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Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415
Attn: Michelle Simmons

MS16
K-3

Re: Radioactive Materials Licenses 06-06697-02
Docket No. 03001265
Control No. 141894

In response to your questions on our request for an amendment to add Cs-131 seeds for prostate implants we would like to submit the following.

To comply with 10 CFR 35.75 and NUREG-1556 Vol. 9 to only allow release of a patient if it can be shown that the effective dose equivalent to another individual is not likely exceed 5 mSv (0.5 Rem) we will use equation U.2 from NUREG-1556. Please see the enclosed analysis titled "NUREG-1556 as Applied to Cesium-131 Seed Implants" that indicates that patients containing Cs-131 implants may be released if the exposure rate is less than 6mR/hr at 1 meter at the completion of the implant.

We will also use the enclosed analysis to determine when a patient will require instructions. This analysis will be performed by replacing the 500 mR in the equation with 100 mR. which then indicates that patients with exposure levels lower than 1.2 mR/hr at 1 meter will not be likely to give an exposure to another individual that would exceed 1 mSv (0.1 Rem). Those patients that exceed exposure rates of 1.2 mR/hr will require instructions.

Radiation exposure at 1 meter will be measured in the OR after completion of the implant with a calibrated Ionization meter and measured levels will be used to ascertain the ability to release the patient and the necessity for instructions.

I hope the above meets with your approval.

Sincerely,

A handwritten signature in black ink, appearing to read 'James Summers', written over a horizontal line.

James Summers, M.S., RSO
Radiation Safety Officer

141894
NMSS/RGNM MATERIALS-002

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:

$$D(\infty) = \frac{34.6 \cdot \Gamma \cdot Q_0 \cdot T_p \cdot (0.25)}{(100\text{cm})^2} \quad \text{Equation U.2 from NUREG-1556}$$

$D(\infty)$ 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:

$$Q_0 \cdot \Gamma = \frac{D(\infty) \cdot (100\text{cm})^2}{34.6 \cdot T_p \cdot (0.25)} = \frac{500\text{mR} \cdot (1\text{m})^2}{34.6 \cdot 9.69 \cdot (0.25)} = 5.96\text{mR/hr} \quad \text{Equation (1)}$$

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/nuregs/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