UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

July 27, 2022

Gaetano Pastore, M.D.
President and Radiation Safety Officer
Cardiology Physicians P.A.
Abby Medical Center
One Centurian Drive, Suite 200
Newark, DE 19713

SUBJECT: CARDIOLOGY PHYSICIANS P.A., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631510

Dear Dr. Pastore:

This is in reference to your application dated May 26, 2022, requesting to renew NRC License No. 07-30713-01. In order to continue our review, we need the following additional information:

It appears you used NUREG-1556, Volume 9, Revision 2, to develop your renewal application. Please note that this guidance was superseded by Revision 3, "Program-Specific Guidance About Medical Use Licenses," which was issued in September 2019 (and can be found here: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf). In order to continue our review, please provide the following additional information, which was taken directly out of NUREG-1556, Volume 9, Revision 3:

1. Please confirm if debbief@cardiocppa.com is the correct email address for Dr. Pastore.

2. Regarding "Training for Individuals Working In or Frequenting Restricted Areas", please provide the following statement: "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."

3. Regarding "Radiation Monitoring Instruments," please provide the following statement: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

4. Regarding "Occupational Dose," please provide one of the following:
    a. A statement that: "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**
    b. A statement that: "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**

c. A description of an alternative method for demonstrating compliance with the referenced regulations.

5. Regarding "Material Receipt and Accountability," please provide the following:

    a. A statement that "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, and records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

6. Regarding "Leak Tests," please confirm if all sources possessed at the licensed locations will be used pursuant to 10 CFR 35 and will be leak tested in-house. If so, provide the following statement:
    a. "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67."

    For any sealed sources possessed outside of 10 CFR 35.67, see Section 8.10.11 for additional information to submit.

7. Regarding "Safe Use of Unsealed Licensed Materials," please provide 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**."

8. Your previous license authorized the use of I-123 for clinical studies. Please confirm if you will continue the use I-123 for research studies. If so, please provide the following:

    a. Please confirm that the studies being performed are diagnostic and not therapeutic studies.
    b. Confirm that the material will be used in the facilities approved and no new facilities will be utilized for the study.
    c. As stated in 10 CFR 35.6, please confirm that the study you are participating in has the approval of an Institutional Review Board as defined by the Federal Policy for the Protection of Human Subjects. Provide information on the members of this committee, e.g. names, titles, degrees, contact information, and their institutional affiliation.
    d. Please confirm that you are obtaining "informed consent," from the human research subject as defined and described in the Federal Policy.
    e. Please indicate whether the clinical study involves the licensed material to evaluate an investigational drug or whether the licensed material is integral to the study, i.e. is the drug being investigated.
    f. If the licensed material is integral to the study, please provide the following:
        i. Indicate whether the material is an Investigational New Drug (IND) with FDA approval. If it is not, please indicate whether the drug is being administered under the oversight of a Radioactive Drug Research

Committee (RDRC) approved by FDA. If so, provide information on the members of this committee, e.g. names, titles, degrees, contact information, and their institutional affiliation.

ii. Relative to RDRC research:
    1. Briefly describe the review process for the research protocol design.
    2. What is the selection process for research subjects?
    3. Provide the criteria established for reporting events to the RDRC.

g. Please state whether the study will involve patients or volunteers. If volunteers are used, please address the following:
    i. What dose will they be receiving and how is the dose being determined?
    ii. Please confirm that volunteers released from the study will not pose an exposure risk to the public in excess of the limits in 10 CFR 20.1301.

For reference, information on I-123 research studies were provided in a letter dated March 17, 2017.

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

Netra Patel, Netra.Patel@nrc.gov
Mail Control No. 631510
USNRC, Region I
Division of Nuclear Materials Safety
475 Allendale Road, Suite 102
King of Prussia, PA 19406-1415

In order to continue prompt review of your application, we request that you submit your response to this letter by August 27, 2022.

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 via electronic mail at Netra.Patel@nrc.gov.

Thank you for your cooperation.

Sincerely,

Netra Patel
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-30713-01
Docket No. 030-35921
Mail Control No. 631510

CARDIOLOGY PHYSICIANS P.A., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631510 DATED July 27, 2022

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