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FINAL REPLY:

Douglas P. Zipes
American College of Cardiology
Carl L. Tommaso
Society for Cardiac Angiography and Interventions

TO:

Chairman Meserve

FOR SIGNATURE OF : ** GRN ** CRC NO: 01-0185

EDO

DESC:

Comments on 10 CFR Part 35, "Medical Use of Byproduct Material"

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SPECIAL INSTRUCTIONS OR REMARKS:

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AUTHOR:	Douglas Zipes		
AFFILIATION:	ACC		
ADDRESSEE:	CHRM Richard Meserve		
SUBJECT:	Concerns 10 CFR Part 35, "Medical Use of Byproduct Material"		
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March 28, 2001

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, and the Society for Cardiac Angiography and Interventions (SCA&I), a medical society that represents 2000 interventional cardiologists, have been active in the revision process of 10 CFR Part 35, "Medical Use of Byproduct Material." We believe the proposed changes will maintain safety, decrease 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 the interventional cardiology procedures: tissue proliferation. Intravascular radiation for restenosis prevention can be performed in many ways. We believe that current iterations of intravascular radiation are first generation tools and significant evolution of this technology will occur. We appreciate the fact the Nuclear Regulatory Commission (NRC) and Part 35 Writing Group recognizes the emerging nature of intravascular radiation for restenosis prevention.

It is important that cardiologists who take responsibility for procedures that use such sources have an appropriate knowledge base. The ACC and the SCA&I are committed to developing the curriculum and training standards for sealed sources in the vascular system. Our recommendations will include the number of cases for requisite clinical experience, amount of didactic training, reasonable clinical experience and a pathway for receiving that experience. We look forward to sharing these recommendations with the NRC once the document is complete and our Board of Trustees has approved it. In our experience, this will probably take at least 18 months to complete. Given the evolving nature of the technology, this will allow for the incorporation of new research and experience in the curriculum and training standards. In the meantime, the team approach required by the NRC and the FDA should continue.

The ACC and SCA&I are committed to ensuring the safety of patients and physicians using byproduct materials and believe our training recommendations will help to ensure that people using this technology are appropriately trained.

Sincerely,

Douglas P. Zipes, M.D., F.A.C.C.
President, ACC

Carl L. Tommaso, M.D., F.S.C.A.I., F.A.C.C.
President, SCA&I

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