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* in 10 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