UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 18, 2024

Douglass Harrison, President & CEO
Wheeling Hospital, Inc.
1 Medical Park
Wheeling, WV 26003-6300

SUBJECT: WHEELING HOSPITAL, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639878

Dear Douglass Harrison:

This is in reference to your application dated February 26, 2024, requesting to renew NRC License No. 47-05322-02. The reference for each of following items can be found in NUREG 1556 Vol 9, Rev 3 Consolidated Guidance About Materials Licenses Program Specific Guidance About Medical Use Licenses https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In order to continue our review, we need the following additional information:

1. Section 8.2 Item 2 Name and Mailing Address of Applicant**:** Since you have requested a name change, please confirm that the management entity overseeing the license has not changed. If there has been any change, please provide a copy of the old and new organizational charts showing the changes.

2. Section 8.3 Item 3 Addresses Where Licensed Material Will Be Used: Please confirm that the previously authorized location of Shiffler Cancer Center is the same as the requested Wheeling Hospital Cancer Institute. If not, please submit decommissioning information for the Shiffler Cancer Center locations.

3. Section 8.5 Item 5 Radioactive Material:

    a. You previously had authorization for North American Scientific, Inc. Model MED3633 Pd-103 sealed sources. Please confirm that this authorization should be removed.

    b. You previously had authorization for Eckert & Ziegler BEBIG, Inc. Model I25.S06, Medi-Physics, Inc. Model 6711, and North American Scientific, Inc. Model MED3631 I-125 sealed sources. Please confirm that these authorizations should be removed.

4. Section 8.6 Item 6: Purpose(s) for which Licensed Material Will Be Used: Please indicate if you request to be approved for any in-patient treatments under 10 CFR 35.300 or 400. If so, please provide a diagram for the in-patient room(s) including the following information: include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed

patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used. Otherwise, your license will be restricted to outpatient treatment only.

5. Section 8.7.2 Item 7: Individual(s) Responsible for the Radiation Safety Program and their Training and Experience: Authorized Users (AUs):

    a. You have requested Authorized User status for Christopher Cory Nicely, M.D. for 10 CFR 35.100-300 I-131; Brian Trent Schambach, M.D. for 10 CFR 35.100-300 I-131; Carl Seynnaeve, M.D. for 10 CFR 35.100-300 (I-131); Christopher T. Taylor, M.D. for 10 CFR 35.100-300 (I-131 less than 33 mCi); Jacob W. Sechrist, M.D. for 10 CFR 35.100-300 (I-131 less than 33 mCi) however you have only provided ABR certificates for each. We are only able to add AUs based on Board Certification alone for 10 CFR 35.100-200 uses. Please submit 313A AUT forms for those physicians seeking 10 CFR 35.300 authorization.

6. Section 8.9.1 Item 9 Facilities and Equipment: Applicants should follow the guidance in Chapter 6 of this NUREG for "Identifying and Protecting Sensitive Information." To determine if the response includes security-related sensitive information and needs to be marked accordingly. Relative to your facility diagrams:

    a. For the Nuclear Medicine Facility:

        i. Confirm that no PET activities are performed in the NM facility. If PET is performed provide shielding calculations for the facilities. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.

        ii. Provide room numbers if applicable.

        iii. Principal use of adjacent rooms, including areas above, beside, and below any PET locations.

        iv. For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

    b. For the HDR facility diagram:

        i. Confirm that the location is 1 Medical Park, Wheeling WV;

        ii. Provide room numbers if applicable;

iii. Principal use of adjacent rooms, including areas above, beside, and below the HDR suite;

iv. Doors should be indicated, and specify which doors are access controlled (i.e. locked). Indicate how the HDR unit is secured within the HDR suite.

7. Section 8.9.2 Radiation Monitoring Instruments: Please provide survey meter probe information and confirm that you will have a meter/probe combination that is capable of detecting I-125 brachytherapy seeds.

8. Section 8.9.3 Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material: Please confirm that you are not using alpha emitters, or for the measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

9. Section 8.9.4 Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use: Please provide the following:

    a. Relative to your Daily Safety Checks please include the following tests required by 10 CFR 35.643(d)

        i. Verification of timer accuracy;

        ii. Verification of the clock (date and time);

        iii. Verification of the presence of emergency response equipment.

    b. Please provide detailed procedures that explain **how** all the checks will be performed.

    c. Confirm that if the results of any of the safety checks indicate a malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

10. Section 8.9.5 Other Equipment and Facilities: For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable.

    a. For manual brachytherapy facilities, provide a description of the emergency response equipment.

    b. For your remote after loader facility, provide a description of the following:

        i. warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;

        ii. area radiation monitoring equipment;

iii. viewing and intercom systems;

iv. steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room;

v. methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons;

vi. emergency response equipment.

11. Section 8.10.6 Emergency Procedures for Therapy Devices Containing Sealed Sources: Please provide the following:

    a. Provide a copy of the emergency procedures posted in the console area of the HDR suite showing:

        i. The names and telephone numbers of the AUs, AMPs and the RSO to be contacted if the unit or console operates abnormally,

        ii. The names of the individuals responsible for implementing corrective actions as indicated in the instructions for responding to equipment failures.

12. Section 8.10.11 Leak Tests: Please provide the following:

    For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (your Cs-137 calibration source)
    • a statement that: “We will conduct leak tests in-house.” AND

    a statement that: “The attached leak test procedures will be followed for leak tests conducted in-house.”
    AND
    • Attach leak test procedures.

    OR
    • a statement that the applicant will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use. For instance, if an applicant possesses a self-shielded irradiator, the applicant may state, “We will implement the model leak test program published in Appendix N of NUREG–1556, Volume 5, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.” OR

    if a contractor is used to perform leak testing, the applicant should state the following: “Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit.”

We will continue our review upon receipt of this information. Please respond by letter signed by management. Your response may be scanned and sent via email to me at robin.elliott@nrc.gov.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

ROBIN ELLIOTT

Digitally signed by ROBIN ELLIOTT
Date: 2024.06.18 08:19:04 -04'00'

Robin L. Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 47-05322-02
Docket No. 030-12570
Mail Control No. 639878

cc: Brian S. Kurko, M.S., CMD
Radiation Safety Officer
C. Kelly Stoneberg

WHEELING HOSPITAL, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639878 DATED JUNE 18, 2024

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