February 2, 2011

Criteria to Start or Restart Prostate Brachytherapy Programs

Facility Steps for Start

1. Prior to initiating a program for low-dose rate prostate brachytherapy, the facility must, in consultation with NHPP and the Director, National Radiation Oncology Program, evaluate inspection results, event reports, best practices, and standard procedures related to VHA facilities with a prostate brachytherapy program. This review is required to establish a facility-level perspective on regulatory compliance requirements, a focus to a safety culture, and oversight by the Radiation Safety Committee and executive management. The documents for review are available at this address on the NHPP Intranet Web site:

    http://nhpp.med.va.gov/radonc.asp

2. The facility must have established a team for prostate brachytherapy procedures, which anticipates performing a minimum of 24 cases per year. The prostate brachytherapy team will include at least the following: a physician authorized user, a radiation oncologist (who may also be the authorized user), a medical physicist, and the Radiation Safety Officer. Also, a urologist should either be part of the team or available for clinical consultation, as needed.

3. The facility must have acquired, completed acceptance tests of, and established quality control programs for all equipment required for prostate brachytherapy procedures. These acceptance and quality control tests must evaluate image transfer among the various imaging modalities and the treatment planning system and be formally documented. A back-up plan for image transfer for post treatment images must be established and tested for circumstances that might result in a loss of connectivity. The quality control program will include interpatient processing of the ultrasound probe.

4. The facility must have written guidelines or criteria for patient selection, pre-implant treatment plans, preparation of written directives, post-implant dose assessment, clinical peer review, and VHA standard procedures.

5. The facility must have written guidelines or criteria for the initial and periodic training for physician authorized users, medical physicists, participating urologists, dosimetrists, and the Radiation Safety Officer and staff. The guidelines must include explicit training requirements for identifying and reporting medical events with delineation of individual roles and responsibilities.

6. The facility must have written procedures for, and must complete, at least quarterly self-audits using the NHPP audit checklist or an alternate self-audit guideline which substantially conforms to the NHPP checklist.

7. If approved for patient treatments, the facility must have an onsite proctor for the first five patient treatments. The proctor must be approved by the Director, National Radiation Oncology Program. The Director, National Radiation Oncology Program, may waive this requirement if the facility will begin the program with an experienced implanting physician. (In some programs, the implanting physician is sometimes a urologist instead of the authorized user physician.)

8. The facility must submit post-implant dosimetry of the first 10 consecutive patient treatments to an external reviewer approved by the Director, National Radiation Oncology Program.

9. The facility must submit a written request to NHPP to start a prostate brachytherapy program and must receive written approval in a permit amendment before beginning implants.

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NHPP Steps for Start

1. NHPP must complete a site visit or inspection to confirm that VHA standard procedures have been developed and implemented. NHPP will use the NHPP audit checklist to evaluate readiness to start and confirm the following:

a. Initial and periodic training for physician authorized users, participating urologists, medical physicists, dosimetrists, and Radiation Safety Officers and staff.

b. Training in medical events to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event.

c. Methods and procedures to verify needle and seed placement during prostate brachytherapy procedures, including appropriate imaging modality quality control.

d. Preparation and completion of written directives.

e. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis, including appropriate treatment planning system and imaging modality quality control.

2. NHPP must confirm the facility has established a safety culture focus, willingness to stop work if regulatory compliance cannot be determined or achieved, and Radiation Safety Committee and executive management oversight.

3. NHPP must recommend to the National Radiation Safety Committee (NRSC) whether the facility should be approved to start patient treatments. NRSC with concurrence by Director, National Radiation Oncology Program, must recommend to senior leadership whether start should be approved. Senior leadership must approve or disapprove start.

4. NHPP will provide continuing oversight through consultation, audits, and onsite inspections. As a minimum, an onsite inspection will be performed of each new prostate brachytherapy program within 6 months of the first implant procedure.

Additional Steps for Restart

1. In addition to the start criteria above, the facility must have resolved any pending issues related to retrospective review of patient treatments, NRC inspections, and NHPP inspections.

2. Director, National Radiation Oncology Program, may upon request waive the requirements for a proctor for new cases if the facility ceased implants for a reason other than poor quality implants.