UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

October 8, 2015

Docket No. 03012977 License No. 47-17567-01
Control No. 588548

Charles O'Brien
Chief Executive Officer and President
Weirton Medical Center
601 Colliers Way
Weirton, WV 26062-5091

SUBJECT: WEIRTON MEDICAL CENTER, VOIDANCE OF APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 588548

Dear Mr. O'Brien:

This concerns the subject application for an Amendment to your material license. Because your Radiation Safety Officer, Mark T. Perna, M.S., informed us that you will not be able to supply the additional information requested by email on September 21, 2015 for some time, we have voided your application. This action is taken without prejudice to the resubmission of your request. If you wish to resubmit your request to add Iodine-125 and Palladium-103 low dose rate brachytherapy seeds used for radioactive seed localization (RSL) of non-palpable lesions, you may resubmit your application in whole or reference mail control number 588548 and provide the following additional information:

1. Regarding Dr. Eric Balzano's training and experience, please have his preceptor, Dr. Terri-Ann Gizienski, confirm that Dr. Balzano's training and supervised work experience included at least 3 cases, wherein Dr. Balzano ordered, received, and unpacked radioactive material safely; performed the related radiation surveys using the appropriate instrumentation; and maintained running inventories of radioactive material on hand. In addition, please provide a copy of Pennsylvania license PA-0310, which lists Dr. Gizienski as an authorized user. Dr. Gizienski should be a 10 CFR 35.490 authorized user.

2. Please confirm that the post implant portion of the written directive will be completed after implantation, but before completion of the procedure.

3. Please provide your medical event reporting criteria (i.e. will you be following a 20% variation from dose or days of implantation).

4. Please submit the following:

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

b. 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
c. 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.

5. 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.

6. 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.

7. 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.

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

9. 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;
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.

10. Please confirm the you will main 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.

11. 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).

If you have any technical questions regarding this deficiency letter, please call Janice Nguyen at (610) 337-5006.

Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer
Branch Chief
Medical Branch
Division of Nuclear Materials Safety

cc:
Mark T. Perna, M.S., Radiation Safety Officer

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SUNSI Review Complete: JNguyen

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