From: Elliott, Robin
To: Mark Gilliam
Cc: Mark Perna (markperna@mac.com)
Subject: Renewal Request for Additional Information License No. 47-16259-01
Date: Wednesday, December 1, 2021 8:13:00 AM

License No.: 47-16259-01
Docket No: 030-10683
Control No: 628758

Licensee Name: Monongalia County General Hospital dba Mon Health Medical Center

This refers to your request to renew your license dated September 16, 2021. To continue our review of your request, the following additional information is needed:

The following items are referring to sections in NUREG 1556 Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses, Volume 9, Rev. 3. https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html The U.S. NRC requires that renewal applications be a complete submittal of all requirements for the materials and uses requested, see Section 9.1 of the referenced NUREG.

1. Please confirm that Mr. Gilliam's title is still Chief Administrative Officer.

2. Please confirm whether Mr. Perna's contact information listed in section 4 of the NRC Form 313 is public or private.

3. Please confirm that your request for the 501 Railroad Ave, Elkins, WV facility is for materials listed in Condition 6B, or "Any by-product material permitted by 10 CFR 35.200."

4. Section 8.7.1 and Appendix I provide information needed to support the Radiation Safety Officer.

    a. The Delegation of Authority you provided should be updated to the current version in Appendix I and replace Pennsylvania Bureau of Radiation Protection with the U.S. Nuclear Regulatory Commission.

    b. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO, as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the size of the program).

    c. Identify an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO in his or her duties. Any such duties should be clearly defined.

    d. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

e. Specify the maximum amount of time it will take the consultant RSO to arrive at the facility, in the event of an emergency that requires his or her presence.

5. Regarding your Authorized Users and Authorized Medical Physicists: Please clarify:

   a. If Dr. Stover's first name is Garrett or Garrent as specified in your request. Your current license lists it as Garrett.

   b. You requested William L. Hirsch, M.D. and your license currently lists William L. Hirsch, Jr., M.D. Confirm the request should be for William L. Hirsch, Jr. M.D.

   c. Your current license lists Tao Han, Ph.D. as an AMP; should he be removed or remain on the license?

6. Reference Section 8.9.1. for information relative to the facility diagrams.

   a. Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390."

   b. Since you have two locations listed on your license, please resubmit the diagrams specifying the location of use (address) to which they apply and provide room numbers if available.

   c. Provide principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET).

   d. Doors should be indicated, and specify which doors are access controlled (i.e., locked)

   e. Include shielding calculations for PET facilities and High Dose-Rate (HDR) After loader vault. 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.

   f. 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.

7. Section 8.9.4 and 8.10.6 provides information required for the use of your HDR.

   a. Provide the procedures required by 10 CFR 35.643

   b. Provide procedures required by 10 CFR 35.610

8. Section 8.9.5 provides other information required regarding equipment/facilities. For your remote after loader facility, provide a description of the following:

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

    b. area radiation monitoring equipment,

    c. viewing and intercom systems,

    d. 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,

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

    f. emergency response equipment.

    g. Please confirm that your HDR unit will not be used in pulsed dose-rate mode.

9. Section 8.10.2 discusses Occupational Dose and licensee's obligation to evaluate potential exposure and monitor exposures. Provide one of the following responses:

    a. We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502." OR

    b. "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'" OR

    c. Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

10. Section 8.10.7 discusses the installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources.

    a. Indicate whether you will contract with personnel who are licensed by the NRC or an Agreement State to perform these services, OR

    b. Provide the following information for employee(s) who will perform the activities:

        1. name of the proposed employee(s) and types of activities requested,

        2. description of the training and experience demonstrating that the proposed

employee is qualified by training and experience for the use requested,

3. copy of the manufacturer's training certification and an outline of the training in procedures to be followed, and

4. written commitment from the licensee that the trained employee will follow manufacturer procedures.

11. Section 8.10.10 discusses Material Receipt and Accountability. As per this section, please provide the following commitment: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: 1) license possession limits are not exceeded, 2) licensed material in storage is secured from unauthorized access or removal, 3) licensed material not in storage is maintained under constant surveillance and control, and 4) records of receipt, transfer, and disposal of licensed material, are maintained."

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

    a. If you plan to conduct your own leak tests: a statement that: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67." OR

    b. If a contractor will be used to perform leak testing, 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."

13. Section 8.10.14 discusses the Safe Use of Unsealed Licensed Material. Please revise the commitment previously provided to state, "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email (preferred); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. To continue a timely review of your application, please provide your response within 30 calendar days from the date of this e-mail.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Direct any questions or concerns to me at the phone number below or via email.

Regards,

Robin L. Elliott
(Pronouns: she/her/hers)
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