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

July 2, 2024

Tina Commisiong, Esq.,MPA, CEO
Schneider Regional Medical Center
9048 Sugar Estate
St. Thomas Virgin Islands 00802

SUBJECT: SCHNEIDER REGIONAL MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 641170

Dear Tina Commisiong:

This is in reference to your letter dated May 28, 2024, requesting to renew NRC License No. 55-17986-01. In order to continue our review, we need the following additional information. Please be aware that, unless stated otherwise, all "Item", "Section", and "Appendix" references below are referring to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/docs/ML1925/ML19256C219.pdf.

1. Your application dated May 28, 2024, was prepared using an outdated revision of the guidance found in NUREG-1556. In this case, your application was prepared using Revision 2, whereas Revision 3 was issued in September 2019. Many of the commitments have minor changes from the prior revision. Please resubmit your application utilizing the guidance and standard commitments found in Appendix C, "Suggested Format For Providing Information Requested In Items 5 Through 11 Of U.S. Nuclear Regulatory Commission Form 313". Additionally, we have identified more significant discrepancies in the following requests – please review and address requests 2 through 7 below as you revise your submittal.

2. Your application included several procedures and program documents that are not specifically required to be reviewed and approved in licensing space; these documents are reviewed during inspections. This prevents you needing a license amendment for any revisions. Please note that, while we may not specifically review and approve your procedures in licensing space, the procedures themselves may still be required and must be developed, implemented and retained in accordance with applicable regulations.

   As such we have neither reviewed nor approved the following procedures or programmatic documents and request their removal from the submittal:

   a. Dose Calibrator Calibration;
   b. Quality Management Program (Item 12 of your submittal)
   c. Model Training Program (Appendix A of your submittal)
   d. Model Personnel External Exposure Monitoring Program (Appendix D of your submittal)
   e. Model Radiation Safety Committee Charter (Appendix F of your submittal) – **Note: The Delegation of Authority letter should be resubmitted as it will be**

reviewed; please do not remove it.

f. Model Program For Maintaining Occupational Radiation Exposure at Medical Institutions ALARA (Appendix G of your submittal)
g. Model Rules for Safe Use of Radiopharmaceuticals (Appendix I of your submittal)
h. Model Spill Procedures (Appendix J of your submittal)
i. Model Guidance for Ordering and Receiving Radioactive Material (Appendix K of your submittal)
j. Model Procedure for Safely Opening Packages (Appendix L of your submittal)
k. Records of Byproduct Material Use (Appendix M of your submittal)
l. Model Procedure for Area Surveys (Appendix N of your submittal)
m. Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations (Appendix O of your submittal)
n. Model Procedure for Waste Disposal (Appendix R of your submittal)

3. Items 5 and 6, Radioactive Material and Purpose(s) For Which Licensed Material Will Be Used – Your application dated May 28, 2024, included a request to possess and utilize any materials authorized under 10 CFR 35.200, but did not specify whether PET materials are used under this license. Please confirm that no PET materials are used under your license or provide the information requested (e.g., shielding calculations, PET specific equipment) in Appendix C to NUREG-1556, Vol 9, Rev 3.

4. Items 5 and 6, Radioactive Material and Purpose(s) For Which Licensed Material Will Be Used – Your application dated May 28, 2024, included a request to possess and utilize any materials authorized under 10 CFR 35.300, without reference to whether inpatient therapies would be administered. However, your current license only authorizes you to possess and utilize sodium iodide iodine-131 for diagnostic studies or therapy procedures permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75. Therefore, please provide the following:
    a. Confirm that you are seeking to expand your authorization for 35.300 to include all isotopes under 10 CFR 35.300. Note that this will require additional information concerning the qualifications of your authorized users, commensurate with 10 CFR 35.390 as opposed to 10 CFR 35.394.
    b. Confirm that you are seeking to expand to inpatient therapies, i.e., possession and utilization of materials authorized under 10 CFR 35.300 for which the patient cannot be released under the provisions of 10 CFR 35.75. Note that this will require additional information on the facilities, including shielding calculations (see Request 7 below).
    c. If not, confirm that you are seeking to retain your current authorizations for possession and utilization of sodium iodide iodine-131 for diagnostic studies or therapy procedures permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

5. Items 5 and 6, Radioactive Material and Purpose(s) For Which Licensed Material Will Be Used – Your application dated May 28, 2024, included a request to possess and utilize materials authorized under 10 CFR 35.400 for the purposes of manual brachytherapy procedures. However, these materials are not currently authorized on your license. You were previously approved for Palladium-103, Iodine-125, and Cesium-131 for manual brachytherapy procedures permitted by 10 CFR 35.400 through Amendment 23 to license 55-17986-01, dated September 15, 2016. However, this authorization was removed with the issuance of Amendment 24, dated February 28, 2018. As such, please provide the following:

a. Confirm that you do not currently possess any materials authorized under 10 CFR 35.400.
b. Confirm that you are not seeking authorization to possess and utilize materials under 10 CFR 35.400. OR
c. If you are truly seeking authorization to possess and utilize materials under 10 CFR 35.400, provide the following:
    i. Identify the specific isotopes you seek authorization to possess and utilize;
    ii. Identify the form (i.e., sealed sources), the source manufacturer, and model of seeds you seek authorization to possess and utilize;
    iii. Identify the max quantity (i.e., maximum activity in mCi or Ci) you seek authorization to possess and utilize;
    iv. Identify the purpose of use for the authorized materials (i.e., manual brachytherapy procedure permitted by 10 CFR 35.400)
    v. Identify what, if any, materials will be utilized for inpatient treatments or confirm that all procedures will be on an outpatient basis.

6. Item 7, Authorized Users – Your application contained a list of proposed Authorized Users (AU) and their proposed authorized uses. Neither of the proposed AUs, both of which are currently on the license, were proposed as being authorized for uses under 10 CFR 35.300, aside from sodium iodide I-131, or 10 CFR 35.400. In accordance with the prior items above, if you are seeking those uses, please identify which AU(s) are proposed for these uses and provide the required supporting information.

7. Item 9, Facility Diagram – Your application dated May 28, 2024, included a facility diagram; however, it was illegible. Please provide the following:

    a. Resubmit your facility diagram. Drawings should be provided in such a manner that they are legible.
    b. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
    c. Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
    d. 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).
    e. Doors should be indicated, and specify which doors are access controlled (i.e., locked).
    f. If applicable, provide shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use. 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.
    g. If applicable, 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.

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@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 610-337-5170 or via electronic mail at **Jonathan.Pfingsten@nrc.gov**.

Thank you for your cooperation.

Sincerely,

JONATHAN PFINGSTEN

Digitally signed by JONATHAN PFINGSTEN
Date: 2024.07.02 06:43:36 -04'00'

Jonathan Pfingsten, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 55-17986-01
Docket No. 030-01287
Mail Control No. 641170

cc: Yuri Peterkin, M.D., Radiation Safety Officer

SCHNEIDER REGIONAL MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 641170 DATED JULY 2, 2024

DOCUMENT NAME: **https://usnrc-my.sharepoint.com/personal/jbp1_nrc_gov/Documents/JBP1/DRSS/02 - MLAB/02 - Licensing/2024 - Licensing/641170 - Schneider - Renewal/02-RAI 1/L55-17986-01.641170.RAI.docx**

SUNSI Review Complete: Jonathan Pfingsten

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