APPENDIX B

Reviewing Licensees' Implementation of Procedures for Permanent Implant Brachytherapy Administrations

If the inspector identifies a weakness in the licensee's radiation protection program during the course of an inspection, he/she should focus on determining whether the weakness resulted in a safety issue.

Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program applicable to their permanent implant brachytherapy program. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the items listed below, the inspection effort expended in reviewing the permanent implant brachytherapy program will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given item, the inspector should conduct a more thorough review of that aspect of the licensee's program and consider expanding the items reviewed. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes.

The following includes some inspection actions associated with review of licensees' implementation of written procedures to provide high confidence that each permanent implant brachytherapy treatment is administered in accordance with the written directive and the associated treatment plan. This list is not all inclusive, and depending on the content of a licensee's program, some of the elements below may not be applicable. In accordance with 87132-03, it is not necessary to review all of the elements outlined below for weaknesses if the inspector concludes from selected observations, discussions, and reviews that the licensee's performance is adequate for ensuring public health and safety:

Observe applicable licensed activities if possible (e.g., treatment planning, treatment administration and post treatment verification). Inspectors should note that for permanent implant brachytherapy, the most important regulatory requirements can be verified pre and post procedure. Furthermore, the inspector's observation of the treatment administration may be contingent upon the patient's acceptance of being observed, and the patient must provide his or her consent prior to any sedative being administered. Since the procedure itself is a surgical procedure, it is necessary that any observation be in a sterile environment. Therefore, inspectors must ensure that they follow all applicable licensee procedures for entering and observing activities in a sterile environment (including special training, etc.), (10 CFR 35.40 & 35.2041)

- Interview selected staff regarding the method used for treatment planning, treatment plan verification, and/or treatment plan approval by authorized user, including the specific roles and responsibilities of the various members of the treatment planning team. (10 CFR 35.41 & 35.2041).

- Interview selected staff regarding acceptance testing on treatment planning software (if applicable). (10 CFR 35.457)

- Interview selected staff (physicists, dosimetrists, physicians, etc) regarding preparation of written directives, ensuring that they: (10 CFR 35.40 & 35.2040)
  - include all required information – patient name, treatment site, dose, etc.
  - are signed and dated by an authorized user before treatment
  - are updated when necessary by an authorized user

- Interview selected staff regarding determination of radionuclide, number, and activity of sources to be ordered. (10 CFR 35.41 & 35.2041)

- If pre-loaded sources are ordered, interview selected staff regarding loading verification. (10 CFR 35.41 & 35.2041)

- Interview selected staff regarding source/seed activity and make and model number verification and calibration. (10 CFR 35.432 & 35.2432)

- Interview selected staff regarding patient identification verification. (10 CFR 35.41 & 35.2041)

- Interview selected staff regarding implantation procedures, including:
  - source counting and tracking (10 CFR 35.406 & 35.2406)
  - source placement and the imaging method(s), if any, to verify placement (10 CFR 35.41 & 35.2041)
  - retrieval of sources from bladder, as applicable (10 CFR 35.406 & 35.2406)
  - surveys after implant (10 CFR 35.404 & 35.2404)

- Interview selected staff regarding verification that treatment was given in accordance with the written directive and the treatment plan (e.g., performing post-implant imaging such as CT and/or MRI, and dosimetry calculations to compare the delivered doses with the prescribed doses). (10 CFR 35.41 & 35.2041)

- Evaluate how the licensee would respond to unusual circumstances (e.g., equipment malfunctions, unavailable personnel, etc.). (License Condition(s))

- Interview selected staff regarding definition and recognition of medical events. (10 CFR 35.2 & 35.3045)

- Review selected patient records:
    - written directives (10 CFR 35.40 & 35.2040)
    - treatment plan (10 CFR 35.41 & 35.2041)
    - post treatment verification (10 CFR 35.41 & 35.2041)