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

November 16, 2022

Joseph Quash, Jr., M.D., Administrator
Capital Cardiology Consultants, P.C.
1160 Varnum Street, N.E., Suite 100
Washington, DC 20017

SUBJECT: CAPITAL CARDIOLOGY CONSULTANTS, P.C., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 632647

Dear Dr. Quash:

This is in reference to your application dated August 15, 2022, requesting to renew NRC License No. 08-30727-01. In order to continue our review, we need the following additional information. Please be aware that 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. 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 Newton Andrews, M.D., is authorized to make legally binding commitments on behalf of the licensee organization.

    OR

    b. If Dr. Andrews is not authorized to make legally binding commitments on behalf of the licensee organization, please have an individual authorized to make legally binding commitments on behalf of the licensee organization provide either of the following:

        i. Confirm that you endorse the requests and statements submitted by Dr. Andrews on behalf of your organization in the renewal request dated August 15, 2022.

        OR

        ii. State that you do not endorse the requests and statements submitted by Dr. Andrews on behalf of your organization in the renewal request dated August 15, 2022, and request to withdraw the requests and statements.

2. Item 3, Address Where Licensed Materials Will be Used or Possessed, and Item 9, Facility Diagram – Your application listed 1160 Varnum St, N.E., Washington, D.C. as the location of use and storage. Your current NRC amendment has this address listed as the mailing address but has the only authorized location of use and storage listed as 106

Irving Street, NW, Physicians Office Building, Suite 3200, Washington, D.C. The location at 1160 Varnum St, N.E., Washington, D.C. had been removed from the license for storage and use as of Amendment 11, dated October 18, 2016. Please confirm the following:

a. Confirm that the only address for the location of use and storage for this license is 106 Irving Street, NW, Physicians Office Building, Suite 3200, Washington, D.C.

b. Confirm that the facility diagrams submitted in your August 15, 2022, letter under Item 9, Facility Diagram, are for 106 Irving Street, NW, Physicians Office Building, Suite 3200, Washington, D.C.

c. Confirm that you do not want to re-add 1160 Varnum St, N.E., Washington, D.C. onto your license as a second location of use and storage.

d. If you did move locations, please provide the following:

i. Confirm the date your operations moved from 106 Irving Street, N.W. back to 1160 Varnum St, N.E., Washington, D.C.
ii. Confirm that all licensed activities at 106 Irving Street, N.W., Suite 3200, Washington, D.C., have ceased and that all radioactive materials procured and/or possessed by the licensee under this license number cited above have been transferred to the new location of use at 1160 Vamum St, N.E., Washington, D.C.
iii. Confirm/provide the following:
    1. Confirm that a radiation survey was conducted by the licensee. The survey confirms:
        a. the absence of licensed radioactive materials
        b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.
    2. Provide a copy of the radiation survey results

3. Item 5, Radioactive Material – Your application did not list the requested chemical and/or physical form for the requested materials permitted by 10 CFR 35.100 or 35.200. The NRC authorizes “any” form of radioactive material for these licensed uses and your license will reflect this. This item is provided for information purposes only; no action is required.

4. Item 7, Radiation Safety Officer (RSO) – The August 15, 2022, renewal application requests both Newton Andrews, M.D., and Joseph Quash, Jr., M.D., be named as Radiation Safety Officer (RSO). The NRC only authorizes a single individual to serve as RSO. Please provide the following:
    a. Confirm which individual you are proposing serve as RSO. Please note that **Dr. Joseph Quash, Jr.** is currently the authorized RSO on the license.

    b. If you are requesting to change the RSO from Dr. Quash, Jr. to Dr. Andrews, please provide the information and/or documentation described in Section 8.7.1 of NUREG-1556, Vol. 9, Rev. 3 and as requested in NRC Form 313A (RSO) found at https://www.nrc.gov/docs/ML1216/ML12164A742.pdf.

5. 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. As such, the roles and responsibilities of the RSO were not reviewed with respect to your license renewal application, though this item may be reviewed in a future inspection. However, we are requesting that you submit a letter by management delegating authority to the radiation safety officer emphasizing the agreement on duties and responsibilities of the RSO by management and the designated RSO. A model delegation of authority letter may be found in Appendix I of NUREG-1556, Vol. 9, Rev. 3.

6. Item 7, Authorized Users (AUs) – Your current amendment and website list a Dr. Newton Andrews. However, your application provided alternative spellings for both the first name (e.g., Newton vs Newtown) and last name (e.g., Andrew vs Andrews). Please clarify the correct spelling of the authorized user currently listed on your license as Newton Andrews, M.D.

7. Item 9, Facility Diagram – You provided two diagrams – a more detailed, focused diagram and a broader floor plan of the premises. However, not all of the information requested under Item 9 of NUREG 1556, Vol. 9, Rev. 3 was provided. Therefore, please provide the following:

    a. As discussed in request 2 above, please confirm the proper address of the location of use and storage for licensed materials and confirm the facility diagrams provided are for this location.
    b. Provide room numbers, if applicable, for rooms or areas where byproduct material is prepared, used, and stored.
    c. Specify which doors are access controlled (i.e., locked).
    d. It appears the hot lab is contained within another room. Please include any access controls (i.e., locked doors) that exist between the two areas or confirm that appropriate controls are in place to ensure compliance with 10 CFR 20.1801 and 10 CFR 20.1802.

8. Item 9, Radiation Monitoring Instruments and Dose Calibrator and Other Dosage Measuring Equipment – Your application contained descriptions of survey meter and well counter calibration and quality control tests. Additionally, it contained your procedures for calibrating your dose calibrator. We do not require this procedure as part of your application process. This information was not reviewed as part of the licensing process; however, it may be reviewed in a future inspection.

    The application did not contain confirmation that the calibrations would be performed in accordance with nationally recognized standards or the manufacturer's instructions. Therefore, please provide the following:

    a. Confirm and update your commitment to the following for radiation monitoring instruments:

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

    b. Confirm and update your commitment to the following for equipment used to measure dosages of unsealed byproduct material:

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

c. Please confirm that you "reserve the right to upgrade survey instruments as necessary, as long as they are adequate to measure the type and level of radiation for which they are used."

9. Item 10, Occupational Dose – Your application contained a description of your personnel monitoring program; however, the commitments referenced regulations other than those contained in **10 CFR 20**. Your application contained a separate commitment in Section 10.1, Occupational Dose, to monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3. Please provide the following:
   a. Confirm that you rescind the commitments contained in Section 9.6, Personnel Monitoring Program.

      AND

   b. Confirm your commitment contained in Section 10.1, Occupational Dose which states:

      > "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."

10. Item 10, Area Surveys – Your application contained commitments under Items 10.2 and 10.6 for Area surveys. Your Item 10.2 did not contain all of the necessary elements; Item 10.6 did. Therefore, we will not be tying down your commitment in Item 10.2. No action is required at this time.

11. Item 10, Safe Use of Unsealed Licensed Material – Your application contained two commitments, Items 10.3 and 10.7, for the safe use of unsealed material. These commitments referenced different regulations. The guidance in NUREG-1556, Vol. 9, Rev. 3, requests the following statement:

    > "We have developed and will implement and maintain **written** procedures for safe use of unsealed byproduct material that meet the requirements of10 CFR 20.1101 and **10 CFR 20.1201**."

    Item 10.7 of your application matches this request. Therefore, please provide the following:
    a. Rescind the commitment made in Item 10.3 of your application which lacked the reference to **written** procedures and referred to 10 CFR 20.**1301**.

       AND

    b. Confirm the commitment made in Item 10.7 of your application which referred to 10 CFR 20.**1201**.

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 B. Pfingsten

Digitally signed by Jonathan B. Pfingsten
Date: 2022.11.16 07:58:56 -05'00'

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

License No. 08-30727-01
Docket No. 03035983
Mail Control No. 632647

cc: Newton Andrews, M.D.
Jody Horner, Practice Administrator

CAPITAL CARDIOLOGY CONSULTANTS, P.C., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 632647 DATED NOVEMBER 16, 2022

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