

May 26, 1998

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The Honorable Richard G. Lugar
United States Senate
Washington, DC 20510-1401

Dear Senator Lugar:

I am responding to your letter dated May 8, 1998, which conveyed reservations expressed by the Indiana Radiological Society, Inc., Chapter of the American College of Radiology about possible changes in the U.S. Nuclear Regulatory Commission's (NRC's) 10 CFR Part 35 regulations on medical use of byproduct material. Particular concerns were expressed about the training and experience requirements that would be applicable to personnel involved in diagnostic and therapeutic uses of unsealed byproduct material.

The NRC staff is scheduled to provide its recommendations on proposed revisions to Part 35 to the Commission in June 1998. The proposed rule is being developed using an increased public participation process that included public workshops; meetings with various medical professional societies (including the American College of Radiology); and the posting of a "strawman" rule text on the Internet for comments. The staff is carefully considering the comments received during these interactions, in preparing the proposal. After Commission approval, a proposed rule will be published in the Federal Register for public comment. We expect to hold additional public meetings during the comment period later this year.

The issue of training and experience has received the most comments during the development of the proposed rule. Viewpoints on this issue have varied. The Commission has received comments both supporting reduction in requirements affecting personnel in the diagnostic area, including the American College of Cardiology and the American Society of Nuclear Cardiologists, and favoring keeping the presently existing requirements. The staff draft, while reducing the number of hours required for certain medical modalities, also specified a focus on radiation safety and proposed that personnel competency be verified through an examination. This proposal appears to be in keeping with the direction the Commission provided to the staff namely, to develop a risk-informed, and where appropriate, a more performance-based rule and it addressed an objection often expressed by some commenters, that NRC requirements sometimes intruded into the practice of medicine.

The Commission will carefully consider the staff proposal in light of public comments such as yours when it is received. The results of that consideration will then be available for additional public comment and discussion.

Sincerely,

L. Joseph Callan
Executive Director
for Operations

EDO r/f IMNS RF
LJCallan
NMSS Dir. Off. r/f

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Thanks, Susan

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DOC NAME: A: Kenn.Pick *See Previous Concurrence LXL2 5/5/98 OP/PROOFED/MAY 18, 1998

OFFICE	RGB	Editor*	IMNS	NMSS Dir.	DEDR
NAME	DFlack	EKraus	DCool	CPaperello	HLThompson
DATE	5/18/98	4/15/98	5/18/98	5/19/98	5/21/98
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