June 12, 2001

LeBoeuf, Lamb, Greene & MacRae
Attn: Mr. Martin G. Malsch, Esq.
1875 Connecticut Avenue, NW
Washington, DC 20009-5728

Dear Mr. Malsch:

I am responding to your letters dated February 12 and April 27, 2001, which provide comments on NRC staff licensing guidance applicable to the Beta-Cath System, manufactured by your client, Novoste Corporation. Your letters requested reconsideration of certain features of that guidance. We share Novoste's interest in protecting the public health and safety of the public and patients in the use of the Beta-Cath System.

Over the past few months, we have considered the Novoste comments, as well as comments received from licensees and other stakeholders. We have revised our internal licensing guidance, which is available to the public, and a copy is enclosed (Enclosure 1). Please note that this revised guidance supersedes previous guidance dated January 26 and February 5, 2001.

With respect to the comments in your February 12 and April 27, 2001, letters, our responses are provided in Enclosure 2.

If you have further comments or questions, please contact me or Dr. Robert Ayres at 301-415-5746.

Sincerely,

/RA/

John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Revised Licensing Guidance
2. NRC Staff Responses to Novoste Comments

June 12, 2001

LeBoeuf, Lamb, Greene & MacRae
Attn: Mr. Martin G. Malsch
1875 Connecticut Avenue, NW
Washington, DC 20009-5728

Dear Mr. Malsch:

I am responding to your letters dated February 12 and April 27, 2001, which provide comments on NRC staff licensing guidance applicable to the Beta-Cath System, manufactured by your client, Novoste Corporation. Your letters requested reconsideration of certain features of that guidance. We share Novoste's interest in protecting the public health and safety of the public and patients in the use of the Beta-Cath System.

Over the past few months, we have considered the Novoste comments, as well as comments received from licensees and other stakeholders. We have revised our internal licensing guidance, which is available to the public, and a copy is enclosed (Enclosure 1). Please note that this revised guidance supersedes previous guidance dated January 26 and February 5, 2001.

With respect to the comments in your February 12 and April 27, 2001, letters, our responses are provided in Enclosure 2.

If you have further comments or questions, please contact me or Dr. Robert Ayres at 301-415-5746.

Sincerely,

/RA/

John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Licensing Guidance
2. NRC Staff Responses to Novoste Comments

Distribution:
Ayres
D.Howe
Sturz

g:\malschltr.wpd

OFFICE	NMSS/IMNS	OGC			
NAME	JHickey	STreby			
DATE	05/24/ 01	06/5/01			

OFFICIAL RECORD

ENCLOSURE 2

NRC STAFF RESPONSES TO NOVOSTE COMMENTS IN LETTER DATED 2/12/01

NRC Contacts: John Hickey and Robert Ayres, 301-415-5746

1. Limitation to 3.5 Millicurie Sources

NRC Staff Response: The FDA premarket approval covers source trains containing sources up to 4.0 millicuries mean activity, and 48 millicuries total. Mr. Malsch's letter dated April 27, 2001, suggests allowance for uncertainty when the licensee verifies the dose rate and associated source activity. Accordingly, we have revised the guidance to specify a maximum mean source activity of 4.2 millicuries, and 51 millicuries total per source train.

In this case, applicants are requesting authorization to possess and use the Novoste device which has been approved under an FDA Pre-Market Approval (PMA), and we want to assure that the maximum amount of radioactive material in the device is accurately characterized for licensing purposes.

2. Authorized Use Condition

NRC Staff Response: We agree that the authorized use need not be limited to FDA-approved uses, and have revised our guidance to authorize any intravascular brachytherapy (IVB) use.

3. Verifying Source Strength

NRC Staff Response: The staff believes that, due to the high dose rates delivered by the Novoste device, independent source measurements are a necessary safety requirement. This is consistent with past practice of requiring independent source measurements for other high dose-rate devices, including teletherapy units and remote afterloaders.

4. and 5. Use of Introducer Sheath and Dual Syringe System

NRC Staff Response: The staff believes that use of these accessories will further protect the radiation safety of patients and reduce the risk of misadministrations. This is based on reports of actual events which could have been prevented by the use of the accessories. However, we have revised the guidance to provide flexibility if the use of the accessories is contraindicated for an individual patient.

6. Characterization of the Novoste Device as a Remote Afterloader

NRC Staff Response: The guidance developed by the staff is based on the fact that the Novoste device delivers high dose rates (greater than 1200 rads per hour), and is not based on whether the device meets the proposed definitions of a manual brachytherapy device or high dose-rate remote afterloader. References which state that the Novoste device is a remote afterloader have been deleted from the guidance.

7. Training and Education Requirements

NRC Staff Response: Intravascular brachytherapy is a relatively new technology, involving high dose rates, and we believe it is premature to consider substantially reduced training requirements for authorized users, as compared to 10 CFR 35.940, which Novoste has proposed.

Intravascular brachytherapy (IVB) is not listed in 35.400 as an authorized use. Therefore, exemptions from this provision of Part 35, "Medical Use of Byproduct Material", are being issued pursuant to 10 CFR 35.19. The exemptions are based on findings that the exemptions are authorized by law, and will not endanger life or property or the common defense and security, subject to certain conditions, as described in the guidance. The purpose of these conditions is to assure that IVB procedures are conducted in a manner that protects the health and safety of the public and patients. Accordingly, we have specified that applicants make certain commitments, including a commitment that authorized users meet the brachytherapy training requirements specified in 10 CFR 35.940.

Note, however, that an interventional cardiologist or other physician may conduct the IVB procedures under the supervision of a qualified authorized user. Such interventional physicians need not meet the training requirements in 10 CFR 35.940.

Furthermore, we do not agree with the Novoste comment that these training requirements are inconsistent with the Georgia Sealed Source and Device Registry certificate. We assume that Novoste is referring to that statement on page 5 of the Georgia certificate, which states, "Training in the proper use and handling of the Novoste Beta-Cath System shall be provided by the manufacturer." The NRC staff views this requirement to be in addition to, not in lieu of, training that is normally required for medical brachytherapy procedures; that is, training required by 10 CFR 940.

8. Reference to Source Trains and Shipping Containers

NRC Staff Response: As suggested by Novoste, the guidance has been revised to provide more clear wording. The reference to "replacement" source trains is deleted, and the authorization will be based on the number of source trains requested by the applicant.