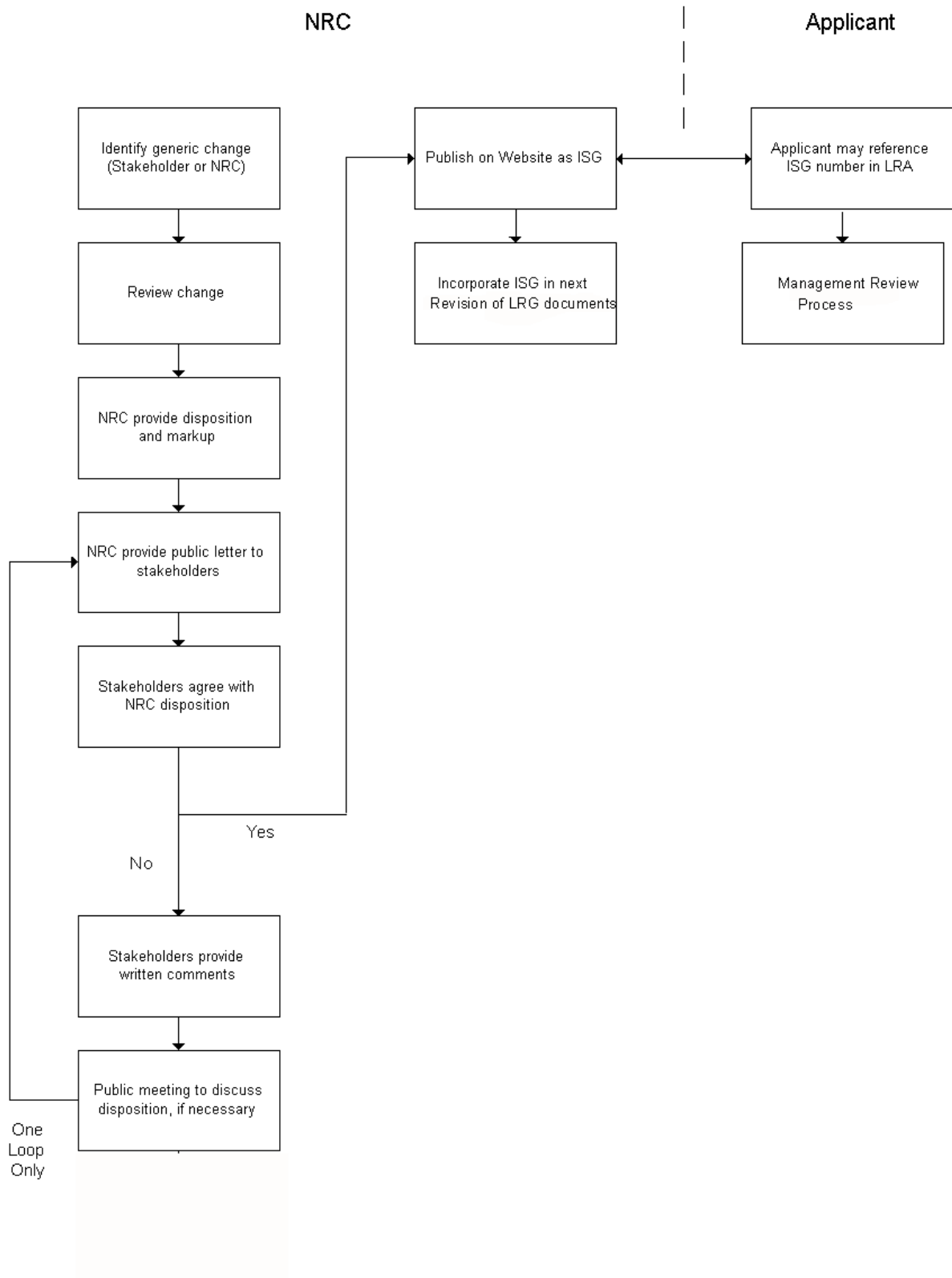
10.0 REFERENCES

1. 10 CFR Part 54, "Requirement for Renewal of Operating Licenses for Nuclear Power Plants."
2. Regulatory Guide 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses."
3. NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants." (SRP-LR)
4. NUREG-1801, "Generic Aging Lessons Learned (GALL) Report."
5. NEI 95-10, Rev. 3, "Industry Guidelines for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule."
6. NRR Office Letter No. 500, Rev. 2, "Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees."

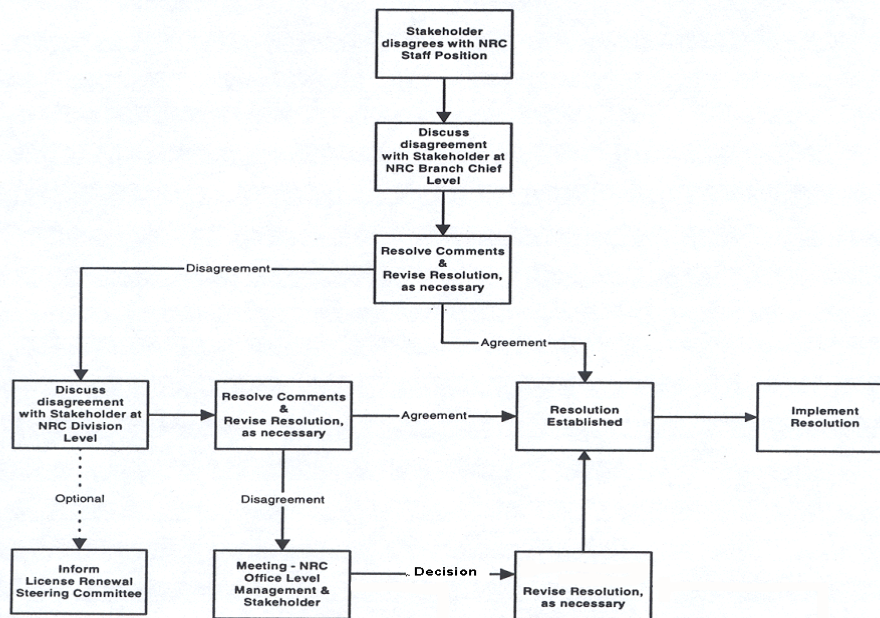
Appendix A: Change History

This is a new instruction.

Appendix B: Interim Staff Guidance Memorandum Process Flow Chart



MANAGEMENT REVIEW PROCESS



NRC Response
to
NEI Comments on ISG Process

By letters dated October 29, 2002, and November 12, 2002, NEI provided the following comments on the ISG process and the management review process.

NEI Comment:

We believe that the backfitting of license renewal evaluations falls into two distinct categories: those of the current term through the 10 CFR 50 regulations, and those of the extended period of operation. A license renewal backfit evaluation for the current term might apply to plants, whether or not a plant had applied for renewal.

Response:

The license renewal ISG process only applies to applicants for license renewal and licensees holding renewed licenses. The license renewal rule contains a provision in 10 CFR 54.37(b) for requiring licensees holding a renewed license to include in the FSAR update any systems, structures and components newly identified that would have been subject to an aging management review or a time-limited aging analyses in accordance with 10 CFR 54.21. Therefore, license renewal ISGs involving matters covered by 10 CFR 54.37(b) do not involve backfits.

For licensees holding a renewed license, the license renewal regulations in 10 CFR 54.37 (b) require:

After the renewed license is issued, the FSAR update required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with §54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in §54.4(b) will be effectively maintained during the period of extended operation.

Therefore, for ISGs involving newly identified systems, structures and components that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the LRGs are updated, the staff will wait until the ISGs have been incorporated into the LRGs before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. After the LRGs have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

NEI Comment:

Second, we have suggested a clarification and an expansion of the Office of General Counsel's (OGC's) role in the process. We believe that OGC should determine whether the ISG is providing an improvement to the process beyond the regulations, thus, constituting a backfit, or whether the ISG represents a clarification that is necessary to comply with the regulations. In each case, OGC will provide a review and determination of the ISG's consistency with the current regulations. In the cases where backfit considerations are involved, OGC's input should clearly indicate whether the ISG was developed to establish compliance with some regulatory provisions where the industry would not necessarily otherwise be in compliance or whether the ISG represents only an improvement or clarification that is beyond the interpretation of 10 CFR 50 or 10 CFR 54 requirements (10 CFR 50.109).

Response:

As stated in the previous response, license renewal ISGs do not involve backfits. The ISGs are generally identified by a technical branch in the Office of Nuclear Reactor Regulation (NRR) to address a technical issue. The technical staff with branch chief review initially determines whether the issue involves a clarification only, or whether 10 CFR Part 54 requires that the license renewal applications address the issue. Only branch chief concurrence is needed for a clarification issue. If the issue involves compliance with the regulations, then the responsible division director reviews the issue. OGC's role in these matters is discussed below.

NEI Comment:

In each case, OGC will provide a review and determination of the ISG's consistency with the current regulations. In the cases where backfit considerations are involved, OGC's input should clearly indicate whether the ISG was developed to establish compliance with some regulatory provisions where the industry would not necessarily otherwise be in compliance or whether the ISG represents only an improvement or clarification that is beyond the interpretation of 10 CFR 50 or 10 CFR 54 requirements. On these issues, OGC determinations will be made available to the public.

Response:

As set forth above, license renewal ISGs do not involve backfits. While OGC reviews all ISGs, OGC's advice to the staff is protected by attorney-client privilege and is not released to the public.

NEI Comment:

Finally, we believe this document provides an opportunity to significantly improve the overall stability and predictability of the rule for future applicants. The method for providing this improvement rests with establishing a more formal process for determining whether those ISGs that do not pass a backfit evaluation should even be issued. We suggest that the NRC perform a formal evaluation of the ISG impact on stability and predictability of the change vs. the benefit and establish that there is a clear benefit with proceeding with issuing these ISGs.

Response:

As set forth above, license renewal ISGs do not involve backfits. One of the staff's goals in developing the ISG process was to reduce unnecessary regulatory burden by increasing the stability and predictability of the license renewal process. The other goal was to improve the effectiveness and efficiency of the process of updating the license renewal guidance documents. The staff does issue a documented evaluation with each ISG. The documented evaluation provides a description of the issue in sufficient detail, such that an informed reader can understand the issue, its basis, significance, applicability (e.g., generic, BWRs only), and ramifications. The staff will document its analysis of the proposed ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.

NEI Comments on the Management Review Process

By letter dated November 12, 2002, NEI provided comments on the NRC's management review process (formerly called the appeals process). The name was changed to more accurately reflect the process. As discussed in your letter, the industry and the NRC recognize the need to define a license renewal management review process. We agree that the management review process must be clearly defined and be useful in resolving differences in the interpretation of license renewal requirements in a timely manner. The NRC, like the industry, also believes that the management review process must be fair to all stakeholders, that the basis for final resolution of an issue is clearly communicated, and that final resolution is incorporated into the associated guidance documents as expeditiously as possible. Further, we agree that the purpose of the management review process is not to change the substance of the regulations governing license renewal.

NEI had two main comments. The comments and the staff's responses are discussed below.

NEI Comment:

The time frames are too long and will require that the licensee (applicant) acquiesce in order to meet schedules.

Response:

The applicant does not need to "acquiesce" to a staff position stated in an ISG in order to receive a renewed license. For instance, a system, structure, or component (SSC) that may be in scope at one facility may not be in scope at another facility, because of differences in plant design or licensing basis. The applicant may evaluate the SSC and determine that the SSC is

not in scope and justify its evaluation to the staff. If the staff agrees with the applicant's evaluation then the ISG has been addressed for that plant. The staff is aware of the impact ISGs can have on the license renewal schedule. The staff discusses proposed ISGs with interested stakeholders and among whom are applicants for license renewal. Therefore, given the schedule for issuing approved ISGs the staff sees no reason why the ISGs cannot be addressed within the application review schedule.

The management review process has an aggressive schedule. The first level of management review is scheduled for 30 days. Each successive level of management review is scheduled for 45 days. The management review process does not include the Commission. The management review process stops at the Director of Nuclear Reactor Regulation. The length of time the management review process would take depends on the number of levels through which stakeholders request review. The management review process can be as short as 30 days or as long as 120 days, if reviewed through the Director of Nuclear Reactor Regulation. In each stage of the process briefing papers are written, public meetings are held, comments are addressed, decisions are made, and reports are issued. Accomplishing all this in 45 days for each stage is an aggressive schedule.

Applicants and NEI should be aware that fees for the management review process will be assessed in accordance with 10 CFR Part 170.

NEI Comment:

Best efforts should be made to have an arbitrator who is knowledgeable, but has not been directly involved in earlier decisions.

Response:

The NRC does not use arbitrators in this manner. The process is established to review the decision through progressively higher levels of management. The higher levels of management are aware of the decisions that were made previously by lower levels of management. However, the process allows a stakeholder to present its viewpoint on an issue to a higher level of management, which can modify a decision made by a lower level of management.