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The Honorable Richard A. Meserve, Chairman United States Nuclear Regulatory Commission One White Flint North 11555 Rockville Pike Rockville, MD 20852-2738

Dear Chairman Meserve:

The American College of Cardiology (ACC), a medical society that represents 25,000 cardiovascular specialists, has been an active participant in the revision process of 10 CFR Part 35,"Medical Use of Byproduct Material." We believe that the proposed changes will maintain safety, decrease the regulatory burden and increase public confidence in the regulation of radiation.

The cardiology community has a special interest in the process not only with respect to the use of diagnostic applications such as myocardial perfusion imaging, but also in the evolving field of intravascular radiation for restenosis prevention (intravascular brachytherapy). We believe that this modality has the potential to overcome the biggest problem associated with interventional cardiology procedures: tissue proliferation. As the attached table (Clinical Trials Using Intravascular Brachytherapy for the Inhibition of Restenosis) demonstrates, inavascular radiation for restenosis prevention can be performed in many different ways. We appreciate the fact that the Nuclear Regulatory Commission (NRC) and Part 35 Writing Group have recognized the emerging nature of intravascular radiation for restenosis prevention and acknowledged these changing circumstances in the draft final rule version of 10 CFR, Part 35.1000. Following adoption of a standard protocol, the NRC will address regulatory treatment of intravascular radiation for restenosis prevention.

Over the years, the ACC has been pleased to nominate cardiologists to serve on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). That representation has allowed the cardiology community to provide input into issues related to nuclear cardiology. The ACMUI has a broad composition that represents all the stakeholders in the medical use of byproduct materials. Dr. Manuel Cerqueira, the cardiology community's representative to the ACMUI, has been named to chair that panel. He is a recognized expert in nuclear cardiology and board certified in nuclear medicine. As chair, he will see that all viewpoints are represented fairly.

Dr. Cerqueira does not practice interventional cardiology or have expertise in the emerging technology of intravascular radiation for restenosis prevention. No one presently serving on the ACMUI has either the clinical and technical knowledge or experience sufficient to provide expertise on intravascular radiation. Given the significance of this emerging modality, the ACC believes it is appropriate for an interventional cardiologist to sit on the ACMUI.

An interventional cardiologist with expertise in intravascular radiation for restenois prevention will provide the committee with the unique perspective required to understand the complicated issues involved in the clinical management of patients in the cardiac catheterization

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Richard Meserve, NRC Chairman, December 20, 1999 page 2

laboratory where the studies will be performed. The addition of a representative from the interventional cardiology community would assure that the committee receive expert information from practitioners in the field. The cardiology community believes that the addition of an interventional cardiologist is critical to guaranteeing the safety of patients and users.

The cardiology community looks forward to a continuing dialogue with the NRC and the ACMUI on issues related to the medical uses of byproduct material in cardiology procedures. Addition of an interventional cardiologist to the ACMUI would assure that the advisory panel could provide the commissioners the most relevant information on new developments related to intravascular radiation for restenosis prevention.

Thank you for considering the views of the more than 25,000 ACC members.

Sincerely,

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Arthur Garson, Jr., M.D., M.P.H., F.A.C.C. President

Attachment

cc: Commissioner Nils J. Diaz Commissioner Greta Joy Dicus Commissioner Edward McGaffigan, Jr. Commissioner Jeffrey S. Merrifield Donald A. Cool, Ph.D. Catherine Haney George A. Beller, M.D., F.A.C.C. Manuel Cerqueira, M.D., F.A.C.C. Warrren K. Laskey, M.D., F.A.C.C. George W.Vetrovec, M.D., F.A.C.C. Lawrence J. Laslett, M.D., F.A.C.C.

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CLINICAL TRIALS USING INTRAVASCULAR BRACHYTHERAPY FOR THE INHIBITION OF RESTENOSIS ÷

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Study Name	Principle Investigator	of Trial	Inal Design	No. of Patients	Vascular Bed	Lesion Type	Treatment	isotope	Type of Radiation	Dose or Activity	Platform	Delivers Method	Contered Source	Results and States
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lilan		thase [Open lanel	<u>,</u>	Coronary	De novo restenosis	Radioactive stent (Palmaz-Schatz stent)	p	Beta	Activity 5.0 and 8.9 . uCi	Stent	Cuneter	Centered	Enrollment started January 1998

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