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P-6

17 April 2008

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania
19406-1415

03008082

RE: Amendment of NRC Material License 45-00935-02 for Cesium-131 Brachytherapy Seeds

Dear Ms. Lanzisera:

Mary Washington Hospital Cancer Center of Virginia will follow the IsoRay Medical, Inc. guidelines for "Patient Release Criteria for Cesium-131 Brachytherapy Seed Implants." Find attached those guidelines from IsoRay Medicial, Inc. dated October 30, 2006.

Thank you for your time and assistance with this matter. If there is anything else you require, please contact William Pan at (540)786-5375 or email: willian.pan@medicorp.org.

Sincerely,

Linda Prowett

Linda Prowett, BLS, CNMT, NCT
Radiation Safety Officer
540-741-1580

Mail Control # 142072

142072

NMSS/RGN1 MATERIALS-002

IsoRay Medical, Inc.

Date: October 30, 2006

To: Health Care Providers

From: IsoRay Medical, Inc.

Re: Patient Release Criteria for Cesium-131 Brachytherapy Seed Implants

The decision to release ^{131}Cs implant patients with documented instructions to limit exposure to family members can be determined by directly comparing ^{131}Cs with ^{125}I. The integrated dose to the patient is proportional to the half-life times the initial dose rate. Since ^{131}Cs has a 9.7 day half-life, and ^{125}I has a 60 day half-life the initial dose rate for a ^{131}Cs therapy would be 6.2 times as high as for ^{125}I if the prescribed dose were the same.

The prescribed dose for a prostate therapy is typically 145 Gy for ^{125}I and 115 Gy for ^{131}Cs. Therefore, the initial dose rate from a ^{131}Cs implant would be 5 times as high as for ^{125}I implanted in the same patient. Since ^{131}Cs and ^{125}I have nearly the same radiation energies, the external integrated dose will be approximately proportional to the prescribed dose.

While the Radioactive Materials License and Regulations place requirements on an institution to provide patient instructions to minimize dose to family and members of the public, patient compliance with the instructions cannot not be assured. The specific restrictions placed on a patient are between the health care provider and the patient. The health care provider can outline trade-offs to make compliance easier for the patient.

Examples of trade-offs may be one patient might choose to maintain separate sleeping arrangements, and maintain distance during the day for a month in exchange for no further restrictions afterwards. Another might find it easier to comply with being able to be within one meter of family members for up to six hours per day, and maintaining distance for the rest of the day.

In summary, while the initial dose rate of ^{131}Cs is higher, the integrated dose can be significantly lower. Moreover, the relatively short half life can permit a great deal more flexibility in determining the specific restrictions to minimize dose to family members.

For additional information or questions please contact Dale Boyce at 509-375-1202.

NUREG-1556 as Applied to Cesium-131 Seed Implants:

Patients who receive cesium-131 brachytherapy seed implants must be released following the applicable NRC guidance and regulations as referenced below. Patients may be released based on administered activity (U.1.1), measured dose rate (U.1.2) or patient-specific dose calculations (U.1.3), as described in NUREG-1556. The following equation provides a rational method for estimating the dose to the general public or an affected individual:

$$D(\infty) = \frac{34.6 \cdot \Gamma \cdot Q_o \cdot T_p \cdot (0.25)}{(100cm)^2}$$ Equation U.2 from NUREG-1556

$D(\infty)$ is the estimated dose to infinite decay that an affected individual is expected to receive. The specific gamma constant (Γ) is the dose rate at one meter per unit activity. Q_0 is the implanted activity. The physical half-life of cesium-131 (T_p) is 9.69 days. The one quarter factor (0.25) assumes that the affected individual is exposed for 6 hours per day.

Rearranging Equation U.2, converting 100 cm to 1 meter, inputting 500 mR for $D(\infty)$, and inputting 9.69 for T_p, the equation then simplifies to Equation (1) as follows:

$$Q_o \cdot \Gamma = \frac{D(\infty) \cdot (100cm)^2}{34.6 \cdot T_p \cdot (0.25)} = \frac{500mR \cdot (1m)^2}{34.6 \cdot 9.69 \cdot (0.25)} = 5.96mR/hr$$ Equation (1)

The factor, $Q_0 \Gamma$, is the dose rate (mR/hr) at 1 meter for the entire implant at the time of patient release. In essence, if the patient is measured with a dose rate instrument and the reading is less than approximately 6.0 mR/hr at 1 meter, the NRC guidance/criteria for patient release is met.

As a comparison, Table U.1 in NUREG-1556 (which does not specifically list cesium-131) indicates that patients may be released at 1 mR/hr at 1 meter for iodine-125 (I-125). Since the half-life of Cs-131 is approximately 1/6th that of I-125, it makes sense that the dose rate could be six times greater at the time of patient release.

References:

(1) http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html
10 CFR 35.75 "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." This regulation authorizes release of individuals who have been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem.

(2) http://www.nrc.gov/reading-rm/doc-collections/nureg/staff/sr1556/v9/nureg-1556-9.pdf
NUREG-1556 Vol. 9 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Appendix U of this guidance document describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 500 mrem.

U.1.1 Release of Patients Based on Administered Activity
U.1.2 Release of Patients Based on Measured Dose Rate
U.1.3 Release of Patients Based on Patient-Specific Dose Calculations
Table U.1 Activities and Dose Rates for Authorizing Patient Release

Below is information from NUREG-1556 Volume 9 Appendix U.2.3.2.
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/nureg-1556-9.pdf

U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for_____days.

- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
  - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
  - Place the container with the seed or pellet in a location away from people.
  - Notify _____ at telephone number _____.