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

July 26, 2022

Frank Godlewski, Radiation Safety Officer
Franciscan Alliance, Inc.
d/b/a Franciscan Health Crown Point
1201 South Main Street
Crown Point, IN 46307

SUBJECT: FRANCISCAN ALLIANCE, INC. D/B/A FRANCISCAN HEALTH CROWN POINT, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 630476

Dear Mr. Godlewski:

This is in reference to your application dated March 22, 2022, requesting to renew NRC License No. 13-15933-01. 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. Item 3, Certification - 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 whether the email address provided for you, Mr. Godlewski, in the application is for personal (i.e., private) or public (i.e., business) purposes.

    AND

    b. Please confirm that Frank T. Godlewski, M.S. is authorized to make legally binding commitments on behalf of the licensee organization;

    OR

    c. If Mr. Godlewski 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 Mr. Godlewski on behalf of your organization in the renewal request dated March 22, 2022;

        OR

        ii. State that you do not endorse the requests and statements submitted by

Mr. Godlewski on behalf of your organization in the renewal request dated March 22, 2022 and request to withdraw the requests and statements.

2. Item 5, Radioactive Material – Your application requested to retain the authorization for possession and use of Gadolinium-153 (Gd-153) for storage only, incident to disposal. However, your renewal application contained a waste manifest dated November 11, 2021, which included two Gd-153 sources. Please confirm that you seek to retain the authorization for possession of Gd-153 for storage only, incident to disposal.

3. Item 5, Radioactive Material – Your application contained a list of requests for possession and utilization of various byproduct materials permitted under 10 CFR 35.100, 35.200, and 35.300, prepackaged kits authorized under 10 CFR 31.11, and the Gadolinium-153 source rod or rod source(s) discussed above. Additionally, your application requested the removal of the authorization for possession and utilization of byproduct materials previously used for activities under 10 CFR 35.400. Finally, your application included the waste manifests for the disposal of various sources. Please provide the following:

    a. Confirm that you are not requesting to possess any additional byproduct material, other than those previously listed, that **does not** fall under 10 CFR 35.65. Please note that this may impact your response to Request 22 (Item 10, Leak Tests) below.

    b. Describe the activities being, or to be, performed utilizing prepackaged kits requiring authorization under 10 CFR 31.11

    c. Confirm that you have disposed of **all** previously possessed brachytherapy sources under 35.400.

    d. Provide a close out survey of the former therapy hot lab.

    e. Confirm that the Sr-90 source that was disposed of was the same Sr-90 eye applicator you have requested that we remove from your license.

    f. The depleted uranium (DU) and the Am-241 that were disposed of are not authorized on your current license. Please confirm that these sources were possessed and disposed of under your license No. 13-15933-01. If they were not possessed under this license, please provide the source of these materials.

4. Items 5 and 6, Radioactive Material and Use – Your application did not directly discuss the use of PET materials. 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:

        i. Please confirm which facility/facilities will utilize PET materials.

AND

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.

AND

iii. Please provide principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, besides, and below PET areas.

AND

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.

5. Item 7, Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) – Your application requested to retain Frank T. Godlewski, M.S. as the RSO for the license. However, the application did not contain a discussion of whether Mr. Godlewski is an employee of the licensee or a contractor. As such, please provide the following:

   a. Confirm that Mr. Godlewski is not a contractor.

      OR

   b. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).

      AND

   c. Identify an in-house representative who will serve as the point of contact during the RSO’s absence.

      AND

   d. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

AND

e. Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his/her presence.

6. Item 7, Authorized Users (AUs) – Your application requested to retain Mir J. Shah, M.D., as an authorized user; Dr. Shah's only authorization is for material and use under 10 CFR 35.400. However, your application requested the removal of all authorizations for materials and uses permitted by 10 CFR 35.400. Please provide either of the following:

   a. Confirm that Mir J. Shah, M.D., is to remain an authorized user and request appropriate uses in accordance with your new possession and use authorizations under Items 5 and 6 of your renewal request. Please note that this would require you to provide the appropriate documentation demonstrating the proper training and/or qualifications to perform work for uses defined under 10CFR35.100, 200, and/or 300.

      OR

   b. Confirm that you seek to remove Mir J. Shah, M.D., from the list of authorized users.

7. Item 7, Authorized Users (AUs) – Your application requests to restrict the authorization for Boris Sagalovsky, M.D., to 10 CFR 35.100 and 35.200, limited to cardiovascular studies. However, your current license amendment does not contain this restriction limiting uses to cardiovascular studies. The NRC authorizes AUs for all uses under 10 CFR 35.100 and 35.200; we do not authorize restrictions such as the requested limitation to cardiovascular studies. Therefore, please confirm the following:

   a. Confirm that you seek to maintain the current authorized uses for Boris Sagalovsky, M.D., to any material and medical use authorized under 10 CFR 35.100, and 35.200.

      OR

   b. Request to remove the authorization limitations for materials and use under 10 CFR 35.100 and/or 35.200 for Boris Sagalovsky, M.D.

8. Item 7, Authorized Users (AUs) – Your application requests to add Faheem Ahm**e**d, M.D., Tahir M. Khokher, M.D., and Mohamad Saeb Martini, M.D. as authorized users for 10 CFR 35.100 and 35.200, limited to cardiovascular studies, based on their authorization as AUs on the Franciscan Alliance, Inc., d/b/a Franciscan Health Olympia Fields license (IL-01289-01). However, IL-01289-01 lists a Faheem Ahm**a**d, M.D. as an authorized user; additionally, the website for Franciscan Health lists a Faheem Ahm**a**d, M.D. Finally, as discussed above, the NRC does not authorize AUs for materials and uses under 10 CFR 35.100 and/or 35.200 with restrictions. Therefore, please confirm the following:

   a. Please confirm the correct spelling for the proposed AU is Faheem Ahm**a**d, M.D.;

b. Given that the NRC does not authorize AUs for materials and uses under 10 CFR 35.100 and/or 35.200 with restrictions, please submit the required information for approving an AU for materials and uses under 10 CFR 35.100 and 35.200 as requested in NRC Form 313A (AUD) for each individual as found at the following link: https://www.nrc.gov/docs/ML1216/ML12164A733.pdf.

9. Item 7, Authorized Users (AUs) – Your application requests to add Jelica Maze, M.D. as an authorized user for 10CFR 35.100 and 35.200, limited to cardiovascular studies, based on Dr. Maze being listed on the Franciscan Alliance, Inc., d/b/a Franciscan Health Olympia Fields license (IL-01289-01). However, IL-01289-01 lists Dr. Maze as an authorized user for the equivalent of 10 CFR 35.100 and 35.200, excluding generators, without being limited to cardiovascular studies. As stated above, the NRC does not authorize AUs for materials and uses under 10 CFR 35.100 and/or 35.200 with restrictions. Therefore, please submit the required information for approving an AU for all materials and uses under 10 CFR 35.100 and 35.200 as requested in NRC Form 313A (AUD) for Dr. Maze, including experience eluting generator systems as required.

10. Item 7, Authorized Users (AUs) – Your application requested to add Randolph Roberts, M.D., as an authorized user for materials authorized under 10 CFR 35.100 and 35.200. You supplied Dr. Roberts' certification from the American Board of Radiology. As part of the NRC-recognition process, the medical specialty boards submit a sample certificate for each recognized specialty area. The certificates are only applicable to the NRC-licensing process when they are issued within the approved date range; an exception applies if the individual was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2). The certification for Dr. Roberts predates the period of authorization for the American Board of Radiology for Diagnostic Radiology but is listed in 10 CFR 35.57(b)(2). However, additional information is needed to name Dr. Roberts as an AU. Therefore, please submit the following:

    a. Provide confirmation of active medical license. The documents provided included an expired "Controlled Substance Registration Certificate" from the US Department of Justice – Drug Enforcement Administration and included a renewal request for a "Medical Professional Liability" policy. The liability renewal application included a medical license number but listed its expiration date as June 30, 2013.

    AND

    b. If you intend to qualify Dr. Roberts as an AU under the pathway of "Individual who was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2)", please provide the following:

        i. Attach documentation demonstrating that the individual was using the requested materials for the uses requested on or before October 24, 2005

        AND

        ii. Attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.

    OR

c. If you cannot satisfy the requirements under Request 10.b above, please submit the information requested under the training and experience pathway for authorization as an AU for materials authorized under 10 CFR 35.100 and 35.200 as described in Form 313A (AUD).

11. Item 7, Authorized Users (AUs) – Your application included a request to add Dennis Prohaska, D.O., as an authorized user for materials and uses per 10 CFR 35.100, 35.200, and 35.300. You included an attestation of training and experience for meeting the requirements of 10 CFR 35.300, however this dated to October 7, 2014, without any additional documentation of recent, related continuing education and experience as required by 10 CFR 35.59. As such, please provide the following for the request to approve Dr. Prohaska as an AU for materials and uses under 10CFR 35.300:

    a. Provide a copy of the referenced Amendment 28 to the specified IL Agreement State License.

    b. Provide a description of the classroom/lab training, supervised work experience, and supervised clinical case experience, including experience with parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required. One means of submitting this would be to utilize the NRC Form 313A (AUT) for 10CFR 35.300 uses located at the following link: https://www.nrc.gov/docs/ML1216/ML12164A741.pdf.

    c. Provide additional documentation of recent, related continuing education and experience if required by 10 CFR 35.59. (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0059.html)

12. Item 7, Authorized Users (AUs) – Your application included a request to add Dr. Granville Batte, M.D., as an authorized user of materials and uses authorized under 10 CFR 35.100, 35.200, and 35.300. The supporting information for adding Dr. Batte included a copy of Amendment 71 of Kentucky Agreement State License Number 202-141-26 dated August 10, 2012; there was no additional attached documentation of recent, related continuing education and experience. Please provide either of the following:

    a. Confirm that Amendment 71 of Kentucky Agreement State License Number 202-141-26 dated August 10, 2012 is the current amendment.

    OR

    b. Provide a more recent (i.e., within the last 7 years) amendment of Kentucky Agreement State License Number 202-141-26 demonstrating that Dr. Batte remained on the license.

    OR

    c. Provide additional documentation of recent, related continuing education and

experience as required by 10 CFR 35.59.

13. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Your application contained a table with groups of staff who may work in or frequent restricted areas and the method and frequency of their training. However, it did not contain information on the content of the training. Please confirm and update your commitment with 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."

14. Item 9, Facility Diagram – Your application contained facility diagrams containing several of the aspects requested under Item 9 of NUREG 1556, Vol. 9, Rev. 3. However, your facility diagrams did not contain all of the requested information. Additionally, if applicable, please see the PET-material related requests listed under Request 4 above. Please provide the following:

    a. Provide the floor and room numbers for each room utilized for patient treatment or areas where byproduct material is prepared, used, and stored.

    b. Your application contains a request to possess and utilize any byproduct material permitted by 10 CFR 35.300. Please clarify whether these patients will be on an inpatient basis. If they will be on an inpatient basis, please provide a facility diagram of the therapy treatment rooms, including shielding calculations. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used. The calculations should include the workload assumptions used.

    c. Specify which doors are access controlled (i.e., locked).

15. Item 9, Radiation Monitoring Instruments – Your application contains a description of your radiation monitoring equipment and the following commitment:

    "(T)hese radiation monitoring instruments will be calibrated by a person authorized by NRC or an Agreement State to perform survey meter calibration."

    However, the requested commitment has been updated in NUREG-1556, Vol. 9, Rev. 3. As such, please confirm and update your commitment with 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."

16. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application contains a description of your dose calibrator and the following commitment:

> "We have developed and will implement written dosage measuring equipment calibration on procedures that meet the requirements in 10 CFR 35.60 and 10 CFR 35.62 as applicable."

The requested commitment has been updated in NUREG-1556, Vol. 9, Rev. 3. Please confirm and update your commitment with the following statement:

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

17. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application did not specify if any specialized measurement equipment is possessed for measurements of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator. If applicable, for measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, please 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.

18. Item 9, Sealed Sources in Therapy Unit - Calibration and Use and Section 8.9.4, Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use – Your application contains a reference to dosimetry equipment required under 10 CFR 35.630. Your application requested to remove authorization for possession and use of byproduct materials permitted under 10 CFR 35.400; additionally, you are not currently authorized, nor have you requested authorization, for possession and use of byproduct materials permitted under 10 CFR 35.600 or 10 CFR 35.1000. Therefore, this information is not required to be submitted as part of your renewal application. This information was not reviewed as part of this renewal application; no additional action is needed.

19. Item 10, Occupational Dose – Your application contained the following commitment:

> "We have developed and will implement written procedures for monitoring dose in accordance with **10 CFR 20.1101** and that meet the requirements of subparts **C and F of 10 CFR part 20**."

Please confirm and update your commitment with 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.'**"

20. Item 10, Spill/Contamination Procedures – Your application contained the following commitment:

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

Please confirm and update your commitment with the following statement:

"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."

21. Item 10, Material Receipt and Accountability – Your application contained the following commitment:

    "We have developed and implemented written package opening procedures that meet the requirements of 10 CFR part 20.1906."

    Please confirm and update your commitment with the following statement:

    "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."

22. Item 10, Leak Tests – Your application contained the following statement:

    "As for sealed sources, leak tests will be performed semi-annually to identify any defective source and if found item leaking will be removed, labeled and stored."

    However, additional information is requested under this item. Please update your commitment by providing the following:

    a. For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:

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

    OR

    b. For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources):

        i. A statement that: "We will conduct leak tests in-house."

        AND

        ii. A statement that: "The attached leak test procedures will be followed for leak tests conducted in-house."

AND

iii. Attach leak test procedures.

OR

iv. A statement that you will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use.

OR

v. If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

23. Item 10, Area Surveys – Your application contained the following statement:

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

However, this statement did not contain a commitment to maintain the written procedures. Please confirm and update your commitment with 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."

24. Item 10, Safe Use of Unsealed Licensed Material – Your application contained the following commitment:

> "We have developed and will implement procedures for safe use of licensed material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301 and 10 CFR 35.69."

However, your commitment did not reference procedures being written or maintained, was not specific to unsealed byproduct material, and does not reflect the current regulations requested to be referenced. Please confirm and update your commitment with the following statement:

> "We have developed and will implement **and maintain written** procedures for the safe use of **unsealed byproduct** material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.**1201**."

25. Item 10, Minimization of Contamination – You are not required to submit a response

under this item provided the that you satisfy the criteria in NUREG-1556, Volume 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees' for the following sections: Sections 8.9, 8.9.1, 8.10, 8.10.5, 8.10.12, and 8.11 on the following topics: facilities and equipment, facility diagram, radiation safety program, spill and contamination procedures, area surveys, and waste management. No response is required for this item with respect to your license renewal application at this time, though it may be reviewed in a future inspection.

26. Item 11, Waste Management – Your application contained the following commitment:

> "We have developed and will implement waste disposal for licensed material in accordance with 10 CFR 20.1101 and that meet the requirements of the applicable section of subpart K to 10 CFR part 20 and 10 CFR 35.92."

However, your commitment did not reference maintaining the written waste disposal procedures. Please confirm and update your commitment with the following statement:

> "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 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov, referencing Mail Control number 630476.

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: 2022.07.26 13:31:48 -04'00'

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

License No. 13-15933-01
Docket No. 030-10047
Mail Control No. 630476

FRANCISCAN ALLIANCE, INC. D/B/A FRANCISCAN HEALTH CROWN POINT, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 630476 DATED JULY 26, 2022

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