INTERACTIONS WITH APPLICANTS AND REVIEW PROCESS FOR U.S. NRC TRANSPORTATION PACKAGE CERTIFICATION

Nancy L. Osgood
Spent Fuel Project Office
U.S. Nuclear Regulatory Commission
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ABSTRACT

The Spent Fuel Project Office of the U.S. Nuclear Regulatory Commission (NRC) certifies transportation package designs under the provisions of 10 CFR Part 71. The Spent Fuel Project Office (SFPO) also conducts technical reviews for foreign-approved designs for import and export shipments to the standards in International Atomic Energy Agency transportation regulations. In an effort to improve the certification and review processes, SFPO developed policies and procedures for interactions with applicants for package approval and a Standard Review Plan for transportation package design review. These were developed to facilitate the certification process and to improve the predictability and efficiency of design certification and review activities. An SFPO protocol was developed to provide structure and consistency in the interactions between the NRC staff and applicants for package review and certification. The elements of the protocol were developed to ensure that applicants provide complete, high-quality applications and the staff provides a technical review and determination that are timely and consistent with regulatory requirements.

A key element in the certification and review process was the development of Standard Review Plans (SRPs) for transportation packages. Two SRPs were developed for transportation package design reviews: one for spent fuel (NUREG-1617) and one for other radioactive materials (NUREG-1609). The SRPs summarize the regulatory requirements for package approval, describe the procedures by which the staff determines that these requirements have been satisfied, and document the practices developed by the staff in previous reviews of package applications. Certification and review activities for transportation package designs have been performed using the internal protocol for several years.

INTRODUCTION

The Nuclear Regulatory Commission is an independent agency established by the U.S. Congress under the Energy Reorganization Act of 1974 to ensure adequate protection of the public health and safety, the common defense and security, and the environment in the use of nuclear materials in the United States. The NRC's scope of responsibility includes regulation of -

- commercial nuclear power reactors; nonpower research, test and training reactors,
- fuel cycle facilities; medical, academic, and industrial uses of nuclear materials, and
- transport, storage, and disposal of nuclear materials and waste.

The NRC is organized into various program offices, including the Office of Nuclear Material Safety and Safeguards (NMSS). NMSS is responsible for the activities listed in the last two bullets above, in other words, activities excluding power and non-power reactors. The Spent Fuel Project Office is one of four divisions within NMSS. The Spent Fuel Project Office (SFPO) was formed in 1995 and is responsible for developing and implementing the NRC's regulatory licensing and inspection program for the storage of nuclear reactor spent fuel and the domestic and international transport of radioactive materials. SFPO serves as the agency lead in spent fuel storage and transportation activities, including certification of Type B and fissile material transportation package designs, inspection of quality assurance for package fabricators and users, and developing regulations and regulatory guidance.

SFPO is divided into two directorates - the Licensing and Inspection Directorate and the Technical Review Directorate. Each Directorate has two sections, and each section has from 12 to 15 staff members.

MOTIVATION FOR SFPO PROCESS STANDARDIZATION

In the mid-nineties, there was a large increase in demand for dry cask storage approvals for spent nuclear fuel at commercial reactors. In addition, the dual purpose casks, that is casks designed for both spent fuel storage and transport, were being developed and submitted to the NRC for approval. The amount of work and the urgency of the needs placed extraordinary demands on the staff performing these functions. After the Spent Fuel Project Office was formed, it became clear that a more formalized process of licensing and review was needed to manage work. The goal was to improve efficiency and effectiveness of the process, to ensure predictability of the process, and to matrix all work throughout the SFPO.

PROTOCOL FOR INTERACTION WITH APPLICANTS

SFPO management developed an office protocol for interactions with applicants intended to facilitate handling the workload demands on the staff. Internally we call these the "Rules of Engagement" and there are three key elements that were necessary in the development and implementation of "the Rules."

The three key elements will be discussed individually: use of Standard Review Plans, prioritization of work throughout the office, and use of scheduling tools and review duration templates.

1. Standard Review Plans and Interim Staff Guidance

NRC has for many years had standard review plans for licensing of commercial nuclear power plants and for various other licensing programs. In transportation we did not have a Standard Review Plan until relatively recently. That is not to say that there was no regulatory guidance - NRC has many regulatory guides and technical reports dealing with various aspects of transportation package design reviews. The most familiar is probably the Standard Format - which lays out the information than an application for package approval should contain and establishes the format of the application. We still have a Standard Format (Regulatory Guide No. 7.9), but it is out

of date and has been superseded by the Standard Review Plan (SRP). What is an SRP and what is the purpose of the SRP?

The SRP summarizes the regulatory requirements for package approval. It describes the procedures the NRC staff uses to determine that the requirements have been satisfied, and it documents the practices developed by the staff in its previous package reviews. It is useful to staff to ensure consistent and thorough reviews, and it is useful to applicants to understand the information and criteria that the staff uses to make its regulatory determination.

The SFPO has developed four SRPs - two for transportation and two specific to spent fuel dry storage. The four SRPs are:

- Standard Review Plan for Transportation Packages for Radioactive Material (NUREG-1609)
- Standard Review Plan for Transport Packages for Spent Fuel (NUREG-1617)
- Standard Review Plan for Dry Cask Storage Systems (NUREG-1536)
- Standard Review Plan for Spent Fuel Dry Storage Facilities (NUREG-1567)

These SRPs were developed by the staff and were issued in draft form for public comment. All four SRPs have now been issued in final form.

The SRPs are intended to be living documents to reflect current regulatory requirements, standard practices and technology. Because it is not practical to continuously issue revisions of the SRPs, another vehicle was developed - the interim staff guidance document (ISG) to address specific emerging technical issues. As discussed in a previous presentation, the ISGs address specific issues and are intended to be incorporated into the applicable SRPs when they are periodically updated. It is interesting to note that most ISGs developed to date deal primarily with spent fuel storage issues. Given the very long history of transportation package design approvals (about 30 years) and the relatively short history of dry cask storage regulations, the number of new issues that arise during storage reviews is understandable. Of course some of the storage issues, such as high burnup spent fuel and burnup credit for criticality safety, may also be applicable to transportation package design review.

Note that the SRPs and ISGs are available, full text, through the NRC website (http://www.nrc.gov). For SRPs go to Reference Library - Technical Reports (NUREGs), and for ISGs go to - News and Information - Resources - Spent Fuel. As described in the earlier presentation, SRPs and ISGs are not regulatory requirements. They provide information for applicants regarding staff practices in performing technical reviews. An applicant may choose to deviate from this guidance. In those cases, the applicant should identify the deviations and justify the alternative approach. That is the first Rule of Engagement - an applicant must identify all deviations from the guidance in the applicable SRP.

2. Prioritization of Work Throughout SFPO

As mentioned above, SFPO has been faced with a very large amount of casework that involves spent fuel storage and dual purpose storage and transport systems. Much of the work is considered urgent due to the limited space for temporary spent fuel storage in spent fuel pools at some reactor plants. It seems to each applicant that its needs should receive highest priority in NRC's review process. It is always a challenge to prioritize work when the number of staff is limited, but the number and urgency of applications does not seem to be. To assist in assigning priority to all work including transportation and spent fuel storage, a numerical hierarchy was established to be used for all work in SFPO. In a nutshell these priorities are:

Priority 1.	Maintaining safety - the highest priority.
Priority 2.	Maintaining operational capability - for example, storage review work for plants that may imminently lose a full core offload capability in their spent fuel pool, or an identified shipment need date.
Priority 3.	Storage and transport needs to support decommissioning facilities.
Priority 4.	Other spent fuel storage and transportation efforts that are budgeted.
Priority 5.	Other non-budgeted activities.

Priorities are assigned to each application that is received by SFPO. In general, it is up to the applicant to identify the specific needs that SFPO staff uses to make its judgement regarding priority.

3. Use of Scheduling Tools and Review Templates

The process for transportation package design reviews begins when an application is received by SFPO. Whether it is a new transportation package design or an amendment request for a spent fuel storage cask, it is initially docketed and given to the Licensing Section. A project manager (called a PM) is then immediately assigned. The project manager develops a draft schedule based on the priority and the complexity of the request using our review templates that lay out time durations for the various review steps. The project manager will also determine what technical disciplines are needed for the review. For example, a new design would need a multi-discipline team of reviewers. An amendment may need only one reviewer - say, a criticality analyst for a modification of contents of a fissile material package. Technical reviewers from the Technical Review Directorate are then assigned based on expertise and availability.

The initial step in the review protocol is the "acceptance review." This review is primarily an administrative review to ensure that the application is complete, includes sufficient detail to perform a complete technical review, and is, in general, consistent with the guidance in the applicable SRP. The acceptance review is typically completed within four to six weeks of receipt of the application. Based on the complexity of the request, the entire review team may perform the acceptance review or it could be just the project manager. Applications that are not complete or do not include sufficient detail are rejected and returned to the applicant with the documented results of the acceptance review. The second Rule of Engagement is that we will not accept for review an

incomplete or obviously deficient application. For applications that are acceptable for review, the applicant is informed of that fact and provided with the review schedule.

A tool that is used to assist in assuring complete and acceptable applications is the pre-application meeting. Applicants may find it useful to meet with SFPO staff to present design information for new packages during design development and prior to the physical testing and the final design stage. These meetings, which are open for public observation, are useful in familiarizing staff with new package designs and are useful to applicants to get an indication of the types of questions that would come up during a review. The meetings are not binding on either side, but are meant to be frank exchanges of technical information. No regulatory decisions are requested or made at such meetings.

The schedules that are developed for casework are based on review templates that establish the review duration for each step of the review. It is expected that any application will be complete and of high quality and will be consistent with the guidance in the SRP. Therefore it is expected that the need for supplemental information during the review should be limited. Assuming a complete and detailed application, a maximum of one staff request for additional information is built into each review schedule. This is the third Rule of Engagement - the review protocol is limited to one staff request for additional information.

The staff request for additional information, or RAI, is worthy of special discussion here. As stated, the review templates schedule only one RAI for a review. The RAI is intended to identify the information that is sufficient and essential for staff to reach a regulatory determination. Each question should have a direct, logical link to a specific regulatory requirement. The expectation is that with the guidance of the SRP and pre-application interactions with staff, that the initial submittal should contain sufficient information in sufficient detail for the staff to reach a regulatory decision. Thus is it really an SFPO goal that there be no RAI for the review. One RAI is acceptable. The response to any RAI, therefore, must be complete and must be responsive to the issues identified by staff. After the RAI is issued, applicants are encouraged to meet with staff to ensure that there is a clear understanding of the information being requested. This is important because the fourth Rule of Engagement is that we will not accept an incomplete response to an RAI. The best time to meet is after the applicant has evaluated the questions and has a proposed response developed. The meeting then can be useful in confirming that the information that the applicant plans to submit will fully answer the staff's questions. The information submitted in response to the RAI should focus on the specific questions identified by staff. New information or new design changes are not appropriate for submittal with a response to an RAI. New information or new design changes will be considered as a new application, and a revised schedule will be developed for the new submittal.

Review schedules include not only the duration of the NRC staff review but the duration of time allotted for the applicant to respond to the request for additional information. If an applicant is not able to meet the schedule for the supplemental information the remainder of the review may be rescheduled due to the availability of the project manager and the technical review staff. That is the fifth Rule of Engagement - failure to meet due dates by an applicant may cause the entire review to be rescheduled.

In summary, the rules of engagement are as follows:

Rule 1.	We will not review incomplete or obviously deficient applications.
Rule 2.	The applicant should identify and justify all deviations from the Standard Review Plan guidance.
Rule 3.	Only one Request for Additional Information (RAI) is scheduled.
Rule 4.	We will not review incomplete RAI responses.
Rule 5.	If an applicant misses a scheduled due date, the entire review will be rescheduled.

Taken as a whole, it is clear how our Rules of Engagement have been developed to improve the efficiency, effectiveness, and predictability of the regulatory process.

REVIEW OF FOREIGN-APPROVED PACKAGE DESIGNS

In the U.S. the responsibility for regulation of transportation of radioactive materials is given by legislation to two agencies - the Nuclear Regulatory Commission and the Department of Transportation. The legislation actually gives joint regulatory authority. To avoid duplication of effort the role of each of the two agencies is defined in a Memorandum of Understanding. In general, the NRC regulates Type B and fissile material packaging, and DOT regulates carriers and packaging for smaller quantities of radioactivity, such as Type A, low-specific activity, and excepted packages. According to the Memorandum of Understanding, DOT regulates safety of international shipments, and DOT serves as the Competent Authority with respect to the International Atomic Energy Agency.

For import and export shipments, DOT is the certifying agency and issues Competent Authority Certificates. For foreign-approved designs used for import and export shipments, DOT may request NRC to perform the technical review of the package design. In that role, NRC is providing a recommendation to DOT regarding the U.S. revalidation of the foreign certificate. In this case, DOT is acting more like our applicant. For companies that have requested a Competent Authority Certificate for a foreign approved package, the government agency that you must interface with is DOT, not the NRC.

How does the review of foreign-approved designs fit into our internal review protocol? There are a number of fundamental differences in the NRC review of foreign-approved designs. First, the review is performed against the IAEA standards, either Safety Series 6 or TS-R-1, depending on whether the design is grandfathered or a new design. Although the staff guidance in the SRPs is generally applicable and is useful for staff in its review, some is not applicable because the IAEA regulations may differ from domestic regulations in 10 CFR Part 71. Second, the role of the NRC is different. NRC is not the certifying agency, DOT is, and therefore the NRC does not issue a certificate or a license, but a letter of recommendation to the DOT. Third, the type of review is different. For foreign-approved designs, another Competent Authority has previously reviewed the design. The review performed by the SFPO technical staff may be less detailed than for NRC-approved designs. The expectation is that the other Competent Authority has done the detailed technical review. Therefore our review does not need to be as detailed, and in fact confirmatory

analyses, which are almost always performed for NRC-approved designs, may or may not be performed for foreign-approved designs.

Although the review may be less detailed, there are factors that sometimes make it a more difficult review. First, in general, all U.S. applications follow the standard format and SRP developed here. So reviewers are very familiar with this format. Other countries have developed other types of formats and major deviations in formatting can cause difficulty for the reviewer in trying to locate all the needed information. Second, although the U.S. regulations are intended to "harmonize" with the IAEA standards, there are differences - some are obvious and some may be very subtle. Third, the practices that have been developed by other competent authorities with respect to their package approvals may be significantly different from the U.S. This is to be expected, since different countries have developed different regulatory frameworks domestically that affect the way designs are reviewed. For example, some countries issue both design and shipping certificates, and that may affect the way a design is reviewed. Fourth, often the translation from a foreign language can cause difficulty in interpreting the safety case that is submitted for review.

All that having been said, the review protocol for a foreign-approved design is very similar to that described above. The work is matrixed within the SFPO and we still, in general, try to apply the Rules of Engagement. I also want to stress that we work very closely with DOT on a day-to-day basis - they are a sister government agency. If foreign applicants or foreign certificate holders wish to meet regarding a design review, DOT will be receptive to arranging such a meeting and we will be receptive to supporting DOT in any such request.

SUMMARY

In the Spent Fuel Project Office a standardized review protocol was developed to increase the efficiency, effectiveness and predictability of the certification of transportation package designs. The development of the protocol was made possible by the use of Standard Review Plans, an internal prioritization system, and a system of office-wide work scheduling.