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| **From:** | Pfingsten, Jonathan |
| **To:** | Jan.d.levine@medstar.net; oluseyi.o.princewill@medstar.net |
| **Cc:** | Nguyen, Jan |
| **Subject:** | NRC Request for Additional Information for Cardiology Associates, LLC d/b/a MedStar Health Cardiology Associates (Mail Control No. 629876) |
| **Date:** | Wednesday, April 13, 2022 12:37:00 PM |

Licensee: Cardiology Associates, LLC
d/b/a MedStar Health Cardiology Associates
License No.: 08-23376-01
Docket No.: 030-20994
Mail Control No.: 629876

*PLEASE REPLY TO THIS EMAIL TO CONFIRM RECEIPT*

Dear Ms. Levine and Dr. Oluseyi O. Princewill:

This is in reference to your application dated January 7, 2022, requesting to renew NRC License No. 08-23376-01. In order to continue our review, we need the following additional information. Please note that the specific requests and suggested format for responses to these items may be found in Appendix C to NUREG–1556, Vol. 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/docs/ML1925/ML19256C219.pdf:

1. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. As such, please provide the following:

    a. Please confirm that Oluseyi Princewill, M.D. is authorized to make legally binding commitments on behalf of the licensee organization; OR,
    b. If Oluseyi Princewill, M.D. is not authorized to make legally binding commitments on behalf of the licensee organization, please provide either of the following
        i. Confirm that you endorse the requests and statements submitted by Oluseyi Princewill, M.D. on behalf of your organization in the renewal request dated January 7, 2022; OR
        ii. State that you do not endorse the requests and statements submitted by Oluseyi Princewill, M.D. on behalf of your organization in the renewal request dated January 7, 2022 and request to withdraw the requests and statements.

2. Items 5 and 6, Radioactive Material and Use – Please confirm that you are requesting to retain authorization to possess "Any" chemical and/or physical form of requested materials.

3. Items 5 and 6, Radioactive Material and Use – Please provide the following:

    a. Confirm that you will not utilize PET materials under this license. OR
    b. Confirm that you will utilize PET materials under this license and provide the following PET-related requests under Appendix C to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-

Specific Guidance About Medical Use Licenses":

i. Please confirm which facility/facilities will utilize PET materials.
ii. Please provide shielding calculations for your PET/CT facility. Please resubmit your PET/CT facility diagram, which should be drawn to scale with scale used indicated, and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The calculations should include any workload assumptions used.
iii. Please provide principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, besides, and below PET areas.
iv. For PET, 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.

4. Item 7, Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) – You are not required to submit the roles and responsibilities of the RSO; however, the list of typical RSO duties and responsibilities have been updated in Appendix I, 'Radiation Safety Officer Duties, Responsibilities, and Delegation' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.' No response is required for this item with respect to your license renewal application though it may be reviewed in a future inspection.

5. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – In your submittal, you provided a description of your training program. Please confirm the following:

   a. Please confirm that your training program will contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, as commensurate with their duties:

      i. Worker's right to contact the regulatory agency with concerns. (10CFRPart 19)
      ii. Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material. (49 CFRPart172)

   b. For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping, dietary, laboratory, security, and life-safety services. Please confirm that the training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 millisievert [100 millirem] will include instruction commensurate with potential radiological health protection problems present in the workplace. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel.

   c. Please confirm that the topics of instruction for ancillary staff will include the following, as commensurate with the individual's duties:

      i. storage, transfer, or use of radiation and/or radioactive material (10 CFR

19.12)

ii. potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12)

iii. the applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12)

iv. responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12)

v. appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12)

vi. radiation exposure reports that workers may request, as per 10 CFR 19.13, “Notifications and reports to individuals” (10 CFR 19.12)

Alternatively, in lieu of providing the responses to 5.a, 5.b, and 5.c above and if you would like the flexibility to make changes to your training program without requiring a license amendment, please provide the following statement in accordance with NUREG-1556, Vol. 9, Rev. 3, Section 8.8, “Training for Individuals Working In or Frequenting Restricted Areas”:

> “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.”

6. Item 9, Facility Diagram – Please provide the following:
   a. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated. Please include the scale and direction of north in your facility diagram.
   b. Doors should be indicated, and specify which doors are access controlled (i.e., locked). Please include a description of access controls in your facility diagram.
   c. The facility diagrams are difficult to read due to the low resolution of the images. Please resubmit the images in a higher quality image to enable proper reading. Please indicate the location, room numbers, and principal use of each room or area where byproduct material is prepared, used, and stored.

7. Item 9, Other Equipment and Facilities – If PET radionuclides are to be utilized, describe the additional equipment for these uses, as applicable.

8. Item 10, Occupational Dose – Please confirm the following 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.'"

9. Item 10, Material Receipt and Accountability – Please confirm the following statement:
    a. "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
        i. license possession limits are not exceeded
        ii. licensed material in storage is secured from unauthorized access or removal
        iii. licensed material not in storage is maintained under constant surveillance and control
        iv. records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

10. Item 10, Leak Test: Please provide the following statement for in-house leak testing of sealed sources used 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."

11. Item 10, Area Surveys – Please confirm the following statement: "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**."

12. Item 10, Safe Use of Unsealed Licensed Material – Please confirm the following statement: "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**."

We will continue our review upon receipt of this information. Please reply to our attention at Janice.Nguyen@nrc.gov and Jonathan.Pfingsten@nrc.gov, referencing Mail Control No. 629876. 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. Your reply must be an originally signed and dated letter from senior management. The letter may be scanned and submitted as a pdf document attached to an email.

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 Jan Nguyen at 610-337-5006 or via electronic mail at Janice.Nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jonathan Pfingsten
Sr. Health Physicist
U.S. Nuclear Regulatory Commission
RI/DRSS/MLA
(610) 337-5170