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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 8, 1999

Charles W. Karpen, M.D., Ph.D.
Prairie Cardiovascular Consultants, Ltd.
503 North Maple
Effingham, IL 62401

Dear Dr. Karpen:

I am responding to your letter to Senator Richard Durbin, dated September 18,1998, in which you provided comments on proposed changes to the U.S. Nuclear Regulatory Commission's (NRC's) 10 CFR Part 35 regulations on medical use of byproduct material. In particular, you supported the proposed changes in the training and experience requirements for the use of byproduct material in diagnostic cardiology. In addition, you felt that it is too early to set any definitive training and experience requirements for physicians using intravascular brachytherapy, which you noted is an investigative procedure.

The Commission considers the overall issue of training and experience to be one of the most important issues addressed during the rulemaking. Adequately trained personnel are key to the safe use of radioactive material in medicine. Therefore, the Commission has proposed that the training and experience criteria for all users of radioactive material be risk-informed and focused on safety. At the same time, however, the Commission recognizes that the proposed rule must be adaptable to the many medical uses of byproduct material, including intravascular brachytherapy. This important issue, among others, was discussed at a Commission public meeting in June 1998. The Commission directed the staff to study the issue further and provide a basis for its current position.

On August 13, 1998, the proposed rulemaking was published in the Federal Register, for a 90-day public comment period. On November 18, 1998, in response to requests, the public comment period was reopened until December 16, 1998. A series of public meetings was also scheduled during the comment period. The meetings took place August 19-20, 1998, in San Francisco, California, and September 16 -17, 1998, in Kansas City, Missouri, and October 21-22, 1998 in Rockville, Maryland. Details of the public meetings were published in the Federal Register on July 24, 1998 (63 FR 39763). As noted in the Federal Register notice for these meetings, the Commission, through the facilitator for the meetings, invited participants who represent a broad spectrum of interests that may be affected by the proposed rulemaking. The American College of Cardiology (ACC) staff worked with the NRC staff to ensure that the

cardiologists' interests were represented at these meetings. Representatives of the ACC and the American Society of Nuclear Cardiology were invited to participate in the public meetings.

The Commission plans to carefully evaluate all the public comments in finalizing the training and experience requirements for all users of byproduct material.

Sincerely,

William D. Travers
Executive Director
for Operations

cc: The Honorable Richard J. Durbin