Petition for Review

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION, Petitioner,	
v.	No. 01-1162
U.S. NUCLEAR REGULATORY COMMISSION and UNITED STATES OF AMERICA, Respondents.	

PETITION FOR REVIEW

Pursuant to Section 189b of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2239(b), and 28 U.S.C §§ 2341-2349, the Novoste Corporation hereby petitions this Court to review the final rule of the U.S. Nuclear Regulatory Commission ("NRC"), entitled: Generic Instructions for Licensing the Novoste Betacath System for Intravascular Brachytherapy Treatments in Response to a Technical Assistance Request from Region IV," adopted and issued on February 5, 2001 (a true and correct copy of this rule is attached as Exhibit 1).

Respectfully submitted,

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Exhibit 1.

Generic Use
February 5, 2001

MEMORANDUM TO: George C. Pangburn, Director
Division of Nuclear Materials Safety, RI

Douglas M. Collins, Director
Division of Nuclear Materials Safety, RII

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety, RIII

Dwight D. Chamberlain, Director
Division of Nuclear Materials Safety, RIV

FROM: Donald A. Cool, Director/RA/
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: GENERIC INSTRUCTIONS FOR LICENSING THE NOVOSTE BETACATH SYSTEM FOR INTRAVASCULAR BRACHYTHERAPY TREATMENTS IN RESPONSE TO A TECHNICAL ASSISTANCE REQUEST FROM REGION IV

The Novoste BetaCath System was recently approved by the Food and Drug Administration (FDA), under their Pre-Market Approval (PMA) process, for the routine use in the treatment of in-stent restenosis in coronary arteries. This system uses Sr-90 sealed brachytherapy sources for intravascular brachytherapy to inhibit in-stent restenosis in coronary arteries. As such, this system meets our definition for a high-dose-rate remote afterloading system, but uses pure beta emitting radionuclide sources. This generic response provides guidance requested by the Region IV Technical Assistance Request, dated September 30, 1999, for the pending licensing actions for Department of Veterans Affairs, San Antonio, Texas.

Licensing Considerations

A. Exemptions from 10 CFR Part 35

1. To authorize NRC medical use licensees of limited specific scope to use the FDA-approved Novoste Beta-Cath System for the treatment of in-stent restenosis of coronary arteries, it is necessary to grant an exemption from the use requirements established in 10 CFR 35.400. 10 CFR 35.400 does not list the treatment of in-stent restenosis of coronary arteries as one of the approved uses for strontium-90 seed

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trains. Such an exemption does not relieve the licensee from compliance with the other requirements of 10 CFR Part 35, including Subpart G requirements and all other applicable radiation safety commitments. This exemption may be granted persuant to 10 CFR 35.19, "Specifications" based on a finding that it is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. The following license condition, as item 9, shall be used on the license :

> "Notwithstanding the requirements of 10 CFR 35.400, one source train to be used for the treatment of coronary arteries for in-stent restenosis lesions (treatable with 20 millimeter balloon), using the Food and Drug Administration's approved (under FDA's PMA P9000018) Novoste Beta-Cath System Model A1732 (30 millimeter source train), and one source train in a shipping container for source train replacement."

2. To authorize use of the Novoste Beta-Cath System for the treatment of in-stent restenosis of coronary arteries, it is necessary to specify the prescribed dose being administered. This is because this treatment system is classified as a high-dose-rate remote afterloader. Thus, the licensee shall specify the radioisotope, treatment site, and total dose, as set forth in item (5) under the definitions for *written directive* contained in 10 CFR 35.2 for high dose-rate-remote afterloading brachytherapy.

B. Training and Experience

1. Only those physicians authorized to use 35.400 byproduct materials and meeting training and experience requirements in 10 CFR 35.940 can be designated as authorized users for this procedure; and,

2. Prior to beginning patient treatments, all personnel involved in the procedure must satisfactorily complete the vendor's training program, which must include all relevant radiation safety and emergency procedures specific to this treatment system.

C. Specific radiation safety issues

1. Novoste has recently revised its SS&D registration from 3.5 mCi to 5.0 mCi sources. Our understanding is that the FDA has not approved these higher activity seeds for clinical use at this time. Therefore, Item 8, on the license authorization for the Novoste Beta-Cath System, should be as follows:

> "No single source to exceed 3.5 millicuries, in a 12 sources per device (Model A1732); two source trains total (84 millicuries total activity);"

2. The treatment team composition must include individuals qualified to function as an interventional cardiologist, authorized user, and a medical physicist;

3. The licensee must commit to requiring the physical presence of the treatment team during the treatment of patients with this system;

4. The licensee must commit to using the Arrow Introducer sheath (or equivalent device)

for all patient treatments to prevent source transport blockages which could lead to misadministrations;

5. The licensee must commit to use of the Novoste dual syringe accessory to avoid misadministrations due to the premature depletion of the source transport fluid;

6. Independent measurement of the source strength must be performed by the licensee's medical physicist prior to the first patient treatment. All dose calculations and treatment plan reviews are to be conducted in accordance with the licensee's Quality Management Program;

7. In accordance with current licensing guidance for high-dose-rate brachytherapy sources, the licensee must commit to preparing written emergency procedures for removal of stuck or detached sources, including provisions for surgical intervention, and appropriate emergency equipment. (Such equipment would include at least a shielded emergency storage container and long handled forceps, that are immediately available during treatment);

8. Licensees must review their Quality Management Program and make any modification necessary to accommodate the addition of this new protocol to their program;

9. The sources shall be leak tested at intervals not to exceed six months;

10. Licensee must commit to locked storage of the lead-lined storage container for the device in a secure location;

11. There must be a commitment or license condition that the device shall be inspected and serviced at intervals established by the manufacturer, and that maintenance and repair shall be performed only by the manufacturer or persons specifically authorized by the Commission or an Agreement State to perform such services;

12. The Regions should include a reminder in the cover letter authorizing the license amendment that there have been numerous instances where source train separations have occurred during patient treatments, and that such occurrences should be evaluated as possible misadministrations; and,

13. The radionuclide used in these sources is a pure beta emitter. Assuming the licensee avoids placing these sources in close proximity to high Z materials, there is no necessity for the licensee to provide calculations and/or confirmatory measurements to demonstrate that 10 CFR Part 20 exposure limits for restricted and unrestricted areas are met.

Summary of Applicant Specific Review Findings:

Based of a review of the amendment application of the Department of Veterans Affairs, Audie I. Murphy Memorial Veterans Hospital Division, San Antonio, Texas, dated June 25, 1999, for authorization to use the Novoste Beta-Cath System for treatment of in-stent restenosis against

the criteria set forth above, the following deficiencies or need for additional information are noted:

The licensee's request for authorization for to use the Novoste Beta-Cath system pre-dates both the SS&D registration of the device and FDA approval for routine clinical use. Now that the Novoste Beta-Cath System has been approved by the FDA for routine clinical use, it is assumed that the licensee would now like to be authorized for routine use of the Novoste Beta-Cath System. For routine clinical use, the guidance in this response to their Technical Assistance Request (TAR) can be used. If the licensee is seeking to have its license amended for participation in an ongoing clinical trial, the existence of the SS&D registration can be used to consider this request pending a re-submission of its previous request amended to reflect the approved SS&D registration for the device and sources.

In reviewing the licensee's amendment request in terms of routine use authorization, deficiencies were found with respect to the information or commitments needed to satisfy licensing considerations set forth in items A2, B2, C1, C3, C4, C5, C6, C7, C8, C9, C10, and C11. In some cases the applicant did not address the item, and in others the response was not adequate. For example, no mention of possible surgical intervention was made in the licensee's commitment to written emergency procedures. The licensee will need to properly address these noted deficiencies before it can be authorized to conduct the requested therapy.

Attachment: TAR dtd 9/30/99

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*See previous concurrence
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CERTIFICATE OF SERVICE

I hereby certify that I have served on this 6 day of April, 2001, a copy of a Petition for Review of a Rule of the U.S. Nuclear Regulatory Commission by first-class mail, postage prepaid, upon the following:

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