Publicly Available

Draft Guidance to NRC Regions for Licensing Cordis and Novoste Intravascular Brachytherapy Systems

February 2, 2001

! Requirements and reviewer information applicable to **both** systems:

" Requirements

- Commit to limit the use of these systems to treat in-stent restenosis of coronary arteries.

- Commit to using a written directive that shall specify the radioisotope, treatment site, and total dose, as set forth in item (5) under the definition for *written directive* in10 CFR 35.2, in lieu of the requirements in item (6) for manual brachytherapy

- Required T&E for the authorized user(s) shall be that set forth in 10 CFR 35.940 for use of 35.400 materials

- Commit to vendor training for the treatment team

- Treatment team composition shall consist of, at a minimum, an interventional cardiologist, authorized user, and a medical physicist

- Physical presence of the treatment team required during all treatments

- Independent verification of the source strength by the licensee

- Commit to preparing written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures

- The sources shall be leak tested at intervals not to exceed six months

" Reviewer Information

- Licensees need to review their Quality Management Program and revise as appropriate

! Unique requirements and reviewer information for **Cordis Checkmate System**:

" Requirements

- Commit not to use source trains after the “use by” date.

- License condition 8, shall read:

> “No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10, or 14 seeds per ribbon; two ribbon sets (2.1 curies total)”

- License condition 9 shall read:

> “Notwithstanding the requirements of 10 CFR 35.400, one ribbon set to be used in the treatment of coronary arteries for in-stent restenosis using the Food and Drug Administration’s approved (under FDA-approved PMA P990036) Cordis Checkmate Catheter System, and one ribbon set in a shipping container for ribbon set replacement.”

" Reviewer information

Licensees need to submit calculations and/or measurements demonstrating compliance with Part 20 requirements and guidance on the use of portable shields, if they are required to comply with Part 20 requirements.

! Unique requirements and reviewer information for the **Novoste BetaCath System**:

" Requirements

- Commit to the use of the Arrow introducer sheath (or equivalent) to prevent source transport blockages during treatment, which could lead to misadministrations.

- Commit to the use of the dual syringe system to avoid misadministrations due to premature depletion of the source transport fluid

- Commit to locked storage of the lead-lined storage container in a secure location, to meet Part 20 requirements

- License condition 8 shall read:

  "No single source to exceed 3.5 mCi; not to exceed 12 sources per source train; two source trains; (84 millicuries total)".

  (Note: Novoste has a new SS&D registration for 5 mCi seeds, but it is NRC's understanding that these increased seed activities have not yet been approved by FDA.)

- License condition 9 shall read:

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

- Commitment or license condition that the device shall be inspected and service 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

" Reviewer Information

- Radiation shielding calculations to demonstrate compliance with Part 20 requirements are not necessary for areas outside the treatment room and device storage areas

- Reminder to licensees in the amendment cover letter that instances where source train separations occur during treatment should be evaluated as possible misadministrations