UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

December 16, 2004

NRC REGULATORY ISSUE SUMMARY 2004-20
LESSONS LEARNED FROM REVIEW OF
10 CFR PARTS 71 AND 72 APPLICATIONS

ADDRESSEES

All holders of, and applicants for, a (1) 10 CFR Part 71 certificate of compliance for a radioactive material transportation package; (2) 10 CFR Part 72 certificate of compliance for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of lessons learned from NRC's review and approval of applications submitted in accordance with Parts 71 and 72, and to communicate NRC's expectations regarding the process for submittal, review, and approval of Parts 71 and 72 applications. No specific action nor written response is required.

BACKGROUND

In 1995, NRC established the Spent Fuel Project Office (SFPO), which is responsible for the review and approval of applications submitted, in accordance with Parts 71 and 72, for radioactive material transportation packages, dry cask storage systems, and ISFSIs. In an effort to standardize the staff's review of applications, SFPO developed four standard review plans (SRPs) -- two for the transportation of radioactive material and two for the interim storage of spent fuel. The SRPs are availabile through NRC's Web site and include:

- SRP for Transportation Packages for Radioactive Material (NUREG-1609), May 1999;
- SRP for Transportation Packages for Spent Nuclear Fuel (NUREG-1617), March 2000;
- SRP for Dry Cask Storage Systems (NUREG-1536), January 1997; and
- SRP for Spent Fuel Dry Storage Facilities (NUREG-1567), March 2000.

Each SRP summarizes the regulatory requirements necessary for approval of an application and describes the procedures that SFPO staff use to determine that the requirements have been satisfied. The SRPs are intended to be living documents that will be updated and revised as regulations or practices change. To help keep the SRPs up to date, SFPO issues interim staff guidance documents (ISGs) to identify emergent issues and develop staff positions in a timely manner. The ISGs are also available on NRC's Web site. In addition to the technical

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review guidance in the SRPs and ISGs, SFPO developed a set of guidelines to define the expectations for interactions between SFPO and licensees and applicants (these guidelines have commonly been called the “rules of engagement”) during the licensing process. The rules of engagement were developed to establish a predictable and consistent methodology for reviewing applications, and included guidelines for the quality and completeness of applications; scheduling the review of an application; performing the acknowledgment and technical review; and preparing requests for additional information (RAIs); safety evaluation reports (SERs); certificates of compliance (CoCs); and licenses.

SUMMARY OF ISSUE

Since development of the SRPs and rules of engagement, SFPO has gained significant experience and lessons learned through the review and approval of hundreds of applications. As a result, this RIS has been developed to share those experiences and lessons learned with licensees, certificate holders, and applicants in an attempt to: (1) help them develop more complete licensing applications; and (2) facilitate their interactions with SFPO during the licensing process. These lessons learned were identified through evaluation and refinement of staff processes and procedures, and through continuing interactions with applicants during the performance of licensing reviews. It is expected that application of these lessons learned will result in a reduced burden on both applicants and SFPO through a more predictable and consistent licensing process.

Guidelines for Interactions Between Applicants and SFPO Staff - Rules of Engagement

The rules of engagement were developed in the late 1990s and discussed in numerous public meetings with licensees and applicants. Since development of the original rules of engagement, there are now many new applicants, licensees, and certificate holders, conducting business with SFPO, who are not necessarily aware of them nor of their purpose. Therefore, a copy of the rules of engagement is provided as Attachment 1 to this RIS. These rules of engagement have been modified to reflect lessons learned since their original development. In a broad sense, the rules of engagement are meant to establish a set of clear expectations, both for NRC staff and the applicant, to guide the licensing review process.

Pre-application Meetings

Pre-application meetings with applicants, open to the public, are encouraged. These meetings significantly benefit both NRC and the applicants, particularly for new designs and complex amendments. They allow the presentation and discussion of technical information on proposed approaches to meet regulatory requirements before the development of a final application. As a result, applicants may identify potential enhancements or refinements that should be incorporated into their applications, before submittal to NRC, to improve the application’s overall quality and completeness. In addition, these meetings allow staff an early understanding of an applicant’s design and analysis, so that once the application is submitted, the staff’s detailed technical review is facilitated. Pre-application meetings should be held sufficiently far in advance of the planned application submittal date, so that applicants can fully consider the feedback received during the meeting and make any necessary refinements or enhancements to their applications.

Notification of Plans to Submit Future Applications

NRC has implemented an integrated planning, budgeting, and performance measurement process. A significant element of the planning and budgeting process is the number of applications that NRC is expected to review during a budget cycle. These applications include new designs, amendments, exemptions, renewals, license transfers, and other requests requiring the expenditure of NRC resources. Many applicants, licensees, and certificate holders routinely inform SFPO of the expected number and type of applications that they plan to submit in the future. This generally occurs through periodic public meetings, discussions with project managers, or submittal of correspondence to NRC, projecting future applications. This information helps NRC budget resources needed, so it can review applications in a timely manner. Without reasonably accurate estimates of the expected number of applications that NRC will receive, NRC's budget estimates may be incorrect, ultimately impeding its ability to process applications on a timely basis. Providing NRC with ample prior notice of incoming licensing actions will not only result in the greater likelihood of a review beginning soon after receipt, but also will most likely result in a more timely and expedient overall review schedule.

Application Submittals

Applications submitted to NRC for review and approval should be complete, well-organized, and of high quality. Technical issues in the Safety Analysis Report should be thoroughly explained and have enough information for the staff to perform an independent review. A quality application that thoroughly describes the proposed design and its ability to meet regulatory requirements is less likely to require clarification through issuance of RAIs. Once SFPO has accepted an application for technical review, it will generally not accept supplemental changes nor the submittal of new information, unless such items are in response to a RAI. The staff may treat the supplemental changes or new information as a new application and establish a new schedule accordingly.

Baseline Documentation for Review of Licensing Actions

Part 72 certificate of compliance amendment applications typically consist of proposed changes and revisions to the updated Final Safety Analysis Report (FSAR), certificate of compliance and technical specifications, and supporting technical data and analysis. The applicant is responsible for providing a clear indication in the application of what information is being requested for approval. In performing the technical review of an application, SFPO evaluates the proposed changes submitted in the application and uses the most recent version of the FSAR submitted in accordance with 10 CFR 72.248. However, the FSAR is only required to be updated every 24 months. There have been numerous occasions in which multiple major amendments to Part 72 certificates of compliance have been approved between the 24-month update periods. In addition, numerous other design changes are made by certificate holders and general licensees under the provisions of 10 CFR 72.48. The changes, from the various amendments, and under the provisions of 10 CFR 72.48, complicate the review of subsequent amendment requests, when the proposed changes are not made explicitly clear, versus those changes previously approved, or made under the provisions of 10 CFR 72.48. The major lesson learned from this situation is that an applicant should clearly identify which version of the FSAR is being changed for a specific amendment request. If there are differences between the most recent FSAR update submitted to NRC and the version submitted with the application, the

applicant should note exactly what changes have been made, and under what process the changes were implemented (i.e., 10 CFR 72.48 or an NRC-approved amendment). Proposed changes should be clearly marked and annotated (e.g., change bars in the margins, red-line, strikeout, etc.). By providing a Part 72 certificate of compliance amendment application that is very clear as to what changes are being requested, SFPO technical review times can be decreased, and any RAIs can focus on the proposed changes versus defining the scope of the licensing action request.

Processing of Concurrent Reviews

On multiple occasions, applicants have submitted several amendment requests, over a short time period, for the same design, which results in concurrent SFPO technical reviews. Applicants should consider the possible effect of approval, delay, or denial of one amendment request on the remaining requests, and the extent to which each amendment stands alone or requires approval of all, or a portion, of another amendment request. When multiple amendment requests are submitted, applicants should note whether any single amendment takes priority over the others, and should define the need to the staff as early as possible. Additionally, applicants should consider consolidation of multiple amendment requests where feasible.

Review of Evolving Designs

The designs of radioactive material transportation packages and spent fuel storage casks continue to evolve to meet the needs of the nuclear industry, most notably in the areas of high-burnup fuel and increased decay heat loads. In response, applicants are proposing new and innovative approaches to meet NRC safety and regulatory requirements. In reviewing new design approaches or methodologies, SFPO must gain an understanding of the information submitted by the applicant and, at times, develop the basis and criteria for which the application can be approved. In such cases, the time to develop acceptance criteria and complete the review is generally longer than more routine licensing actions. Applicants should recognize the increased demands associated with reviewing and approving evolving designs and factor this into their planning. As noted above, applicants are encouraged to routinely notify SFPO of their proposed incoming licensing applications, in particular, those that contain new and innovative approaches. This will facilitate SFPO's planning and help meet the needs of the applicant. In addition, as noted above, applicants are encouraged to request pre-application meetings with SFPO, to discuss these new designs. Experience continues to show that, for complex reviews involving new and innovative designs, at least one RAI is necessary. As a result, SFPO recommends that applicants consider meeting with the staff after receipt of a RAI to ensure a thorough understanding of the information being requested. In addition, applicants should consider a subsequent meeting with the staff to discuss their proposed RAI response to ensure that the proposed response fully addresses the issues identified in the RAI. The purpose of these meetings is to ensure that all parties have a common understanding of the issues and what is needed to resolve them. As a result, the potential for an inadequate or incomplete RAI response being submitted to NRC is reduced, along with the potential for a second RAI.

Proprietary Information

On June 29, 2004, NRC issued RIS 2004-11, "Supporting Information Associated with Requests for Withholding Proprietary Information," to all submitters of proprietary information to NRC. This RIS provided a detailed discussion of the requirements associated with submitting proprietary information to NRC, including the need to sufficiently support the basis for the proprietary determination and the need to identify each portion of the submittal that falls under the claim of proprietary information. The top of the first page of the document and the top of each page containing such information must be clearly marked to indicate that the page contains proprietary information. Additionally, each document or page, as appropriate, to be withheld from public disclosure, should contain adjacent markings, which clearly indicate which portions are to be withheld. SFPO continues to receive applications that do not meet the requirements for properly marking proprietary information. In several instances, the initiation of NRC's review of the application has been delayed for several months pending resolution of the proprietary markings. SFPO encourages applicants, licensees, and certificate holders to revisit RIS 2004-11, to avoid the potential for unnecessary delays in review of an application.

BACKFIT DISCUSSION

This RIS requires no action nor written response and is, therefore, not a backfit. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain any information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below.

/RA/

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Note: NRC generic communications may be found on the NRC public website, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

Attachment:
"Guidelines for Interactions Between Applicants and Spent Fuel Project Office Staff"

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GUIDELINES FOR INTERACTIONS BETWEEN APPLICANTS AND SPENT FUEL PROJECT OFFICE STAFF (RULES OF ENGAGEMENT)

1. PRE-APPLICATION INTERACTIONS

   (a) Applicants are encouraged to meet with Spent Fuel Project Office (SFPO) staff at public meetings to discuss potential licensing actions. The purpose of these meetings is to provide applicants with an opportunity to discuss their proposals with staff and solicit feedback regarding regulatory positions. No regulatory decisions nor commitments will be made at these meetings.

2. POINT OF CONTACT

   (a) The SFPO Project Manager (PM) is the primary point of contact between SFPO and the applicant. The PM is responsible for, and is the focal point for, all interactions with the applicant.

3. TELEPHONE INTERACTIONS

   (a) Phone conversations with applicants are encouraged, as they directly contribute to clear understanding and efficiency during the review.

   (b) Phone conversations are not public meetings and therefore they only involve general information exchange [e.g., clear understanding of a request for additional information (RAI)].

4. SUBMITTALS

   (a) Applicants shall submit a complete, high-quality application that is clear and well-organized. This includes:

      (1) Using the recommended format and content of the appropriate Regulatory Guides, Standard Review Plans, and Interim Staff Guidances. Deviations from regulatory positions should be clearly identified and include sufficient technical basis.

      (2) Thoroughly explaining all issues in the Safety Analysis Report and including enough information for a technical reviewer to perform an independent review.

   (b) Although not required by the regulations, applicants should consider submitting a draft certificate of compliance (CoC) or license for a new application and a draft mark-up CoC or license for an amendment.

5. ADMINISTRATIVE REVIEW OF APPLICATION

(a) The PM will perform an acknowledgment review generally within 30 days of receipt. The acknowledgment review is not a technical review; it is an administrative evaluation to determine the completeness of the application and to identify any significant omissions of information.

(b) For most applications, an acknowledgment letter and tentative schedule will be sent to the applicant once the schedule is developed.

(c) Applications that do not pass the administrative review because of incompleteness will not be accepted for a technical review. The applicant will initially be notified via phone regarding an incomplete application and the PM will give the applicant the opportunity to withdraw the application.

(d) After the application has been accepted for technical review, no additional changes to the application will be allowed, except for those that result from responding to a RAI. All additional changes, supplements, or enhancements will be treated as a new application.

6. REQUESTS FOR ADDITIONAL INFORMATION

(a) Applicants will be given a set time period to respond to RAIs. This time period will be based on the complexity of the application and its priority.

(b) An applicant who cannot meet this schedule, should submit a letter at least 2 weeks in advance of the RAI response due date and provide the new submittal date and the reasons for the requested change.

(1) The applicant should understand that not meeting the RAI response due date may cause rescheduling of the application because of other previously scheduled casework and competing priorities.

(c) Applicants are encouraged to meet with the NRC staff in a public meeting to discuss proposed RAI responses. The purpose of these meetings is to ensure that the proposed responses address the staff's issues and thus avoid the potential for a second RAI. If the applicant requests clarification of an unclear RAI, then SFPO may schedule a conference call with the appropriate technical reviewer to provide clarification.

(d) Applicants are advised against sending a partial RAI response. The staff will not perform a technical review of the RAI response until a complete response to the RAI is received.

(e) SFPO will not initially schedule a second RAI. If a second RAI is needed, and the responses to the second RAI are not sufficient for the staff to make a licensing determination, then SFPO will identify its positions and concerns in a public meeting, and suspend further technical review.