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

July 11, 2023

Joseph Giardina, M.S., DABSNM
Jeffrey P. Thompsen, M.D., LLC
d/b/a Center for the Healthy Heart
15 Palomba Drive, Suite 2
Enfield, CT 06082

SUBJECT: JEFFREY P. THOMPSEN, M.D., LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 636057

Dear Joseph Giardina:

This is in reference to your application dated June 8, 2023, requesting a new NRC License, preliminarily assigned License No. 06-35712-01. Many of the items below reference NUREG-1556, Volume 9, Revision 3, which can be found online at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In response to the items below, you may consider individual responses or submitting a revised application. In order to continue our review, we need the following additional information:

1. Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.6 “Purpose(s) for Which Licensed Material Will Be Used,” strontium/rubidium generators are typically used under the authority of 10 CFR 35.200 “Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required.” Your application’s purpose statement was unnecessarily restrictive. Please confirm if authorization for imaging and localization studies permitted by 10 CFR 35.200 is sufficient for your proposed operations or provide additional supporting information.

2. The proposed Radiation Safety Officer (RSO) was listed on current and active New York City radioactive materials license. Please confirm whether or not the RSO is an outside consultant/contractor. If the RSO is an outside consultant/contractor, please address the applicable responses from Section 8.7.1 of the NUREG, starting on page 8-25, including:

    a. 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);
    b. Identify an in-house representative who will serve as the point of contact during the RSO’s absence;
    c. 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; and
    d. 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.

3. Your application requested Dr. Jeffrey P. Thompsen be authorized as the Authorized User under 10 CFR 35.200. Your application included an outdated Form 313A (dated August 2005).

    a. If Dr. Thompsen is authorized on a current or recent radioactive materials license as authorized for 10 CFR 35.200 and/or 35.300, please provide a copy of the applicable radioactive materials license.
    b. If Dr. Thompsen does not appear on a radioactive materials license described above, please provide sufficient information to demonstrate Dr. Thompsen's credentials, as described in 10 CFR 35.290, for example:
        i. Evidence Dr. Thompsen has been certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State.
        ii. Evidence Dr. Thompsen has completed commensurate training and experience as described in 10 CFR 35.290(c). Please complete a current NRC Form 313AUD (which can be found online at: https://www.nrc.gov/materials/miau/med-use-toolkit.html#forms).

    In addition, please note that if Dr. Thompsen's training and experience is over seven years old, consistent with 10 CFR 35.59, please provide evidence of continuing education and experience.

    If you are challenged producing the above information, please reach out as soon as possible, as it may be impossible to issue a new 10 CFR Part 35 license without a commensurate Authorized User.

4. Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.9 "Facilities and Equipment,"

    a. Your license application included a shielding diagram and room diagram showing the control room and imaging room. This is insufficient in that it does not address all location where licensed radioactive material is to be prepared, used or stored (such as the application's described hot lab). In addition, the application did not address other elements described as necessary for a response in NUREG-1556, Volume 9, Revision 3, Section 8.9.1. Please revise your facility diagram and associated descriptions to address the elements in Section 8.9.1 of the NUREG, starting on page 8-50, including:
        i. The diagram should be to scale, and the scale used should be indicated. The direction of north should be indicated;
        ii. The diagram should address the location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored;
        iii. Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below Positron Emission Tomography (PET) use areas.
        iv. Doors should be indicated, and specify which doors are access controlled (i.e., locked).

v. Shielding calculations for your facilities to enable independent verification of the calculation. Please note that your submission included shielding calculations, but did not explicitly describe the parameters of your calculations (e.g. type, thickness, and density of shielding, workload assumptions, occupancy factors, distances, uptake time, or other assumptions that underpin your conclusion).

vi. 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. Your application included a description of radiation instrumentation consistent with the use of PET radionuclides. In addition, and consistent with NUREG-1556, Volume 9, Revision 3, Section 8.9.2, please commit to the following:

If you intend to outsource your calibration services to an outside party:

"*Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations;*"

OR

If you intend to perform calibration in-house:

"*We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements in 10 CFR 35.61.*"

Please note that if you intend to perform in-house calibrations, additional radioactive material authorizations may be required beyond those authorized generically in 10 CFR Part 35.

c. Your application included a description of dose calibrator equipment consistent with the use of PET radionuclides. Your commitment to address the calibration and use of the suggested a nationally recognized standard *and* a manufacturer's recommendations. Please revise this commitment with the following:

"*Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions*."

d. Your application included a description of additional safety equipment, standard for nuclear medicine (i.e. I would not understand you would need syringe shields for the use of a Ru/Sr generator). Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.9.4, please confirm this equipment is commensurate with the hazards of PET radionuclides.

5. Regarding NUREG-1556, Volume 9, Revision 3, Section 8.10.4 “Occupational Dose:”

    a. Your application included a policy titled “Personnel Monitoring – Occupational Dose Reports,” which in turn includes a statement: “*when only one individual monitoring device is used and it is located at the neck outside the protective garment, the reported deep dose equivalent value multiplied by 5.6 shall be the effective dose equivalent for external radiation.*” Please note that you do not need to provide and it is not recommended to submit a policy to support the associated occupational exposure monitoring commitment. Your policy content and implementation will be reviewed as part of the NRC’s inspection oversight. Please further note that the use of a “5.6” multiple does not appear to be consistent with any NRC-accepted methodology to calculate an effective dose equivalent for external radiation (you may consider reviewing NRC Regulatory Guide 3.4 “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses”). No response is required for this item.
    b. Your application committed to *providing* dosimetry. Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.10.4 “Occupational Dose,” please revise your commitment to:

        “*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.’*”

6. Regarding NUREG-1556, Volume 9, Revision 3, Section 8.10.14 “Safe Use of Unsealed Licensed Material,” your application misquoted the second regulation as “10 CFR 20.1301” rather than “10 CFR 20.1201.” Please correct your commitment to the following:

    “*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.*”

7. Your application did not provide commitments consistent with NUREG-1556, Volume 9, Revision 3, Sections 8.10.10, 8.10.11, and 8.11. Please provide the following commitments consistent with the aforementioned sections:

    a. Section 8.10.10 “Material Receipt and Accountability:”

        “*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 (either from the licensee’s own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.”*
    b. Section 8.10.11 “Leak Tests:”

        For in-house leak testing of sealed sources pursuant to 10 CFR Part 35:

        “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 (continued on next page)

For licensed third-party leak testing:

"*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.*"

c. Section 8.11 "Waste Management:"

"*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.*"

Please confirm that you understand that disposal of waste by incineration or compaction requires additional authorizations.

8. Please note that by the nature of the strontium/rubidium generator, it cannot meet all of the NRC's regulatory requirements. In order to be considered for future enforcement discretion, you must meet the requirements of Enforcement Guidance Memorandum (EGM)-13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," dated April 18, 2013 (which can be found here: https://www.nrc.gov/docs/ ML13101A318.pdf). It may also be helpful to review Regulatory Issue Summary 2013-12, "Notice of Issuance of Enforcement Guidance Memorandum—Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," dated August 23, 2013 (which can be found here: https://www.nrc.gov/docs/ML13157A346.pdf). No response is required for this item.

We will continue our review upon receipt of this information. Please reply to my attention at:

R1DRSSMail.Resource@nrc.gov
Reference – Jason vonEhr
Mail Control No. 636057

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 and Procedure," 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) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jason E. VonEhr

Digitally signed by Jason E. VonEhr
Date: 2023.07.11 08:17:21 -04'00'

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

License No. 06-35712-01
Docket No. 03039348
Mail Control No. 636057

cc:
J. P. Thompsen, M.D, Pending Authorized User and Principle
C. Smitherman, MS, DABR, DABSNM, Pending Radiation Safety Officer

JEFFREY P. THOMPSEN, M.D., LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 636057 DATED JULY 11, 2023

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SUNSI Review Complete: JEV
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NAME	Jason vonEhr							
DATE	07/11/2023							

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