

**June 12, 2001
Generic Use
Publicly Available**

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: REVISED GUIDANCE FOR LICENSING INTRAVASCULAR
BRACHYTHERAPY PROCEDURES

This memorandum provides revised guidance for licensing intravascular brachytherapy (IVB) procedures. It supersedes my memorandums dated January 26 and February 5, 2001.

The attached guidance should be used in reviewing medical use applications requesting authorizations for IVB procedures. The key changes from the previous guidance include: (1) licensees are not limited to procedures involving coronary arteries, (2) physical presence requirements have been modified, and (3) the source strength authorization for the Novoste device has been increased.

Attachment: Revised IVB Licensing Guidance

CONTACTS: John Hickey or Robert Ayres, NMSS/MSIB
(301) 415-5746

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ADAMS Accession Number: ML011630113

OFC	MSIB		MSIB		MSIB		OGC - no legal objection		IMNS
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DATE	6/7/2001		6/7/2001		5/24/2001		6/5/2001		6/12/2001

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Attachment

(Revised 6/12/01)
Guidance to NRC Regions for Licensing
Cordis and Novoste Intravascular Brachytherapy Systems

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

General approach: License as a brachytherapy procedure pursuant to an exemption from 35.400, "Use of sources for brachytherapy". Intravascular brachytherapy (IVB) is not listed in 35.400 as an authorized use. Therefore, an exemption from this provision of Part 35, "Medical Use of Byproduct Material", is being issued by license condition, pursuant to 10 CFR 35.19. This exemption is based on a finding that it is authorized by law, and will not endanger life or property or the common defense and security, subject to the additional license conditions discussed below.

The exemption does not relieve the licensee from compliance with the other requirements of 10 CFR Part 35. In particular, 10 CFR 35.32, "Quality management program", requires licensees to establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. [Note: "Source stepping" is permitted, if the licensee establishes appropriate procedures in accordance with 10 CFR 35.32(a). Source stepping procedures are not covered by the manufacturers' instructions, so the licensee could not merely follow the manufacturer's instructions if the licensee chooses to conduct source stepping.]

Note that, because IVB is a new technology, and the devices deliver high dose rates (greater than 1200 rads per hour), certain training and physical presence guidance is included.

The authorized use is not restricted to procedures reviewed and approved by FDA as part of the FDA pre-market approval (PMA). Note that 35.7 states that nothing in Part 35 relieves a licensee from complying with applicable FDA, other Federal, and State requirements.

A. IVB Guidance for Limited Specific Use Medical Licensees

1. Conditions for both Cordis and Novoste Systems

–Commit that authorized users will meet the training and experience requirements in 10CFR 35.940, "Training for use of brachytherapy sources".

–Commit that the authorized user, interventional cardiologist/physician, and medical physicist will receive the vendor training for use of the device.

–Commitment or license condition as follows: Procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and medical physicist prior to initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the medical physicist.

–Commit that prior to treatment, the written directive will specify treatment site, the radionuclide, and dose.

–Commit to independent measurement of source output by the medical physicist, prior to the first patient treatment.

–Commit to developing, implementing, and maintaining written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

2. Conditions for the Cordis System

–Commit that source trains will not be used after the “use by” date.

–Applicant should submit calculations and/or measurements demonstrating compliance with Part 20 requirements, and guidance on the use of portable shields, as appropriate.

–License condition 8 should read (for each ribbon set requested): No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10, or 14 seeds per ribbon, 1.1 curies total (per set)

–License condition 9 should read: Notwithstanding the requirements of 10 CFR 35.400, for use in the Cordis Checkmate Catheter System for intravascular brachytherapy.

--Cover letter should state that the licensee’s Quality Management Program should be revised as appropriate.

3. Conditions for the Novoste System

–In order to protect the radiation safety of patients and to reduce the risk of misadministrations, commit to use of an introducer sheath, unless such use is contraindicated for an individual patient.

–In order to protect the radiation safety of patients and to reduce the risk of misadministrations, commit to use of a dual syringe system, unless such use is contraindicated for an individual patient.

–Commit to locked storage of the storage container in a secure location.

–Commitment or license condition that the device shall be inspected and serviced at intervals recommended by the manufacturer, and that maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

–License condition 8 should state: 12 sources per train, not to exceed 4.2 millicuries mean activity per source, 51 millicuries total. (for each source train requested by applicant)

Note: As of May 15, 2001, the FDA Pre-Market Approval (PMA) allows Novoste to distribute Model A1732 devices with source trains up to 48 millicuries, with a maximum mean source activity of 4.0 millicuries per source. The license authorization of 4.2 millicuries mean source activity and 51 millicuries total allows for measurement variations between Novoste and the licensee users.

–License condition 9 should read: Notwithstanding the requirements of 10 CFR 35.400, for use in Novoste Beta-Cath System Model A1732 devices for intravascular brachytherapy.

–Cover letter should state that: (1) the licensee’s Quality Management Program should be revised as appropriate, and (2) source separations during treatment should be evaluated as possible misadministrations.

–Note: Shielding calculations are not necessary for areas outside the treatment room and device storage areas, because Sr-90 is a beta emitter.

B. IVB Guidance for Medical Broad Licensees

–If the medical broad license already covers possession of the radioactive material, then no amendment is required to authorize intravascular brachytherapy. Note that condition 9 of broad medical licenses does not limit brachytherapy uses to those listed in 35.400.

–If the medical broad license possession limits do not cover the radioactive material, then the possession limits can be amended accordingly by the licensing staff.