

July 21, 2004

Mr. Alex Marion
Senior Director, Engineering
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW., Suite 400
Washington, DC 20006-3708

SUBJECT: STAFF RESPONSE TO "INDUSTRY QUESTIONS ON THE NUCLEAR REGULATORY COMMISSION (NRC) INTERIM STAFF GUIDANCE PROCESS DOCUMENT DATED DECEMBER 12, 2003" - RESPONSE TO YOUR LETTER DATED FEBRUARY 13, 2004.

Dear Mr. Marion:

By letter dated December 12, 2003, we issued our final guidance document related to the interim staff guidance (ISG) process. By letter dated February 13, 2004, you submitted a series of questions and requested clarifications on the process. Our responses to your questions are enclosed. As Ram Subbaratnam of my staff has discussed with Fred Emerson, if you have any additional questions or comments on the ISG process, we will discuss them during our upcoming meeting on August 3, 2004.

If you have any questions regarding this matter, please contact Mr. Subbaratnam at 301-415-1478.

Sincerely,

/RA/

Pao-Tsin Kuo, Program Director
License Renewal and Environmental Impacts Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Project No.: 690

Enclosure: As stated

cc w/encl: See next page

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Senior Director, Engineering
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OFFICE	LA: RLEP:DRIP	PM:RLEP:DRIP	SC:RLEP:DRIP	OGC (NLO)	PD:RLEP:DRIP
NAME	MJenkins	RSubbaratnam	SWest	RWeisman	PTKuo
DATE	7/1/04	7/7/04	7/20/04	7/20/04	7/21/04

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RLEP RF

Ram Subbaratnam (PM)

E-MAIL:

RidsNrrDrip

RidsNrrDe

G. Bagchi

K. Manoly

W. Bateman

J. Calvo

R. Jenkins

P. Shemanski

J. Fair

RidsNrrDssa

RidsNrrDipm

D. Thatcher

R. Pettis

G. Galletti

C. Li

M. Itzkowitz (RidsOgcMailCenter)

R. Weisman

M. Mayfield

A. Murphy

S. Smith (srs3)

S. Duraiswamy

Y. L. (Renee) Li

RLEP Staff

C. Julian

R. Gardner

M. Modes

J. Vora

L. Kozak

**Responses to Nuclear Energy Institute Questions
on the “Process for Interim Staff Guidance Developments and Implementation”**

Question 1:

Please indicate the status of this process document as the current plans for GALL update are carried forward.

Issue 1: Current plans for updating the GALL report, as discussed at a January 21, 2003, meeting, would appear to replace the ISG process with a database of GALL update information. The need for this process document revision is therefore not clear, especially in the light of the other questions and concerns discussed below.

Response:

Our letter of December 12, 2003, provided our final guidance document entitled, “Process for Interim Staff Guidance Development and Implementation” (the ISG process). The ISG process provides a vehicle to expeditiously develop guidance to address license renewal issues and serves as a bridge until we revise the guidance documents to address the issue and provide the needed guidance. As discussed in our letter, if we approve an ISG, we will incorporate it into the next revision of the license renewal guidance documents. As you noted, we are currently updating the guidance documents and plan to issue a preliminary draft on the NRC web site by September 30, 2004. However, this update will not replace the ISG process; we will continue to use it to expeditiously develop and implement license renewal guidance as needed.

Question 2:

Please indicate whether the letter dated December 12, 2003, was intended to be a final staff position or was a process revision intended for comment.

Issue 2: The December 12, 2003, letter included significant changes from the version of the ISG process issued for comment in July 2002, without the opportunity for stakeholder comment.

Response:

The ISG process included with our letter of December 12, 2003, is the final ISG process and was not a process revision intended for comment. Our letter included our responses to the Nuclear Energy Institute (NEI) comments on the draft ISG process.

Question 3:

Please indicate the staff’s current intent for the application of the backfit process to ISGs (see also Question 4 below).

Issue 3a: References to 10 CFR 50.109, NRR Office Letter No. 500, Revision 2, *Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees*, and Revision 7 to *The Charter for the Committee to*

Enclosure

Review Generic Requirements (CRGR), were provided in the version of the ISG process issued for comment in July, 2002. The December 12, 2003, version of the ISG process made no references to these documents, thereby creating confusion as to the intended application of the backfit process to plants with renewed licenses. These references added guidance, credibility, and accountability to the proposed ISG process.

Issue 3b: The provisions of 10 CFR 50.109(a)(4) clearly allow for such backfit of LR scope basis following a new or different interpretation by the staff involving a “compliance” issue. The reason for not taking advantage of this process is not apparent.

Response:

Following discussions with the Committee to Review Generic Requirements (CRGR), we changed the draft ISG process to clarify our position on the application of the license renewal rule and the backfit process to ISGs. We stated our position in enclosure 2 to our letter of December 12, 2003. Specifically, the license renewal rule contains a provision in 10 CFR 54.37(b) requiring licensees holding a renewed license to include in the final safety analysis report (FSAR) update any systems, structures and components (SSCs) newly identified that would have been subject to an aging management review or an evaluation of 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. However, ISGs that do not involve newly identified SSCs, e.g., an ISG that changes an aging management program for a previously identified SSC, would, for licensees holding a renewed license, be subject to the requirements of 10 CFR 50.109, the backfit rule.

Question 4:

Please indicate the proper application of 10 CFR 54.37(b) versus the use of the backfit process (10 CFR 50.109).

Issue 4: According to Section 4.2.5 of the December 12, 2003, ISG process document, “ISGs that do not involve newly identified SSCs would...be subject to the requirements of the 10 CFR 50.109, the backfit rule.” This implies that ISGs that do involve newly identified SSCs are not subject to the backfit rule, but apparently only subject to 10 CFR 54.37(b). It is not apparent how they can represent a compliance issue and therefore be applicable to renewed licensees if they are not subject to the backfit rule.

Response:

The license renewal rule in 10 CFR 54.37(b) requires an action by the licensee after the renewed license is issued. Specifically, the licensee must include any newly identified SSCs that would have been subject to an aging management review in its next FSAR update. The FSAR update must describe how the effects of aging will be managed such that the intended function(s) in Section 54.4(b) will be effectively maintained during the period of extended operation. This requirement of the license renewal rule is a specific exception to the general requirements of the backfit rule (10 CFR 50.109). Therefore, there is no need to perform an analysis in accordance with the backfit rule when communicating newly identified SSCs to

licensees holding a renewed license. However, for licensees holding a renewed license, ISGs that involve previously identified SSCs could represent a compliance issue and would be subject to the requirements of 10 CFR 50.109.

Question 5:

Please indicate where ISGs currently undergoing comment can be found on the NRC website.

Issue 5: Section 4.2.4 states that ISGs out for comment are “published on the NRC license renewal Website.” The five approved ISGs are available, but not the ISGs currently undergoing comment.

Response:

Approved ISGs are available on the license renewal web site. Proposed ISGs that have been issued for public comment are available through ADAMS but are not currently published on the license renewal web site.

Question 6:

How are the existing approved and draft ISGs going to be handled with respect to the process defined in the NRC letter?

Issue 6: It is not clear whether approved ISGs are to be incorporated into the LR guidance documents, or whether the draft ISGs will be noticed in the *Federal Register*.

Response:

As discussed in our letter of December 12, 2003, and the “Process for Interim Staff Guidance Development and Implementation,” we will notice proposed ISGs in the *Federal Register* and will incorporate approved ISGs into the next revision of the license renewal guidance documents. Thus, we will handle the ISGs that are currently approved and those that are under development in the following ways. We will not notice the currently approved ISGs in the *Federal Register* but will include them in the ongoing update of the guidance documents. We will not notice in the *Federal Register* any proposed ISGs that we have already issued for comment by letter. We will notice in the *Federal Register* any proposed ISGs that we are currently developing but have not yet been issued for public comment by letter. For the ISGs currently under development, we will incorporate any ISGs that we approve by August 2004 in the ongoing update of the license renewal guidance documents.

Question 7:

What are the criteria for issuing a new ISG?

Issue 7: It appears that the only criterion for a new ISG is “an issue that would cause a current or future applicant to revise their LRA.” Other criteria may be appropriate as well.

Response:

We agree that new ISGs may involve issues that cause applicants to revise their license renewal applications, but that is not the criterion for issuing a new ISG. The rationale for issuing a new ISG is to incorporate license renewal experience and lessons learned into the ongoing license renewal program for the benefit of both the staff and the industry. The license renewal program is a living program; the staff and industry gain experience and develop lessons learned with each renewed license. ISGs typically involve new issues that expand the scope of the issues currently addressed in the guidance documents. In accordance with the ISG process, after we approve and issue an ISG, we incorporate it into the next revision of the license renewal guidance documents. It is important to note that because ISGs could have implications for current and future applicants for license renewal as well as for licensees holding a renewed license, we use the ISGs process to help preserve the stability and predictability of the license renewal program.

Question 8:

Of the existing approved and draft ISGs, which ones are considered “clarifications” and which ones are “compliance?”

Issue 8: A clearer definition of these terms and their applicability to current ISGs would be helpful.

Response:

Clarification ISGs provide additional guidance to applicants that the staff or stakeholders feel is necessary to reduce unnecessary RAIs. 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 license renewal guidance (LRG) documents. Clarification ISGs do not apply to licensees holding a renewed license. Compliance ISGs involve actions that are necessary to demonstrate compliance with the license renewal regulations. Compliance ISGs typically apply to licensees holding a renewed license as well as applicants for a renewed license. Examples of ISGs considered clarification are ISGs 6 and 7, and compliance, ISGs 17 and 20.

Question 9:

If the ISG process remains useful can earlier industry input to the development process be provided?

Issue 9a: Earlier in the license renewal process (prior to 2001), it appeared that having generic guidance (ISGs) on certain issues like concrete aging, (a)(2) scoping, fire protection scoping, aging management program attributes, etc. would simplify the NRC review process. The reality has been that licensees take exception to many ISGs since NRC may not reflect positions already accepted on a plant-specific basis. This creates more RAIs and discussion than before the ISG existed. The screening of ISGs before significant time is spent developing them would alleviate this unnecessary use of NRC and licensee resources.

Issue 9b: Before ISGs are issued for comment there has been extensive internal NRC review, and staff positions are well established. It therefore is more difficult (challenging) to reflect external stakeholder comments. Earlier industry input is an appropriate way to reflect valid views into the ISGs.

Response:

We agree that early stakeholder input on individual ISGs is beneficial. We believe that the ISG process in combination with our philosophy of encouraging public involvement provide opportunities for early and appropriate stakeholder involvement in the development of new ISGs. We typically share information on potential ISGs before staff positions are fully developed (e.g., in public meetings and during telephone calls with NEI and utility representatives) and will continue to do so. Moreover, consistent with other NRC processes (e.g., the rulemaking process) we rely on industry and public comments on proposed ISGs to gather external stakeholder views. We reflect those views in our final positions, as appropriate.

Your claim that the ISG process has resulted in more requests for additional information (RAIs) does not reflect our experience. Admittedly, our view is based on anecdotal information. Nevertheless, should you care to provide specific examples of how ISGs have created more RAIs, we will factor this experience back into the ISG process.

Question 10:

What is the effective date of this document?

Issue 10: Section 9.0 states the effective date of the document as August 15, 2003. It would seem more appropriate that this process be applied in 2004 and not retroactively.

Response:

The "Process for Interim Staff Guidance Development and Implementation" was effective December 12, 2003.

Question 11:

Why did the NRC eliminate the one iterative loop for comment on an ISG after the NRC issues a revised draft ISG?

Issue 11: The first draft of the ISG process included one opportunity for comment and dialog after the NRC issues Revision 1 of the draft in response to stakeholder comment. The revised process allows the NRC to make significant changes to the ISG and issue as final without stakeholder comment. This is a significant concern if the NRC did not correctly interpret the comment and made changes that do not address the comment, or if the changes are so significant that the intent of the ISG is changed.

Response:

While the NRC may issue an ISG after only one round of public comment, we do not believe this impairs any stakeholder's ability to raise issues with respect to an ISG. Consistent with our stated goal of preserving the stability and predictability of the license renewal program, it has been our practice to fully discuss issues with both internal and external stakeholders before making final decisions on ISGs. For example, for some ISGs we have provided multiple opportunities for review and comment and have held multiple public meetings. Implementation of the formal ISG process will support our ability to continue to meet this goal. The ISG process provides opportunities for external stakeholder involvement including an opportunity to submit comments for our consideration in response to the *Federal Register* notice as well as an opportunity for a public meeting to discuss the issue, if needed. Thus, the process is consistent with other longstanding NRC processes (e.g., the rulemaking process) and is adequate for achieving its intended objectives. Moreover, the process, in and of itself, will not preclude us from offering other opportunities for public involvement should we determine that they are warranted to fully discuss any particular issue. Therefore, the change in the process should not result in reduced stakeholder input to ISGs.

Question 12:

Has the NRC considered the impact of ISGs on the current licensing basis of plants that have not renewed their license? This could apply to plants that are not going to renew, or won't be renewing for a long time.

Issue 12: The NRC has considered the impact of scoping changes that the NRC considers to be under the purview of 10 CFR 50.54.37(b) as being "newly identified." The NRC has not addressed the impact of these positions on other plants that are not pursuing license renewal. For example, what is the impact of the ISG on Station Blackout (SBO) scoping that either redefines or clarifies the extent of off site power sources that are part of equipment credited for SBO? Should this clarification/change to the NRC position be communicated to all licensees so that they can include this equipment properly in Maintenance Rule scoping or other programs?

Response:

The applicability of section 10 CFR 54.37(b) is specific to license renewal. The license renewal rule requires licensees holding a renewed license to include in the final safety analysis report (FSAR) update any systems, structures and components newly identified that would have been subject to an aging management review or an evaluation of time-limited aging analyses in accordance with 10 CFR 54.21. This requirement does not apply to the current licensing basis (CLB). In the event an ISG somehow raises an issue involving current operations, the issue would be treated in accordance with normal NRC processes for resolving such issues.

Question 13:

How will the NRC implement the ISG process when plants have entered the period of extended operation?

Issue 13: As currently written the ISG process assumes plants with renewed licenses have not entered the period of extended operation. This allows the NRC to wait until ISGs are incorporated in guidance documents to notify licensees with renewed licenses. This process will not be timely if there are long periods of time between updates of guidance documents, especially after plants have entered the period of extended operation. A plant with a renewed license could wait five years or more to be notified of the requirement to add SSCs into the scope and perform aging management. If these issues are significant to bypass the backfit process, then they should be implemented in a timely fashion.

Response:

We agree that ISGs should be implemented in a timely fashion for plants operating in the period of extended operation. If the ISGs have been incorporated into updated guidance documents, the staff will issue a generic communication informing the industry of the need to review the guidance documents for ISGs applicable to their facility and to update their FSAR in accordance with 10 CFR 54.37(b). If the guidance documents are not scheduled for an update in a timely fashion, the staff may issue a generic communication to inform the industry of the need to review the ISG for applicability to their facility.

NUCLEAR ENERGY INSTITUTE

Project No. 690

cc:

Mr. Joe Bartell
U.S. Department of Energy
NE-42
Washington, DC 20585

Ms. Christine S. Salembier Commissioner
State Liaison Officer
Department of Public Service
112 State St., Drawer 20
Montpelier, VT 05620-2601

Mr. Fred Emerson
Nuclear Energy Institute
1776 I St., N.W., Suite 400
Washington, DC 20006-3708

Mr. William Corbin
Virginia Electric & Power Company
Innsbrook Technical Center
5000 Dominion Blvd.
Glen Allen, VA 23060

Mr. Frederick W. Polaski
Manager License Renewal
Exelon Corporation
200 Exelon Way
Kennett Square, PA 19348

George Wrobel
Manager, License Renewal
R.E. Ginna Nuclear Power Plant
1503 Lake Rd.
Ontario, NY 14519

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

Ronald B. Clary
Manager, Plant Life Extension
V.C. Summer Nuclear Station
Bradham Blvd.
P.O. Box 88
Jenkinsville, SC 29065

Mr. Paul Gunter
Director of the Reactor Watchdog Project
Nuclear Information & Resource Service
1424 16th St., NW, Suite 404
Washington, DC 20036

Mr. Hugh Jackson
Public Citizen's Critical Mass Energy &
Environment Program
215 Pennsylvania Ave., SE
Washington, DC 20003

Mary Olson
Nuclear Information & Resource Service
Southeast Office
P.O. Box 7586
Asheville, NC 28802

Talmage B. Clements
Manager - License Renewal
Nuclear Engineering Services
CP&L
410 South Wilmington St.
Raleigh, NC 27602

Mr. Charles R. Pierce
Manager - License Renewal
Southern Nuclear Operating Company
P. O. Box 1295
Birmingham, AL 35201

Mr. Garry G. Young
Manager, License Renewal Services
1448 SR 333, N-GSB-45
Russellville, AR 72802

Richard J. Grumbir
Project Manager, License Renewal
Indiana Michigan Power Company
Nuclear Generation Group
500 Circle Drive
Buchanan, MI 49107

Mr. Timothy E. Abney, Manager
Licensing and Industry Affairs
Browns Ferry Nuclear Plant
Tennessee Valley Authority
P.O. Box 2000
Decatur, AL 35609