



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

September 12, 2012

Docket No. 03036911
Control No. 576907

License No. 52-25430-03

David Rhoe
Radiation Safety Officer
CRMI
D-4 Calle Tivoli
Paseo de la Fuente
San Juan, PR 00926

SUBJECT: CRMI, VOIDANCE OF APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 576907

Dear Mr. Rhoe:

This is in reference to your application for an amendment to your material license dated February 4, 2012. Specifically, you requested an exemption from the requirements in 10 CFR 35.92 to allow disposal by decay-in-storage of radionuclides with a physical half life of up to 275 days. The request was submitted as a Technical Assistance Request to our Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Materials Safety and State Agreements for review.

The exemption request was evaluated against NUREG 1556, Volume 20, "Consolidated Guidance About Materials Licensees: Guidance About Administrative Licensing Procedures," Section 4.13 "Processing of Exemptions for Materials Licensees." The guidance states that requests for exemptions must be accompanied by:

- A description of the licensee-proposed exemption and the reason why it is needed;
- A description of specific compensatory safety measures that will provide a level of protection equivalent to the regulation for which the licensee-proposed exemption is being requested; and
- A discussion of the reasonable alternatives that have been considered by the licensee.

Although you provided a description of the proposed exemption (10CFR 35.92) and reasons why you believe the exemption is necessary, we believe that the reasons failed to sufficiently describe why an exemption is necessary. Also, your proposed compensatory measures were insufficient to determine that they would provide a level of protection equivalent to the regulation. Finally, a discussion of the reasonable alternatives that had been considered was not included in the request. Therefore, FSME has determined that they were unable to

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completely evaluate the subject exemption request. Based on the determination made by FSME, we have voided your application.

Decay-in-storage of sources with physical half lives exceeding 120 days, particularly cobalt-57, germanium-68, and gadolinium-153, may be a generic issue for medical licensees. If information is provided to FSME by many medical licensees that possess these sources, and disposal is not a viable option for managing these sources, an appropriate regulatory solution, such as rulemaking, will be evaluated.

Please note that the office of the Region I Division of Nuclear Materials Safety has moved. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

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