UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 11, 2024

Erin C. Bell, MHP, DABSNM
Radiation Safety Officer
Community Health Network, Inc.
1500 N Ritter Ave.
Indianapolis, IN 46219

Dear Ms. Bell:

This letter is regarding the application dated February 26, 2024, signed by Derek McMichael, Pharm.D., M.B.A., FACHE, Vice President, Hospital Administrator, Vice President, Network Medical Imgaing, for the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-06009-01.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 9, Rev. 3, dated September 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." This guidance is available on the U.S. NRC website at:
https://www.nrc.gov/docs/ML1925/ML19256C219.pdf

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 8.5.1, "Item 5: Radioactive Material," of the guidance, specifies that the license application should indicate all byproduct material requested, including the element, mass number, chemical and/or physical form, and the maximum activity that will be possessed at one time.

   The submitted license application omitted previously authorized manual brachytherapy sources authorized for use in accordance with Title 10 of the Code of Federal Regulations (10 CFR) §35.400.

   Clarify the status of the licensed sources. If applicable, include documentation of transfer and/or disposal of the licensed sources along with documentation demonstrating that any areas dedicated for the receipt, preparation, usage and storage of the licensed sources are free of any radioactive contamination.

2. Section 8.7.1, "Radiation Safety Officer," of the guidance, identifies that the Radiation Safety Officer (RSO) is responsible for the oversight of licensed operations. The RSO must have sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices.

   Submit an updated delegation of authority supporting your continuing appointment as RSO. Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation," of the guidance includes an example delegation of authority on page I-4. Note that the delegation of authority should be signed by the RSO and a management representative. Include the printed name, title and date for each individual signing.

3. Section 8.7.2, “Authorized Users,” of the guidance, indicates that the application should include the medical license number and issuing entity for each Authorized User.

   Your request did not provide the Indiana Medical Licensing Board Medical License Number for each requested Authorized User. This information is available from the following web address: https://mylicense.in.gov/EVerification/Search.aspx

   Please confirm that all requested Authorized Users are actively licensed with the Indiana Medical Licensing Board and include each physician’s medical license number in your response.

4. Section 8.9.1, “Facility Diagram,” of the guidance, states that application must include a description of the proposed facilities and equipment, as required by 10 CFR §30.33(a)(2) and 10 CFR §35.12. The facility diagram should include the room or rooms where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property. Provide all of the following, as applicable:

   - Facility diagrams, including the address on each facility diagram or drawing. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.

   - Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.

   - 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).

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

   - Shielding calculations for PET facilities, in-patient rooms for 10 CFR §35.300 and 10 CFR §35.400 use, High Dose-Rate/Pulsed Dose Rate and Low-Dose Rate Remote Afterloaders, Teletherapy, and Gamma stereotactic radiosurgery (GSR). 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.

   - 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 10 CFR §35.1000, applicants should provide information described in the guidance on the Medical Uses Licensee Toolkit Web page.

5. Section 8.9.1, “Facility Diagram,” of the guidance, specifies that your application should include shielding calculations for your HDR Remote Afterloading Brachytherapy facilities, including a description of the shielding materials (type, thickness and density) to be installed, distances to adjacent areas, occupancy factors, workload assumptions (including the number of exposures per day, time per exposure in minutes and number of workdays per week) and should account for the maximum activity authorized for medical use.

   Please resubmit the diagrams of your HDR Remote Afterloading Brachytherapy facilities identifying the type and thickness of the shielding materials installed. In addition, please identify the distances to adjacent areas from both primary and any secondary treatment locations within the HDR Remote Afterloading Brachytherapy vault.

6. Section 8.9.3, “Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material,” of the guidance, identifies the requirements for the use, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

   Your application does not identify your dose calibrator and other equipment used to measure dosages of unsealed byproduct material.

   The “Response from Applicant” section of the guidance states that the following should be provided:

   - A statement that: “Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions.”; and
   - A description of the equipment used to measure the dosages; and
   - For 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.

   Please provide an acceptable and complete response.

7. Section 8.10.2, “Occupational Dose,” of the guidance specifies that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure in accordance with 10 CFR §20.1502.

   Your application identifies that you provide dosimetry to individuals meeting the criteria specified in 10 CFR §20.1201, 10 CFR §20.1207 and 10 CFR §20.1208. Though, your application does not identify if you will maintain records of the evaluation performed to demonstrate that unmonitored individuals are not likely to receive a radiation dose exceeding the limits in 10 CFR §20.1502.

   The “Response from Applicant” section of the guidance states that the following should be provided:

- The statement, “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.”; and/or
- The statement, “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, in lieu of these statements,
- Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

Please provide an acceptable and complete response. For additional information, you may refer to Section 8.10.2 and Appendix M, “Model Procedures for Occupational Dose Monitoring Program,” of the guidance.

8. Section 8.10.6, “Emergency Procedures for Therapy Devices Containing Sealed Sources,” of the guidance, identifies that you must develop, document, implement, and submit written emergency procedures in accordance with 10 CFR §35.610.

   The Emergency Procedures must include:

   - instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
   - the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
   - the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

   Your HDR remote afterloader brachytherapy emergency procedure did not include all of the information specified above. Therefore, please revise and resubmit your HDR remote afterloader brachytherapy emergency procedures with applicable revisions addressing all of the above areas.

9. Section 8.11, “Item 11: Waste Management,” of the guidance, describes that radioactive waste must be disposed of in accordance with regulatory requirements and license conditions.

   The “Response from Applicant,” section of the guidance specifies that the following statement should be provided:

   “We have developed and will implement and maintain written waste disposal procedures for licensed material, in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92.”

   Your application included a commitment to developing, implementing and maintaining written Waste Disposal Procedures; however, a typographical error exists in the regulatory references. Therefore, please restate your commitment in accordance with the statement from the guidance.

10. Section 5.4, “Team Approach,” of the Y-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, Rev. 10.2, states that the applicant shall commit to provide training in the licensee’s procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual’s duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

    Your request did not include a commitment to provide training to all individuals involved in Y-90 microsphere use.

    Therefore, please include a commitment in your revised request to provide training to all individuals involved in Y-90 microsphere use.

In accordance with 10 CFR §2.390 of the NRC’s “Rules of Practice,” a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of your request, please submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by JASON KELLY
Date: 2024.06.11 16:21:29 -05'00'
Adobe Acrobat version: 2024.002.20759

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-01625
License No.: 13-06009-01
Control No.: 639769