



SENTARA

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October 31, 2006

U.S. Nuclear Regulatory Commission
Region I Office
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406

Br. 1

To whom it may concern:

03003331

Please consider this an amendment request for the Sentara Careplex Hospital, NRC license number 45-09087-01.

Please see our attached request to add authorization for cesium-131 seeds for prostate implants. Our Radiation Safety Committee has approved this change.

If you should have any questions or comments regarding this amendment application, please do not hesitate to contact David Weimer, Chief Physicist, at (757) 827-2444 or our Radiation Safety Officer, Sandy Wolff, at (757) 388-3030.

Sincerely,

Torie Bashay
Interim Director, Facilities and Patient Care Services
Sentara Careplex Hospital

139682

NMSS/RGNI MATERIALS-C02

Byproduct material requested: IsoRay Medical, Inc. Model CS-1.

Sealed Source and Device Registration No. WA-1220-S-101-S

Maximum activity requested: 1800 millicuries (3 patient doses of 600 mCi each)
Total 35,400 activity requested: 3 curies

Maximum activity requested per seed: 10 millicuries

Written Directives:

The written directive form currently used for seed implants, will be revised to list Cesium-131 as a possible isotope and will be used to include:

Before implantation: treatment site, the radionuclide, and dose; and

After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total dose

Procedures for administrations requiring a written directive will describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive

Safety procedures:

Seeds will be implanted in one of our operating rooms (diagrams previously submitted).

Surveys will be made after implantation to ensure that all seeds are accounted for.

Seeds will be accounted for in a log as to number implanted and in storage.

Storage of seeds will be in our secure hot lab when not attended.

Calibration of seeds will be in accordance with the manufacturer's instructions.

Unused seeds will be held for decay in storage.

Release of patients:

Method for assuring that patients are released in accordance with 10 CFR 35.75
(See attached).

Radiation Safety Procedures:

- (a) We will take surveys to ensure that the photon emissions from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75
- (b) We will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where license conditions place further restrictions.
- (c) We will comply with all requirements of 10 CFR (specifically Parts 19, 20, and 35) and conditions of our NRC license.

Dose assay:

We use a re-entrant well that is calibrated every two years for all the isotopes used. It will be calibrated for Bard's Pd-103, Source Tech Medical's I-125, and Isoray's Cs-131. The Cs-137 dose calibrator standard is counted each day of use for constancy. Quarterly a calibrated seed is ordered, alternating between the isotopes used.

The following Authorized Users may be involved in Cs-131 implantation:

Authorized User	Material and Use on Current NRC License
Mark Sinesi, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400
Scott Williams, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400
Christopher Sinesi, M.D.	Medical use described in 10 CFR 35.300, 10 CFR 35.400
Michael Miller, D.O.	Medical use described in 10 CFR 35.300, 10 CFR 35.400 and Ir-192 in a remote afterloader

Training

All authorized users and all personnel involved in dose preparation and treatment administration will be provided the specific vendor training in the use of Cesium-131 seeds, before first use.

Sentara Healthcare, Department of Radiation Oncology
Home Instructions for Cesium-131 Prostate Implant Patients

Radioactive Cs-131 seeds, similar to grains of rice, but gray in color, will be permanently implanted in your prostate gland for treatment of your condition. The following recommendations are made to minimize the radiation exposure to other people from the sources inside your body.

A. Partner, caregiver, pregnant women and children:

1. These individuals should stay at least 6 feet from the patient for 2 weeks.
2. They should stay least 3 feet from the patient for 2 additional weeks.
3. Brief periods of closer contact such as hugging or kissing are permissible.

B. Sleeping Arrangements:

1. Separate beds are recommended for the first 3 days.
2. If separate beds are not available, the spouse should sleep on the couch for the first 3 days.

C. Displaced seeds:

1. Examine bandages and linens for any discharged seeds.
2. If found, pick up with a spoon and place in a container with a lid.
3. Store away from people and call the Radiation Safety Officer, listed below.

If you have any questions, please do not hesitate to contact:

Radiation Safety Officer, Sandy Wolff, at (757) 388-3030, Pager (888) 341-5703.

Patient statement:

The above recommendations and the reasons for them have been reviewed with me by a Radiation Oncologists or Medical Physicist. I was then given the opportunity to ask any questions regarding my treatment or limitations. I agree to abide by the above recommendations to minimize radiation exposure to others.

Patient Signature

Date

Radiation Oncologist / Medical Physicist

Date

This is to acknowledge the receipt of your letter/application dated

10/31/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 45-09087-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 139682.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.