WEIRTON MEDICAL CENTER

July 14, 2015

U.S. Nuclear regulatory Commission
Materials Licensing Branch
Region I
475 Allendale Road
King of Prussia, PA 19406

Br. 1

RE: Amendment to Radioactive Material License No. 47-17567-01/03012977
Weirton Medical Center

To Whom It May Concern:

Please add 35.1000 authorization to our license for temporary I-125 or Pd-103 low dose brachytherapy seeds used for localization of non-palpable lesions. In addition, please add 35.1000 authorization for Eric Balzano, M.D. Documentation of Dr. Balzano's training is attached. In addition, add the pathology laboratory at Weirton Medical Center to the license as an area of use.

Authorization 6: Iodine-125 or Palladium-103
Authorization 7: Sealed source
Authorization 8: 1.5 mCi maximum per treatment and 15 mCi total
Authorization 9: For use as temporary implants to localize non-palpable lesions

A facility diagram for pathology is attached.

Eric Balzano, M.D. is already on our license for 35.100 and 35.200.

We will provide training for the general surgeons that will include performing related radiation surveys using appropriate instrumentation and preparing, implanting and safety removing brachytherapy sources, performing routine monitoring before, during and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source and Emergency procedures, including how to respond to a leaking source. The training will be provided either by the Authorized User or the Radiation Safety Officer.

We will provide training for the pathology personnel that will include: minimizing time handling specimens, using an appropriate survey instrument to perform surveys of hands and work areas following handling the specimen, routine monitoring before, during and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source, emergency procedures to be followed in the event contamination is

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identified, accountability, security for the seeds post-implantation and proper disposal of the seeds and/or specimens containing the seeds.

Written directives will be prepared and signed prior to administration. Copy of written directive form is attached.

Written procedures for routine monitoring and emergency procedures are attached.

We commit to the followings actions for all departments involved in the RSL procedure, including the survey and pathology laboratory.

-Emergency response equipment will be available near each surgery suite and pathology laboratory during specimen handling
-Procedures will be conducted under the supervision of the authorized user, who should consult with the surgeon prior to implanting the sources
-Surveys will be performed and records will be maintained as described in 10 CFR 35.404
-All sources will be accounted for and all records maintained as described in 10 CFR 34.406
-Procedures will be developed, implemented and maintained for source accountability from implantation to explanation and final disposal
-Written waste disposal procedures will be developed, implemented and maintained for licensed material in accordance with 10 CFR 20.1101 that meet the requirements of the applicable section of Subpart K to 10 CFR 20 and 10 CR 35.92
-Patients will be instructed in writing before implantation and agree in write to return for removal of the radioactive seeds.
-Training will be provided at least annually and covering the topics described in 10 CFR 35.410 and records described in 35 CFR 410.
-All personnel involved with the RSL procedure will be trained on routine monitoring and emergency procedures

Emergency Response Equipment: In the event of an emergency such as a lost or ruptured seed, we will have on hand: gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument and caution radioactive materials (CRAM) labels.

Procedures: We confirm that we will meeting the requirements for temporary implants and develop, implement and maintain the appropriate procedures in the following regulations: 10 CFR 35.40(a)(b)(6), (c) and (d), 35.41,35.67, 35.75, 35.310, 35.404, 35.406, 35.410, 35.432.

Weirton Medical Center confirms that we will maintain records of authority and responsibilities for radiation protection programs

Weirton Medical Center confirms that we will maintain records of radiation protection program changes

Weirton Medical Center confirms that we will maintain records for procedures for administrations requiring a written directive

Weirton Medical Center confirms that we will maintain records of calibrations of instruments used to measure the activity of unsealed byproduct materials

Weirton Medical Center confirms that we will maintain records of leak tests and inventory of sealed sources and brachytherapy sources

Weirton Medical Center confirms that we will maintain records of the release of individuals containing unsealed byproduct materials or implants containing byproduct material

Weirton Medical Center confirms that we will maintain records of safety instruction

Weirton Medical Center confirms that we will maintain records of surveys after source implant and removal

Weirton Medical Center confirms that we will maintain records of brachytherapy source accountability

Weirton Medical Center confirms that we will maintain records of calibration measurements of brachytherapy sources

Weirton Medical Center confirms that we will follow the requirements for the report and notification of a medical event in 10CFR35.3045

Weirton Medical Center confirms that we will follow the requirement for the report and notification of a dose to an embryo/fetus or nursing child

Weirton Medical Center confirms that we will follow the requirements for the reporting of a leaking source.

Charles O'Brien
CEO & President

This is to acknowledge the receipt of your letter/application dated 07/14/2015, and to inform you that the initial processing which includes an administrative review has been performed.

47-17567-01 (Amendment)

[X] 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

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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** 588548
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader