



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET SW SUITE 23T85
ATLANTA, GEORGIA 30303-8931

September 6, 2000

Princeton Radiation Oncology Center
ATTN: Greg Madison, M.S.
Medical Physicist
210 New Hope Rd.
Princeton, West Virginia 24740

SUBJECT: REQUEST FOR CLARIFICATION OF THE REQUIREMENTS OF 10 CFR
35.940 AND THE USE OF IR-192 FOR INTRAVASCULAR BRACHYTHERAPY

Dear Mr. Madison:

This refers to your letter dated August 8, 2000, in which you requested clarification of NRC's position on whether a diagnostic radiologist can become an authorized user for an iridium 192 (Ir-192) intravascular brachytherapy device, pursuant to the treatment of restenosis following an angioplasty procedure.

In accordance with 10 CFR 35.940, licensees shall require that authorized users of brachytherapy sources listed under 10 CFR 35.400, be certified in any of the specific certifications by the institutions listed under 10 CFR 35.940(a) or be qualified based on the requirements specified in 10 CFR 35.940(b). To achieve this process, licensees must ensure that they comply with the requirements of 10 CFR 35.13 (license amendments) and 10 CFR 35.14 (notifications).

However, use of Ir-192 for the treatment of restenosis is not listed under 10 CFR 35.400, and must be reviewed on a case by case basis. At the present time, only institutions participating in the Food and Drug Administration (FDA) approved protocol for the clinical trials are authorized to use such devices, provided that some basic licensing information is supplied to the NRC. For your convenience, I have enclosed a list of the basic licensing information that will be required to process a request of this kind. Please note that only physicians authorized under 10 CFR 35.940 will be authorized as users of the Ir-192 intravascular brachytherapy device.

If you have any further questions, please call me at (404) 562-4736 or 800-577-8510, or contact me via Internet mail to: jxd2@nrc.gov.

Sincerely,

/RA/

José M. Díaz Vélez, Health Physicist
Division of Nuclear Materials Safety

Enclosure: As stated

OFFICE	RII:DNMS						
SIGNATURE	/RA/						
NAME	JHenson						
DATE	9/6/2000	9/ /2000	9/ /2000	9/ /2000	9/ /2000	9/ /2000	9/ /2000
E-MAIL COPY?	YES NO						

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INTRAVASCULAR BRACHYTHERAPY

Information needed from medical use licensees of limited scope pursuing the review of applications for participation in intravascular brachytherapy human research trials for the prevention of restenosis. (All six items must be met.)

1. The radiation source(s) and/or device(s) used in the research must have undergone an appropriate sealed source and/or device safety review(s) and be approved by the NRC or an Agreement State for intravascular brachytherapy;
2. The conditions allowing research involving human subjects as authorized under 10 CFR 35.6, "Provisions for research involving human subjects," are satisfied. For high risk procedures such as intravascular brachytherapy this is satisfied through participation in an U.S. Food and Drug Administration (FDA) approved Investigative Device Exemption (IDE) and identification of the assigned IDE number in the licensing request;
3. Only those physicians authorized to use 35.400 byproduct materials and/or meeting training and experience requirements in 10 CFR 35.940 can be designated as authorized users for this procedure; and,
4. Radiation safety commitments must be contained in a document suitable for public release. The radiation safety commitments must include, but are not limited to:
 - a. The treatment team composition, which must include an interventional cardiologist, radiation oncologist, radiation physicist, and radiation safety officer;
 - b. Pregnancy test required for all women participants;
 - c. Source ribbons not to be used after the "Use By Date";
 - d. Independent verification of the source seed strength must be performed by the licensee;
 - e. Only the Radiation Safety Officer and radiation oncologist are to be present in the catheterization laboratory during placement and removal of the sources;
 - f. Radiation survey of the patient required after completion of treatment; and
 - g. Emergency source removal procedures for removal of stuck or detached sources; and
5. NRC must, to carry out its regulatory responsibilities, have access to confidential information pertaining to medical use, device performance, and radiation safety concerns with the device during licensing activities, routine, and reactive inspections; and,
6. An exemption from the requirements of 10 CFR 35.400(d) is granted to authorize the use of Ir-192 seed for intravascular brachytherapy.