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

MAY 30 1997

MEMORANDUM TO: Cassandra Frazier, Acting Chief
Nuclear Materials Safety Branch
Division of Nuclear Materials Safety, RIII

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED APRIL 4, 1997, (CONTROL NUMBER 302384) REGARDING THE CLEVELAND CLINIC FOUNDATION, LICENSE NO. 34-00466-01

I am responding to your technical assistance request (TAR) (attached) dated April 4, 1997, regarding the request by the Cleveland Clinic Foundation for authorization to use phosphorus-32 (P-32) for intravascular use as a cardiac stent. We have reviewed the TAR and have determined that the ion-implanted stent is not a sealed brachytherapy source as defined in 10 CFR 35.2 and authorized under 10 CFR 35.400, *Use of sources for brachytherapy*, nor does it fit into the uses of unsealed byproduct material for therapy as authorized under 10 CFR 35.300, *Use of unsealed byproduct material for therapeutic administration*. Therefore, neither an exemption from the provisions of 10 CFR 35.400 nor an authorization for use under 10 CFR 35.300 is appropriate.

NRC does not intend to prevent the research allowed under the Investigational Device Exemption (IDE) granted by the U.S. Food and Drug Administration, in the absence of applicable medical use regulations. Therefore, after review of the information submitted, I suggest that the region grant the licensee's request for authorization to use the P-32 stents under the IDE by using the following license condition:

> "As requested in the licensee's letter dated March 24, 1997, the licensee is authorized to order, receive, and implant phosphorus-32 (P-32) ion-implanted Palmaz-Schatz Balloon-Expandable IsoStent for use under the Investigational Device Exemption (IDE) of the device, authorized by the U.S. Food and Drug Administration (FDA) in the FDA letter to IsoStent, dated May 28, 1996, and subsequent phases of the IDE process associated with the device which are approved by the FDA. The devices are to be used by, or under the supervision of only those physicians who: 1) are identified in the licensee's letter requesting this authorization; 2) are subsequently authorized by the licensee pursuant to 10 CFR 35.13; or 3) are subsequently authorized, by license amendment, pursuant to 10 CFR 35.930(b) for use of 10 CFR 35.300 materials."

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In addition, it is our understanding that the FDA considers use of this device for treatment to prevent restenosis as a "significant risk" procedure; therefore, the granting of the IDE for these trials represents a detailed review of the radioactive stent, the associated implantation procedures, and research protocol. Since the research is conducted under an FDA IDE, and the FDA has adopted the Federal Policy for the Protection of Human Subjects, no additional information is needed from the licensee regarding compliance with Section 35.6, *Provisions for research involving human subjects*. This approach to human research will satisfy the informed consent and approval provisions of Section 35.6.

Per my recent telephone conversation with Patty Pelke, the staff is unable to grant the licensee's request for alternative authorized user criteria of 10 CFR 35.940 at this time. However, the staff plans to further explore this, and other criteria, relating to the authorization for use of the stents with the Office of General Counsel in the near future. For the present we are following the president established with the Borgess TAR response.

Attachment: RIII TAR dtd 4/4/97