

October 29, 1999

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

SUBJECT: RESPONSE TO FEEDBACK REGARDING NRR OFFICE LETTER 803,  
REVISION 2

Dear Mr. Marion:

Thank you for your letter dated August 23, 1999, addressing industry feedback regarding NRR Office Letter (OL) 803, Revision 2, *License Amendment Review Procedures*. Our responses to your comments are attached for your review. As you know, we are interested in addressing industry and public concerns with the Nuclear Regulatory Commission's (NRC) processes and procedures. These processes and procedures will be revised as necessary consistent with the goals of maintaining safety, reducing unnecessary regulatory burden, increasing public confidence, and increasing efficiency and effectiveness.

Following our meeting on September 29, 1999, the staff has had internal discussions on the planned issuance of our next revision to Office Letter 803. We are evaluating the comments received from the Licensing Action Task Force (LATF) as well as internal NRC stakeholders. Our plan remains to issue the revision by the end of the year. We may, if the revision is nearly complete, provide the LATF with a draft version of the Office Letter at our next meeting. We are not, however, currently planning to ask the LATF to comment on the draft in time to support the next revision. Our preference is that interested stakeholders, including members of the LATF, forward suggestions or comments which will be considered in subsequent revisions.

If you have any questions or additional concerns about this issue please contact me at (301) 415-1453/scb@nrc.gov or Larry Burkhart at (301) 415-3053/ljb@nrc.gov.

Sincerely,  
**ORIGINAL SIGNED BY**  
Suzanne Black, Deputy Director  
Division of Licensing, Project Management  
Office of Nuclear Reactor Regulation

Enclosure: as stated

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**NRC Response to NEI Comments  
on NRR Office Letter 803, Revision 2  
"License Amendment Review Procedures"**

**A. Response to General Comments**

1. Feedback from licensees indicates that, in general, Revision 2 to Office Letter (OL) 803 is a useful document that provides important insights into the license amendment review process. Project Managers (PMs) appear to be using the Office Letter, and there have been several examples of submittals being clarified through early telephone communications. Feedback has been positive on PM's (and NRR management's) commitment to improve the efficiency of the review/approval process.

RESPONSE: No response required.

2. The Office Letter should be expanded to include guidance on the processing of other types of "licensing actions" (e.g., relief requests, exemption requests, topical reports, generic communications, etc.).

RESPONSE: Since some aspects of processing other licensing actions such as relief and exemption requests are very similar to processing license amendments, guidance will be included to recommend that the PM utilize applicable sections of OL 803 for the processing of exemption requests, relief requests and other licensing action requests. As an example, the Request for Additional Information (RAI) guidance contained in OL 803 can and should be applied to exemption and relief requests. In addition, the staff is working to develop general guidance for the various types of licensing actions (OL 807, "Control of Licensing Basis for Operating Reactors") and specific process standards for each type of licensing action or other licensing task for work planning purposes. In the long term, the staff plans to have improved procedures defined for all of its routine activities. The interactions planned between the staff and the LATF team for licensing submittals (other than Technical Specifications) may be a forum for improving some of our current practices.

3. Minor administrative or non-safety changes to the Technical Specifications (i.e., "cleanup" changes) receive a relatively low review priority. A simplified administrative process for reviewing "minor Tech Specification changes" should be incorporated into the Office Letter. Minor changes need not be subjected to the same degree of process control as safety/risk-related changes.

RESPONSE: As discussed in the September 29, 1999, LATF meeting, this issue is unlikely to be resolved by the scheduled issuance date of Revision 3 to OL 803. Appropriate guidance will be included in OL 803 when this issue is resolved and a policy for handling these types of changes is established.

4. NEI supports the scheduling of NRC workshops for relatively small groups of licensees where attendees can discuss issues pertaining to submittal quality. The NRC staff can describe the criteria used to determine the completeness of a proposed submittal, and licensee staff can comment on the quality of the NRC review process. The cumulative

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effect of the workshops should be the documentation of consistent guidance usable by the entire licensee community, perhaps through subsequent revisions of OL 803.

RESPONSE: The tentative schedule of licensing workshops was provided at the last LATF meeting. To date the workshops have been highly successful by providing an informal forum for the exchange of information and ideas between the industry and the NRC. Currently, all licensees are scheduled to attend a workshop over the next year. Meeting summaries are produced for every workshop. In addition to discussions at the workshops, the staff will place additional recommendations regarding the content of license amendment submittals into the next revision of OL 803.

5. The Office Letter should include guidance on electronic transfer of information. Some PMs typically request electronic copies of licensees' "no significant hazards consideration" (NSHC) evaluations to expedite the publishing of proposed amendments in the Federal Register. PMs should also be encouraged to provide electronic copies of approved amendments to licensees.

RESPONSE: Currently, hard copies of documents are required to be submitted for license amendment, relief, exemption, and other licensing requests. It is acknowledged and encouraged that PMs use electronic copies of submittals, voluntarily forwarded by the licensee, to facilitate the license submittal review process. For example, the use of electronic copies of amendment requests enables the efficient and timely production of the Federal Register notice that includes the no significant hazard consideration determination (NSHCD).

Due to planned, improved electronic information processing capability, the NRC is encouraging the increased use of electronic media for all correspondence. The NRC is currently piloting an Electronic Information Exchange (EIE) process with the Atomic Safety Licensing Board Panel (ASLBP) and the participants in the relicensing hearing before it. The process uses Digital certificate and a Digital signature to assure verification and validation. The NRC provides the participants the capability to digitally sign the submittals at no charge to the licensee or participants. This is the same system that will be implemented on a full scale for all submittals to the agency.

The next step in the process of implementing EIE capability is to issue a Regulatory Issues Summary in November that will allow Part 50 submittals in electronic form if accompanied by one hard copy. The Regulatory Issues Summary will grant a blanket exception to allow for the submittal of the one hard copy with the electronic submittal.

In the summer of 2000, a rule will be published allowing all NRC trading partners to submit electronically in lieu of any hard copy.

Guidance addressing the use of electronic media will be included in the next revision of the Office Letter to the greatest extent possible.

6. The Office Letter does not address changes to the Technical Specification Bases. Guidance for processing Bases changes may be useful, especially for plants with non-standard Technical Specifications. The Bases are an important source of information, and both licensees and NRC staff should maintain consistent, up-to-date versions.

RESPONSE: This issue is being tracked and addressed by the LATF and may not be resolved by the date of issuance of Revision 3 of OL 803. At the September 29, 1999, LATF meeting, NEI stated that they would forward a recommendation for handling TS Bases changes. Guidance will be included in Revision 3 of OL 803, if available and as appropriate.

7. When possible, references to internal NRC memoranda should be avoided. Relevant portions of a memo should be incorporated into the body of the Office Letter, or the memo should be attached to the Office Letter.

RESPONSE: The staff is reviewing the information contained in the internal memoranda and will incorporate portions that are relevant and necessary. Internal memoranda may be placed in the public domain, if deemed appropriate. This will allow the public to review these memoranda without including the entire text in OL 803.

8. Additional guidance is recommended throughout the Office Letter to assist the PM in contractor management and oversight.

RESPONSE: Contractor management is an infrequent responsibility of the PM and is rarely an issue in processing license amendments. In general, contractors are utilized during reviews of relief requests, topical reports, and as technical support in some other staff activities. In these cases, contractors are supervised by the cognizant technical branch. The staff will review the issue of contractor management as it prepares guidance for other review activities.

#### B. Comments on the Office Letter

1. *Section C, "Preparation of the Safety Evaluation," states that project managers are responsible for determining, "with assistance from technical branch personnel, who will perform the safety review (the PM or technical branch staff)."*

It seems more appropriate to make this guidance part of *Section A, "Preparation of the Work Plan."*

RESPONSE: The possible relocation of this responsibility will be considered.

2. *Section D, "Review and Concurrence of the Amendment Package," states: "The Office of the General Counsel (OGC) shall review all amendment packages for legal adequacy and defensibility, unless a memorandum of agreement is developed stating that specific amendments do not require OGC concurrence." (Also see footnote 4 on page 5.3 of the attachment to the Office Letter.)*

OGC review of amendment packages should be the exception, not the rule. To improve administrative efficiency, Project Directors and PMs in the NRR Division of Licensing Project Management should play a role in determining when OGC input is needed. Criteria for obtaining OGC review should reside in an internal NRC memorandum of understanding between the General Counsel and the NRR Office Director. Written guidance is needed on the role of OGC in the amendment process.

RESPONSE: It is the current policy that all amendment, relief, and exemption requests be reviewed by OGC. Any change, if desired, to this policy will require detailed review and negotiation by NRR and OGC. The staff will pursue this issue; however, it is unlikely that a change as recommended above will be included in the next revision of the Office Letter.

C. Comments on the "Guide for Processing License Amendments"

1. *Section 2.0, "Work Planning," describes the steps that should be addressed by PMs in developing an amendment review work plan.*

Although this section contains timeliness goals for the overall process, NRC should consider adding individual timeliness expectations for the key administrative steps necessary to process a proposed license amendment, for example, Federal Register notifications.

RESPONSE: We expect that the work planning initiative within NRR will address the scheduling of sub-tasks. In general the proposed approach is to estimate the resource requirements (staff-hours) of a sub-task and assign the sub-task to the appropriate organization or individual. The availability of resources would normally determine the expected completion date (unless priority or other circumstances dictate that other work assignments be deferred to complete an incoming task).

2. *Section 2.3, "Search for Precedent Licensing Actions," describes the use of precedent in the review process.*

This section of the Office Letter should emphasize the importance of PM communication with the appropriate technical branch(es) early in the review phase. Early agreement on use of precedent between the PM and technical reviewers will help expedite the review process. See Enclosure 2 for additional comments on the use of precedent.

RESPONSE: The staff is not aware of a problem in this area but will consider adding additional emphasis on early communication between PM and technical branches

3. *Section 2.4, "Develop a Work Plan," states: "PMs should give special attention to those reviews that involve multiple TB [technical branches] or PM reviewers. The work plans for such amendment requests need to ensure that the scope and schedule for each reviewer are well-defined and understood."*

One of the main objectives of OL 803 is the consistent and timely processing of license amendments. A work plan, as described above, is necessary to accomplish this objective. For example, the work plan should consolidate RAIs from different technical branches into a single set of RAIs. The work plan should screen out duplicate questions from different branches, screen out questions solely informational in nature, eliminate questions that are not relevant to the proposed amendment and minimize the number of technical reviewers. PM work planning should establish appropriate constraints on the scope of Branch reviews. The Office Letter should contain supplemental guidance or refer to internal work planning procedures to assist PMs in defining the appropriate technical review scope.

RESPONSE: The work planning initiative may resolve some of these concerns. The staff needs, however, to maintain enough flexibility in its guidance to address the wide variety of issues that arise during reviews. For example, some licensees would prefer that RAIs not be consolidated but that an RAI from each branch be sent when ready. Regarding additional guidance on determining the scope of technical reviews, the Office Letter is primarily a process control document. Although it specifies that the staff should establish the appropriate scope and depth of reviews, the wide variety of technical and regulatory issues cannot be captured in the Office Letter (i.e., the Office Letter cannot serve the function of an updated standard review plan). Given its importance to the process and in light of your comments, the staff will consider adding emphasis to the issue of scope and depth of technical reviews.

4. *Section 2.4.1, "Scope and Depth of Review," states: "A memorandum to the staff ... dated October 30, 1998, provides guidance for the review of applications classified as risk-informed licensing actions."*

The role of the PSA [Probabilistic Safety Assessment] Branch of the NRR Division of Systems Safety & Analysis (DSSA) in the review of proposed license amendments, whether "risk-informed" or "deterministic," has become an important issue. The Office Letter should be revised to include additional guidance on "groundrules" for the role of the PSA Branch in establishing the scope and duration of the overall NRC staff review.

Additional guidance is needed to specify how the staff will accept the "burden of proof" when deciding to undertake a risk-informed review of a purely deterministic submittal. The outcome should be an objective, scrutable, decision-making process subject to response and rebuttal from the licensee. The PM should be a part of the process and should be able to explain the staff's decision to the licensee.

RESPONSE: The staff has recently prepared a Commission Paper on this issue. We plan to add additional guidance to the Office Letter regarding this subject.

5. *Section 2.4.3, "Licensing Action Timeliness Goals," specifies timeliness goals to be used as performance measures to monitor the efficiency and effectiveness of NRC staff completion of licensing actions.*

The Office Letter should make clear that timeliness goals should never be used as a basis for denying a proposed amendment or for encouraging a licensee to withdraw a proposed amendment. NRC management oversight will help ensure the integrity of the timeliness goals.

RESPONSE: The staff agrees that the timeliness goals should not be routinely used as a basis for denying a licensing action request. The staff will, however, consider denying amendment requests if a licensee is being unresponsive to requests for information. The denial would make clear that the rationale was a lack of information and not the technical merits of the amendment application. This will be made clear in the next revision.

6. *Section 3.0, "Public Notification."*

Section 3 should include guidance on hybrid hearing procedures for expansion of spent fuel storage capacity (10 CFR 2.1107 requires particular wording in the Federal Register notice). Section 3 should also include guidance on environmental assessments. Processing can be delayed if PMs are not aware of special administrative steps associated with certain amendments (such as spent fuel pool expansions).

RESPONSE: The staff agrees and more guidance will be included in the next revision.

7. *Section 3.1, "Normal (30-day) Public Notification," states: "Project Managers are expected to prepare the notice as soon as convenient following receipt of an incoming amendment request."*

It is not clear whether this occurs before or after the initial acceptance review. In any case, a target time period (e.g., one week) should be specified for preparation of public notification to ensure prompt initiation of the review process.

RESPONSE: The evaluation and issuance of a notice comes after the acceptance review. In general, it is best to issue the FR notice as soon as practicable after receipt of the license amendment request and the latest that the notice should be published is 30 days prior to the desired amendment issuance date. This will be emphasized more clearly in the next revision.

8. *Section 3.1, "Normal (30-day) Public Notification," states: "All applications and supplements to an application should be sent under O&A (50.30). [Oath & Affirmation]"*

It would be helpful if the Office Letter included examples of when an O&A is, or is not, required.

RESPONSE: More detailed information will be included in the next revision of the OL.

9. *Section 4.1.1, "Project Manager Review," discusses project manager (PM) feedback on submittal quality as input to the plant issues matrix (PIM).*

It is important for PMs to put negative input on a single submittal in the context of all submittals. Similarly, balanced input should be made for all types of licensee submittals, not just proposed license amendments. If only negative feedback reaches the PIM, a single sub-par submittal could outweigh numerous quality submittals. This could adversely and erroneously impact the plant performance review (PPR).

RESPONSE: PIM entries are event-specific evaluations and not an overall performance evaluation. PIM entries made by the PM addressing licensing performance should include both good and bad performance. Additional guidance will be included in the next revision.

10. *Section 4.1.2, "Technical Staff Review," discusses technical branch (TB) input to the PM regarding licensee performance.*

RESPONSE: PIM entries are made by the PM, with possible insights from a technical reviewer or TB manager. The TB staff would not be expected to prepare a PIM entry without interacting with the PM. Please see response above.

11. *The second sub-bullet of Section 4.2, "Use of Precedent Safety Evaluations," states: "ensure that the precedent meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to industry, and technical content."*

The discussion of what constitutes appropriate precedent should be expanded. More explicit guidelines will help licensees and the NRC staff cite precedent safety evaluations with greater confidence.

RESPONSE: The staff intended the phrase to simply caution against the use of a precedent evaluation without considering the possibility that the NRC technical position or preferred safety evaluation content might have changed in the period between applications (sometimes years). The staff will consider adding some clarification to the Office Letter. See subsequent response for more detailed discussion of precedents.

12. *Section 4.3, "Requests for Additional Information," contains guidance on the content and timing of RAIs.*

- RAI guidance should apply to all NRC requests, not just proposed license amendments.

RESPONSE: As discussed in A.2 above, additional information will be included to ensure adherence to RAI guidance for other licensing action requests, such as exemption and relief requests.

This section should state that the number and nature of RAIs are not indicators of the quality of staff review. The long-term objective is to improve the communication of mutual expectations such that the need for RAIs decreases over time. A goal of "zero RAIs" is reasonable and achievable.

RESPONSE: The number of RAIs, by itself, does not necessarily indicate the quality of a licensee's submittal. The need for clear communications will be emphasized so that unneeded RAIs will not be issued.

- If the first paragraph of Section 4.3 were reformatted as a list, it would better emphasize the importance of ensuring that each RAI question is warranted.

RESPONSE: Suggested format will be considered.

- With respect to item 1 on page 4.3, technical branch reviewers should be sure to include the regulatory basis for their questions so the PM can include it in RAI telecons and letters to licensees.

RESPONSE: Clearer guidance will be included in the next revision and additional staff training will be provided, as needed. The staff is considering reactions from various internal and external stakeholders regarding the format of RAIs. Although

RESPONSE: Clearer guidance will be included in the next revision and additional staff training will be provided, as needed. The staff is considering reactions from various internal and external stakeholders regarding the format of RAIs. Although the importance of having a nexus between RAI questions and our regulatory finding will continue to be emphasized in the Office Letter, it is not certain that the guidance will require an explicit reference to a regulatory requirement for each question. The staff is attempting to balance the various factors (burden, efficiency, etc.) in developing the specific guidance.

With respect to item 3 regarding communications prior to issuing an RAI (page 4.3) and item 6 regarding communications after issuing an RAI (page 4.4), a PM/TB/Licensee conference call would be useful in both cases. Technical branch participation in conference calls will help assure that technical questions are clearly communicated and understood by all parties. The conversation may obviate the need for at least some of the questions.

RESPONSE: Clearer guidance will be included in the next revision.

RAIs should not be used as general information requests, or as a means to encourage commitments from licensees.

RESPONSE: This will be emphasized clearly in the new Office Letter. The staff would, however, caution against making communication protocols too rigid in terms of the questions that can be asked during conference calls. Licensees should understand that a few general questions during a conference call may be the most efficient and cost-effective way for a reviewer to complete an evaluation. Hopefully, both staff and licensees can work to reach the appropriate level of questions to meet the needs and efficient use of resources of both parties.

13. *Section 4.4, "Regulatory Commitments," discusses the potential for escalation of commitments into license conditions.*

The NRC should discontinue the practice of escalating commitments into license conditions. If a licensee has submitted a license amendment application under oath and affirmation, and the NRC staff has approved the amendment, associated commitments should be managed through a formal commitment-management program. If commitments are not being satisfied, the NRC has sufficient authority to take enforcement action when warranted.

RESPONSE: The staff intended the guidance to reflect the general hierarchy of the licensing bases that has been discussed between industry and NRC on several occasions (see SECY 98-224). The Office Letter states that the staff should not routinely make commitments into license conditions. However, it is possible that a licensee might make a commitment in an application that the staff believes should be escalated into a regulatory requirement (e.g., a license condition). The guidance to be included in OL 807 will clarify this issue.

14. *Section 4.5, "Safety Evaluation Format," discusses various technical and format considerations associated with NRC staff safety evaluation reports (SERs).*

Section 4.5 does not discuss differences between licensee submittals and NRC staff SERs. The Office Letter should include guidance for citing the differences, including the reasons for the differences. This would allow all parties to verify that the SER satisfies the backfit rule (10 CFR 50.109).

RESPONSE: The staff will add guidance in this area

15. *Section 5.0, "Review and Concurrence," discusses the process by which the quality and consistency of an amendment package is verified.*

The discussion in this section should include Tech Spec Bases changes. If Bases changes are part of an amendment package, the NRC's SER and transmittal letter should explicitly state that the Bases changes are part of the NRC staff's approval. Otherwise licensees are left to assume that proposed Bases changes have been approved by the NRC staff's review.

RESPONSE: As previously discussed, the staff and LATF plan to refine guidance for the NRC and licensees regarding Bases changes.

16. *Section 5.0, "Review and Concurrence," discusses the attributes of a completed amendment package.*

If final NRC concurrence cannot be reached to approve the amendment package, the licensee should have the opportunity to communicate with cognizant NRC staff to provide additional clarification or information in support of the proposed amendment. Any meeting or conference call should occur before NRC takes final written action.

RESPONSE: This is the general practice. The staff will consider adding additional guidance to the OL.

#### General Comments on Enclosure 2 - Use of Precedents

The staff is not aware of general issues regarding the inclusion or exclusion of reviews in terms of our use of precedents. In general, if a reviewer believes that a review (in whole or in part) is relevant, we want to encourage the use of the review as a precedent. We do not foresee adding significant guidance in this area. We will consider some of the suggestions in Enclosure 2 such as improving our documentation regarding the use of precedent reviews.