

October 21, 2003

Mr. James Mallay
Director, Regulatory Affairs
Framatome ANP
3315 Old Forest Road
P.O. Box 10935
Lynchburg, VA 24506-0935

SUBJECT: IMPLEMENTATION OF A REVISED REVIEW PROCESS FOR TOPICAL
REPORTS

Dear Mr. Mallay:

This letter is to inform you that, as part of our ongoing efforts to improve the effectiveness and efficiency of the topical report program, effective for all topical reports submitted after October 1, 2003, we have implemented revisions to our topical report review process. This letter supersedes our earlier letter dated July 1, 2003, regarding a proposed prioritization and scheduling process for topical report reviews and considers comments received in response to that letter. Details of the revised process are given below:

1. The revised process requires that submittal letters for all topical reports include a requested completion date with a detailed explanation of the basis for the date.
2. Based on the requested completion date and its basis, report complexity, available staff resources, potential generic benefits, and relevance to NRC's performance goals, the staff will establish proposed optimum milestones for issuing the request for additional information (RAI), receiving responses to the RAI, and the safety evaluation (SE) issuance for that topical report.
3. During the acceptance review of the topical report, a telephone conference will be held among the project manager, technical branch supervision, and the submitter of the topical report to discuss and obtain a mutual agreement on the review schedule milestones. Once agreed upon, the report-specific review schedule will be considered a "commitment" by the staff and the submitter of the report.
4. The revised process will typically require that responses to RAIs be submitted within 30 calendar days of receipt. Proposed RAIs will be discussed before issuance, as is the current practice.
5. The agreed-upon schedule will be documented in the acceptance for review letter for the topical report, along with estimated review cost, which will include staff review hours, time required to coordinate the review and develop and issue the SE, i.e., project management time, and the estimated contractor cost, if applicable and available. Typically, the acceptance for review letter will be issued within 45 calendar days of receipt of the topical report.

6. In order for this process to be successful, the established schedules must be adhered to by both the submitter of the topical report and the staff. In the event of a lack of support from the submitter, such as an incomplete or late RAI response, the staff can extend the review schedule until the complete RAI response is submitted, or suspend its review of the topical report. In such situations, after receiving all requested information, the staff would establish a revised review schedule, based upon available staff resources, and other considerations. The revised review schedule would be documented in a letter to the submitter of the topical report.
7. Effective immediately, pursuant to 10 CFR 2.790, a draft SE will be issued on the approval of the topical report and will not be placed in the public document room for a period of ten working days from the date of the SE transmittal letter to provide the submitter an opportunity to comment on the proprietary aspects of the SE. After ten working days, the draft SE will be made publicly available, and an additional ten working days will be provided to the submitter to comment on any factual errors or clarity concerns contained in the SE. The final SE will be issued after making any necessary changes, and will also be made publicly available. The staff's disposition of submitter's comments will be discussed in the final SE.

If you have any questions, or need clarification, please call Girija Shukla, Project Manager, Topical Report Program, at 301-415-8439, Steve Dembek at 301-415-1455, or me at 301-415-1395.

Sincerely,

/RA/

Herbert N. Berkow, Director
Project Directorate IV
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Project Nos. 693 and 728

cc: See next page

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Sincerely,

/RA/

Herbert N. Berkow, Director
Project Directorate IV
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B&W Owners Group

Project No. 693

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