Donna Janda
Health Physicist
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

April 19, 2006

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MS-16

Ms. Janda: 03008485

In response to your e-mail questions concerning the amendment for Retreat Hospital, License # 45-15048-01, Control # 138445, our medical physicist, Van McComas, has provided me with the following responses.

Question:
1. Please confirm that patients who will be hospitalized after prostate implant brachytherapy will not be hospitalized because they cannot be released under 10 CFR 35.75. They will be hospitalized for other reasons.

Answer:
Calculations show that the exposure rate from an I-125 implanted patient at 1 meter would have to exceed 0.24 mR/hr to expose an individual to an effective dose equivalent greater than 0.5 rem. That would assume that an individual would be at one meter for the mean life of the isotope, or 2,073.6 hours, a highly unlikely scenario. Routine exposure readings using a Model 451P survey meter, shows exposures at one meter from all our implanted patients to be no greater than background. In addition, all patients are provided with release instructions that recommend the patient restrict close contact for a period of two weeks and to prohibit close contact of children and pregnant women for this period as well. Patients treated at Retreat hospital are those candidates that present with other health issues, such as cardio-pulmonary health risk, who may need hospitalization due to these problems.

If, at any time, a patient presents with exposure rates at one meter that would result in the limits of 10 CFR 35.75 to be exceeded, proper radiation safety precaution will go into effect until exposure limits are below the calculated limits set by 10 CFR 35.75.

Question:
2. Please provide a description of Retreat Hospital's emergency response equipment for manual brachytherapy.

Answer:
Attached you will find our Emergency Procedures for Seeds Jammed in the Mick Applicator and our Emergency Procedures for Broken Seed.

Question:

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3. Please describe the training Retreat Hospital's RSO, who appears to be a diagnostic authorized user, will receive in the regulatory and safety aspects of I-125 manual brachytherapy.

Answer:

Attached you will find a brief of the implant program that has been given to the current RSO, Dr. Timothy Taylor. We have reviewed this attachment as well as the entire package sent to the NRC as part of his training for this modality. Dr. Taylor will be invited to observe one of our implant procedure at the next available time slot.

Question:

4. Please provide the manufacturer and model no. for the NaI probe to be used to detect dislodged I-125 sources.

Answer:

Retreat Hospital has a Model 44-C survey meter with a Model 44-3 NaI crystal probe, serial number PR237751.

Question:

5. Can the possession limit for 35.300 authorization be decreased from 10 curies (as stated currently on license) to a more realistic value such as 100 mCi or 500 mCi? Based on past inspections, Retreat Hospital does not appear to need such a high possession limit. I understand that this may have to be discussed at the next RSC meeting. This decision will not hold up this amendment request. Retreat can request a change in possession limit at a later date.

Answer:

Please amend our license to set the limit of possession for I-131 at 300 mCi.

Question:

6. Please confirm that the correct name on the license should read "Retreat Hospital, Inc. d/b/a Retreat Hospital". I would like to get this corrected on this amendment.

Answer:

The license should read Retreat Hospital, Inc.

Sincerely,

Erica Gulrich
Assistant Administrator
Retreat Hospital

Emergency Procedures for Seeds Jammed in the Mick Applicator

Should an I-125 or Pd-103 seed become stuck in the Mick Applicator the following steps should be taken:

1. Do not force the seed or seed cartridge out of the Mick Applicator. At any time it is determine a seed is either broken or bent, Emergency Procedures for a Broken Seed must be put into place.
2. Partially unscrew the head of the magazine (no more than one turn), thereby relieving the downward pressure on the seeds. Note that the magazine head and the cartridge are NOT designed or intended to be taken apart. This is only to relieve the spring pressure on the seeds.
3. Carefully attempt to remove the cartridge from the applicator, never use excessive force.
4. Flush the jammed seed out of the applicator using light pressure water flush. This must be done over a collection pan situated such that all seeds are collected and accounted for.
5. If the seeds cannot be removed safely, place the applicator in quarantine by placing in a plastic bag and then wrapping or covering the applicator in a lead apron. The medical physicist will be responsible for checking the applicator and trying to remove the stuck seed.
6. If the seed cannot be removed from the applicator, the applicator will remain in radiation isolation quarantine for 10 half-lives. A qualified medical physicist will evaluate the applicator at this time.
7. If the seed can be removed safely, the applicator must be surveyed by swipes and checked with a NaI crystal detector to determine if there is radiation contamination.
8. If the applicator is contaminated and cannot be de-contaminated by the medical physicist, then the applicator must remain in radiation isolation quarantine for 10 half-lives.
9. Once the applicator is either de-contaminated or the contamination has decayed to safe levels, then the applicator will be returned to the manufacture for evaluation and repair.

Emergency Procedures for Broken Seed

Should an I-125 or Pd-103 seed break prior to implantation in a patient, the following steps should be taken:

1. All personnel in the OR room should immediately put on face masks that covers both nose and mouth.

2. The air circulation system to the room must be shut off to avoid contamination of the facility. Once the seed is isolated and the okay is given by the medical physicist, the air circulation system may be turned on again.

3. If possible, isolate the seed by placing it in a lead pig and/or cover the broken seed and the instruments it might have come in contact with a damp (wring out) towel. Then cover this will a lead apron.

4. The medical physicist will then take charge of the seed, applicator, and instruments.

5. All personnel and instruments will be surveyed by the brachytherapy tech or medical physicist using a NaI crystal detector for contamination. Any contaminated material will be placed in a plastic bag and turned over to the medical physicist.

6. Finish the procedure using the backup Mick Applicator.

7. Attend to the patient's needs. Under no circumstances should anyone leave the OR room until cleared by the medical physicist; doing so may further contaminate the facility.

8. The OR room will be surveyed and cleared by the medical physicist before it is placed back in use.

9. Notify the Radiation Safety Officer for the State or NRC license.

McComas Enterprises Inc.

Van H. McComas, MS, DABR

Medical Physics Consultant

Summary of the Prostate Seed Implant Program for Retreat Hospital

The following is a brief outline of the Prostate Seed Implant Program being developed at Retreat Hospital. The key participants are: Erica Gulrich, Assistant Administrator; Linda Baldwin, Director of Endoscopy; Debbie Willis, Director of Radiology; Bernard Tisdale, MD, Radiation Oncologist; and Van McComas, MS, Consulting Medical Physicist.

Prostate implants will be conducted in one of the procedures rooms in Endoscopy. An operating room surgery table will be used for the procedure as well as a C-arm fluoroscope for post implant view of the implant. Initial we will be using palladium-103 (Pd-103) as the isotope for the implants (we have the amendment from the State) however; we have submitted an amendment to the NRC for the use of iodine-125 (I-125). The Radioactive Materials requested are:

a) Iodine -125 (NRC)
b) Palladium -103 (VDH)
c) Manufacturer: Bard Brachytherapy Inc.
d) Form: Seal Source (seeds) for use as per 10 CFR Part 35.400.
e) Maximum Quantity I-125: 0.5 mCi per seed with maximum total limit on site of 1.0 curie.
f) Maximum Quantity Pd-103: 2.0 mCi per seed with maximum total limit on site of 2.0 curie.
g) Procedures for either isotope will be the same.

The survey equipment for this project will be:

a) Model 451P survey meter.
b) Model 14C G-M counter.
c) Model 44-9 pancake probe for the 14C.
d) Model 44-3 Scintillation probe for low energy gamma, 1" NaI crystal
e) The Inspector Digital G-M detector.

The Authorizer User for this project is Bernard Tisdale, MD. Dr. Tisdale is listed as both the Radiation Safety Officer and an Authorized User for 10 CFR Part 35.400 on NRC license 45-25582-01. Dr. Tisdale is ABR Certified and meets the requirements in accordance with 10 CFR Part 35.490.

The Radiation Safety Officer for this license, Timothy Taylor, MD will not change, however radiation safety for this project will be overseen by Van H. McComas, MS. Mr. McComas is

ABR Certified in Therapeutic Radiological Physics and is named on NRC license 45-25187-01 as both the Radiation Safety Officer and the Authorized Medical Physicist.

Training for individuals working in or frequenting restricted areas, as well as Operating Room (Endoscopy) staff, nursing staff for recovering patients, ward nursing staff for patients who must remain in the hospital, and Nuclear Medicine staff who will handle this material will be trained by the medical physicist in accordance with 10 CFR Part 35.410. (See Attachment 1, Sample Training Form).

Facility:

a) Attachment 2 (Second Floor) show the area of storage and use. The radioactive seeds will be received into Nuclear Medicine's Hot Lab (noted on Attachment 2 and 3) for wipe test, surveys, inventory, and assay.

b) Seeds will be assayed in accordance with 10 CFR Part 35.432. At least 10% of the seeds received will be assayed by the manufacturer. Two seeds from the same batch will be assayed by the medical physicist and compared to the manufacturer's calibration and assay report. (See Attachment 4, Sample Assay & Inventory Form).

c) Seeds will arrive from the manufacturer shielded and sterilized. This will reduce the exposure to staff handling the seeds for assay.

d) The medical physicist will transport the sterilized seeds to the Endoscopy Room (Attachment 5, Third Floor) for the implant procedure. The patient will recover in the recovery room (attachment 6) located down the hall from the procedure room. Appropriate surveys of the patient will be performed at the end of the implant procedure in accordance with 10CFR Part 35.404 (see Attachment 7, Sample Survey form).

e) Unused seeds will be returned to the Hot Lab for decay in storage. Source accountability will be maintained in accordance with 10 CFR Part 35.406. (See Attachment 8, Sample Waste Form).

Emergency Procedures for Jammed and/or Broken Seed in the Mick Gun are attached.

Sincerely,

Van H. McComas

Van H. McComas, MS,
Consulting Medical Physicist
President, McComas Enterprises Inc.