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

November 15, 2022

José R. Cumba Quiles, M.D.
José R. Cumba Quiles, M.D.
P.O. Box 130
Bayamon, Puerto Rico 00960

SUBJECT: JOSÉ R CUMBA QUILES, M.D., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631781

Dear Dr. Cumba Quiles:

This is in reference to your letter dated May 26, 2022, requesting to renew NRC License No. 52-19670-01. 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 the following address: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf.

1. Item 3, Address Where Licensed Materials Will Be Used or Possessed – Your renewal application listed the physical address where materials will be used or possessed as **Ave**. Aguas Buenas in Santa Rosa, **Rosa Bayamon**, PR; your current amendment lists the physical location as Aguas Buenas **Street** in **Bayamon**, PR. Please confirm the proper address, and provide GPS coordinates, for the location where materials will be used or possessed.

2. Item 4, Person to be Contacted about this application – Your application included a gmail email address for Dr. Cumba Quiles

    a. Please confirm whether the "gmail" email address provided for Dr. Cumba Quiles in the application is for personal (i.e., private) or public (i.e., business) purposes.

    b. If the "gmail" email address is private, please provide an official, business-related email address for contacting Dr. Cumba Quiles.

3. Items 5 and 6, Radioactive Material and Use – Your application did not include a request for any specific materials, in any specific form, in any specific quantity, or for any specific purpose. Your current license amendment authorizes you to possess Strontium-90 permitted by 10 CFR 35.400, in sealed source form (Isotope Products Laboratories, Inc. Model BF 90Ti Series), 150 mCi, for use in a Nuclear Associates Model 67-850 applicator for ophthalmic radiotherapy permitted by 10 CFR 35.400. Please confirm you seek to retain the current authorizations and are not requesting any additional material.

4. Item 7, Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) – Your application did not include a request for authorization of a specific individual as RSO. You, Dr. Cumba Quiles, are currently authorized as RSO on the license. Please confirm you seek to retain this authorization as RSO for the license.

5. Item 7, Authorized Medical Physicist (AMP) – Your application did not specifically list any individuals to serve as the AMP for this license. Your current license amendment lists Mr. David Rhoe as AMP. Please confirm you seek to retain Mr. David Rhoe's authorization as AMP for this license.

6. Item 9, Facility Diagram – Your application did not contain a facility diagram. Please submit a facility diagram containing the necessary components as listed in Section 8.9.1 of NUREG -1556, Vol. 9, Rev. 3.

7. Item 9, Radiation Monitoring Instruments – Your application did not contain the requested information. Therefore, please provide the following:

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

        AND/OR

    b. A statement that: "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 of 10 CFR 35.61."

        AND

    c. A description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys is attached.

8. Item 9, Other Equipment and Facilities – Your application did not contain a description of the emergency response equipment possessed as a manual brachytherapy facility. Therefore, please provide a description of the emergency response equipment possessed as a manual brachytherapy facility.

9. Item 10, Material Receipt and Accountability – Your application did not contain the requested information concerning material receipt and accountability. Therefore, please provide the following:

    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
    - 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, Safe Use of Unsealed Licensed Materials – Your application contained the standard commitment concerning the use of unsealed licensed materials. However, your license does not authorize the use of any unsealed licensed materials. No action is required.

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov, referencing Mail Control number 631781.

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: 2022.11.15 08:28:55 -05'00'

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

License No. 52-19670-01
Docket No. 03019053
Mail Control No. 631781

cc: David Rhoe, AMP

JOSÉ R CUMBA QUILES, M.D., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631781 DATED NOVEMBER 15, 2022

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L52-19670-01.631781.RAI.docx
SUNSI Review Complete: Jonathan Pfingsten
After declaring this document "An Official Agency Record" it **will** be released to the Public.
To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	RI:DRSS	N	RI:DRSS	N				
NAME	RElliott / by email		JPfingsten/ JBP					
DATE	11/14/2022		11/14/2022					

OFFICIAL RECORD COPY