

February 27, 2010

MEMORANDUM TO: Chairman Jaczko
Commissioner Klein
Commissioner Svinicki

FROM: R. W. Borchardt **/RA by Martin J. Virgilio Acting for/**
Executive Director for Operations

SUBJECT: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM M090625B
TO ADDRESS PROCESS IMPROVEMENTS FOR RESPONDING TO
THE DEPARTMENT OF TRANSPORTATION'S REVALIDATION
REQUESTS

The purpose of this memorandum is to respond to Staff Requirements Memorandum (SRM) M090625B. On June 25, 2009, Dr. Darrell R. Fisher, Ph.D., of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) briefed the Commission on current issues involving the availability and use-of medical isotopes. One of the issues raised was the lack of availability of certain medical isotopes based on a shortage of approved shipping packages. As an outcome of the briefing, in SRM M090625B dated July 1, 2009, the staff was requested to "provide recommendations to the Commission on possible improvements to NRC's process for responding to Department of Transportation's (DOT's) requests for technical recommendations with respect to transportation container designs that are certified by other countries under International Atomic Energy Agency transportation safety standards."

The DOT requires that the design of certain radioactive material transportation packages approved by foreign governments must be revalidated in order to be used for import and export shipments to or from the United States. Under a memorandum of understanding (published in the *Federal Register* at 44 FR 38,690, July 2, 1979), DOT may ask the NRC to review foreign package designs for compliance with International Atomic Energy Agency (IAEA) transportation safety requirements in TS-R-1, "Regulations for the Safe Transport of Radioactive Material." After the NRC conducts such a review, the NRC recommends whether DOT should revalidate a foreign package approval, and if necessary, provides a list of any conditions that should be applied to any imports to or exports from the U.S. which use these packages. The final decision on the revalidation of a foreign package design lies exclusively within DOT authority, and is documented through DOT's issuance of a Certificate of Competent Authority.

Since 2000, DOT has asked the NRC to perform 40 revalidation reviews and 34 resulted in the NRC making a positive recommendation for revalidation. Ten of the requests were for the approval of transportation package designs for medical isotopes. Most of the remaining requests were for the shipment of fresh fuel, spent fuel, large sources and radiography cameras. Of the six requests that did not result in a positive recommendation, the reviews

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were terminated due to deficiencies noted by the staff's reviews, including failure to provide sufficient information in response to requests for additional information (RAIs), such as RAIs related to drop test and shielding analyses. Three of the six were reviews for transportation of medical isotopes.

Subsequent to the Commission briefing, NRC staff met with Dr. Fisher on October 20, 2009, to further explore the ACMUI concerns with the shortage of approved package designs for the transportation of medical isotopes, and its overall effect on isotope availability. The staff informed Dr. Fisher that it was currently reviewing applications for two domestic package designs for medical isotopes, which, if ultimately certified, could help address the shortage of medical isotope transportation packages. The staff also communicated the processes and challenges involved in approving foreign packages for the import of medical isotopes into the United States.

The staff has undertaken several activities that will improve the effectiveness of the NRC's process for responding to DOT requests for reviews of foreign package designs. Specifically, the staff has developed a procedure, Spent Fuel Storage and Transportation (SFST) Office Instruction 20, "Review of Foreign-Approved Transportation Packages," dated February 18, 2010, (Agencywide Documents Management and Access System Accession No. ML100351272) that provides specific guidance to technical reviewers and project managers for applying IAEA transportation safety requirements (TS-R-1) to DOT revalidation requests. The NRC performed previous reviews relying primarily on guidance developed for the review of domestic package designs under the requirements of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." The adoption of a formal procedure is expected to improve the review process by clearly identifying specific IAEA requirements for each technical discipline, and by providing a more clear and simple format to document the results of the staff's safety evaluations. The procedure also serves as a knowledge management tool to help new staff identify the potential differences in the processes and safety requirements used in NRC certification of domestic package designs and the staff's review for DOT on revalidation of foreign-approved package designs.

Second, the staff has taken several actions to improve communication with DOT and foreign competent authorities during the review process. During a revalidation review, the NRC submits all RAIs to DOT for subsequent transmittal to the applicant. Responses to RAIs follow a similar process, with the applicant responding to NRC via DOT. In many cases, this process has proven to be time consuming and inefficient. Experience also shows that the review process can be further complicated by the need to translate applications into English and by time zone differences that make telephone calls more difficult to schedule. The staff plans to meet with DOT on March 3, 2010, to discuss suggested improvements in the communication process for revalidation reviews. The staff will continue to coordinate improvements with DOT in these periodic interface meetings.

In response to SRM M090625B, the staff has: 1) reviewed its processes for responding to requests from DOT for technical reviews of transportation package designs certified by foreign competent authorities; 2) met with Dr. Fisher; 3) issued a procedure for the review of the revalidation packages; and 4) has undertaken activities to improve communications with DOT and applicants. These activities will improve the effectiveness of the NRC's process for

The Commissioners

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responding to DOT requests for the review of foreign package designs and will be completed within currently budgeted resources. The Office of the General Counsel has reviewed this memorandum and has no legal objection.

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