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

June 21, 2024

Bassam Moushmoush, M.D.
Practice Owner
Cardiovascular Consultants, PLLC
331 Laidley Street, Suite 402
Charleston, WV 25301

SUBJECT: CARDIOVASCULAR CONSULTANTS, PLLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 640410

Dear Dr. Bassam Moushmoush:

This is in reference to your application dated April 15, 2024, requesting to renew NRC License No. 47-30849-01. The items below are organized by and frequently 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 order to continue our review, we need the following additional information:

1. Regarding Section 8.5 and 8.6:

    a. Please note that your list of radioactive materials included a camera calibration flood source, well counter calibration sources, and dose calibrator testing sources, all of which appear be within the criteria of 10 CFR 35.65. Therefore, they do not need to be listed in your application, nor will they be included in your license as they are generally authorized under the above-quoted regulation. No response is required for this item.

    b. Your application did not describe nor prohibit the use of isotopes for Positron Emission Tomography (PET). Please either: (1) confirm that you will not use PET radioisotopes, or (2) provide commensurate information from Section 8.9 regarding the use of PET radioisotopes.

2. Consistent with Section 8.7.2, please confirm the list of authorized users (AUs) for your NRC license and the associated authorization (e.g., “Ahmed M. Sakkal, M.D., 10 CFR 35.200”). Please clearly identify any AUs that are requested to be removed from the license. If you need to add any AUs that are not already authorized on your NRC license, please refer to Section 8.7.2 for the necessary supporting information. Guidance is also available on the NRC’s Medical Uses Licensee Toolkit, available here: https://www.nrc.gov/materials/miau/med-use-toolkit.html.

3. Your application included a description of training pursuant to Section 8.8. However, your application did not address developing and implementing a written procedure, the qualifications of the instructors (or developers of training content), methods for assessing the success of the training, or that the training will be provided initially prior to engaging in licensed activities. Please either (1) revise your application's submission to address the above or (2) replace your application's description with the following commitment:

   "*We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.*"

4. Your application included a description of your dose calibrator and well counter testing and calibration, but did not fully address Section 8.9.3. Please revise your application to include the following:

   a. A commitment that:

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

   b. A description of the equipment used to measure the dosages, including the manufacturer and model.

   c. For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, either: (1) 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, or (2) commit to not using alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator.

5. Your application includes, with regards to radiation instrumentation, that the survey meter "*will be calibrated off site by a licensed facility following an established procedure*." However, your application later commits to develop and implement Appendix K from NUREG-1556, Volume 9, Revision 3, "*General Radiation Monitoring Instrument Specifications and Calibration*." Please address the following:

   a. Please clarify if calibrations for your radiation monitoring instruments will be in-house or by a vendor, as specified in Section 8.9.2, "*Radiation Monitoring Instruments*." If survey meter calibrations will be performed in-house: please either (1) provide a description of your calibration program commensurate with Appendix K of NUREG-1556, Volume 9, Revision 3, or (2) commit to the following:

      "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."

      OR

If survey meter calibrations will be performed by a vendor, please commit to the following:

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

b. In addition to the above, please provide a description of the instrumentation that will be used to perform required surveys, including the make and model number of the instrument and probe.

6. Please note that the procedures you provided and appendices you referenced will be commitments and any change to these procedures in the future will require an amendment request. If you wish to permit additional flexibility in your licensed activities, please provide the commitments from the NUREG for each indicated section in lieu of the associated NUREG appendices:

   a. Section 8.10.2, "*Occupational Dose*," please commit to one of the following:

      "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

      "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.'"

   b. Section 8.10.5, "*Spill/Contamination Procedures*," please commit to the following:

      "*We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."*

c. Section 8.10.10, "*Material Receipt and Accountability*," please commit to the following:

"We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
- *license possession limits are not exceeded*
- *licensed material in storage is secured from unauthorized access or removal*
- *licensed material not in storage is maintained under constant surveillance and control*
- *records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."*

d. Section 8.10.11, "*Leak Tests*," please commit to the following:

"*We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.*"

e. Section 8.10.12, "*Area Surveys*," please commit to the following:

"We have developed and will implement and maintain written procedures for area surveys, in accordance with 10 CFR 20.1101, that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

f. Section 8.10.14, "*Safe Use of Unsealed Licensed Material*," please commit to the following:

"We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

g. Section 8.11, "*Waste Management*," please commit to the following:

"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 note that your description of your waste management program, under item 4 of "*Disposal by Decay-in-Storage (DIS) T½ < 120 days*" includes a requirement to hold radioactive waste for at least 10 half-lives. Consistent with 10 CFR 35.92, you are only required to store radioactive waste until its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

7. Please also note that 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 – Withold Under 10 CFR 2.390*." For future submittals, please include the security banner when appropriate. No response is required for this item.

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

R1DRSSMail.Resource@nrc.gov
Reference – Kelli Trotter
Mail Control No. 640410

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 Kelli at (610) 337-5370 or via electronic mail at Kelli.Trotter@nrc.gov.

Thank you for your cooperation.

Sincerely,

JASON VONEHR

Digitally signed by JASON VONEHR
Date: 2024.06.21 13:30:18 -04'00'

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

License No. 47-30849-01
Docket No. 030-36436
Mail Control No. 640410

cc: Bruce Morton, B.S., J.D.

CARDIOVASCULAR CONSULTANTS, PLLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 640410 DATED JUNE 21, 2024

DOCUMENT NAME: https://usnrc.sharepoint.com/teams/RegionIDRSSLicensing/Shared Documents/Licensing Actions/MLAB Pending Actions/640410- Cardiovascular Consultants, PLLC/L47-30849-01.640410.RAI.docx

SUNSI Review Complete: Kelli Trotter

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DATE	06/21/2024		06/21/2024					

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