Walt, Geralyn

From: Nguyen, Janice
Sent: Monday, September 21, 2015 11:37 AM
To: markperna@mac.com
Subject: NRC Request for Information for Weirton Medical Center (Mail Control Number 588548)

Licensee: Weirton Medical Center
License No: 47-17567-01
Docket No: 030-12977
Control No: 588548

Hi Mr. Perna,

Could you please reply back to this email to confirm receipt?

This is in response to your amendment request dated July 14, 2015, requesting to add Iodine-125 and Palladium-103 low dose rate brachytherapy seeds used for radioactive seed localization (RSL) of non-palpable lesions. In order to continue our review, we need the following additional information:

1. The amendment request letter dated July 14, 2015, indicated that the following information would be attached, but it was not. Please submit the following:

    a. Documentation of Dr. Balzano's training;

    b. Facility diagram for pathology (please indicate what areas are adjacent, above, and below);

    c. A copy of the written directive form;

    d. Written procedures for routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; and

    e. Written emergency procedures for responding to an abnormal situation to include: (i) instructions for responding to a source rupture (e.g. cut by a scalpel) during surgical removal to include procedures for retrieval of leaking/cut sources, contamination control, decontamination of the patient and area from a ruptured source and saturation of the patient's thyroid with stable iodine in the case of an I-125 source rupture; (ii) instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and area; (iii) the process for restricting access to and posting of the implantation/explantation/pathology area in the event of an unaccounted for or ruptured source to minimize the risk of inadvertent exposure from seeds; (iv) patient follow-up should they not return for explantation, including a commitment to make multiple attempts at contacting the patient and to perform a dose assessment; and (v) names and telephone numbers of the authorized users and the Radiation Safety Officer to be contacted.

2. Please provide the manufacturer and model numbers for the seeds you wish to be authorized for. Please confirm that the possession limit should be 1.5 millicuries maximum per treatment and 15 millicuries total.

3. Please provide the address of use and submit a facility diagram and description of the location where the radioactive sources will be received, used, and stored.

4. Please commit to the following actions for all departments involved in the RSL procedure, including the surgery and the pathology laboratory:

    a. The activity of sealed sources will be verified prior to each patient implant using an instrument calibrated in accordance with nationally recognized standards or the manufacturer's instructions and retain a record that includes: (i) the radioisotope; (ii) the patient's name or identification number; (iii) the measured activity; and (iv) the name of the individual who measured the activity.
    b. All personnel involved with the RSL procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.

5. Please submit a description of the survey instrumentation and calibration for the instruments you will use for RSL.

6. Please confirm if your facility would like the ability to make certain changes to your existing Iodine-125 and Palladium-103 seed localization programs under 10 CFR 35.26, "Radiation protection program changes," to the RSL safety program that might otherwise require a license amendment. If you request the authorization to allow future changes to your radiation safety program, please confirm that the following conditions will be met:

    a. The revision is in compliance with the regulations of the NRC or Agreement State;
    b. The revision is based on the current guidance for RSL 35.1000 use posted on the NRC website;
    c. The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;
    d. The affected individuals are instructed on the revised program before the change is implemented;
    e. The licensee will retain a record of each change for 5 years; and
    f. The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

    If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

7. Please confirm that you will maintain records for seed localization in accordance with the requirements for temporary implants to include the following regulations:

    10 CFR 35.2024 Records of authority and responsibilities for radiation protection programs;
    10 CFR 35.2026 Records of radiation protection program changes;
    10 CFR 35.2041 Records for procedures for administrations requiring a written directive;
    10 CFR 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials;
    10 CFR 35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources;
    10 CFR 35.2075 Records of the release of individuals containing unsealed byproduct materials or implants containing byproduct material;
    10 CFR 35.2310 Records of safety instruction;
    10 CFR 35.2404 Records of surveys after source implant and removal;
    10 CFR 35.2406 Records of brachytherapy source accountability;
    10 CFR 35.2432 Records of calibration measurements of brachytherapy sources.

8. Please confirm that you will report any medical event, except for those that result from medical intervention, in accordance with 10 CFR 35, Subpart M, or the equivalent Agreement State regulation, to include:

    10 CFR 35.3045 Report and notification of a medical event;

10 CFR 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child;
10 CFR 35.3067 Report of a leaking source.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov>; select Nuclear Materials; Med, Ind, & Academic Uses; then Licensee Toolkits, see our toolkit index page. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 588548.

If we do not receive a reply from you within 15 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application. Please feel free to contact me with any questions you may have.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you in advance for your help.

Sincerely,

Jan Nguyen

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