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

September 22, 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 and letter dated September 7, 2022, responding to our July 26, 2022, request for additional information. 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. In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant. Your September 7, 2022, letter did not explicitly confirm that Mr. Godlewski is authorized to make legally binding commitments on behalf of the licensee’s organization. Additionally, the September 7, 2022, letter referenced the original RSO position acceptance letter, however the acceptance letter was not attached. As such, please provide the following:

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

    OR

    b. 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, and letter dated September 7, 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 letter dated September 7, 2022, and request to withdraw, replace, or supplement the requests and statements.

2. Item 5, Radioactive Material – Your application contained a list of requests for possession and utilization of various byproduct materials including prepackaged kits authorized under 10 CFR 31.11. Additionally, your application included the waste manifests for the disposal of various sources. Please provide the following:

   a. Your September 7, 2022, letter described the activities being, or to be, performed utilizing prepackaged kits requiring authorization under 10 CFR 31.11. However, the uses described do not appear to meet the intent of 10 CFR 31.11. For example, 10 CFR 31.11 explicitly authorizes specific radionuclides, up to specific maximum quantities, and for specific uses; Tc-99m is not among the authorized materials. Additionally, 10 CFR 31.11 does not authorize internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals. Please confirm and elaborate on how your intended usage requires authorization under 10 CFR 31.11.

   b. The depleted uranium (DU) and the Am-241 that were disposed of are not authorized on your current license. Am-241 was previously authorized on this license in Amendment 9 dated October 1, 1985, through at least Amendment No. 11, dated October 28, 1988, but not Amendment 13 dated September 4, 1990; please note that a complete copy of Amendment 12 could not be retrieved for review. This item will be referred to the region with inspection oversight responsibilities for this license for further review. No other actions are required at this time.

3. Item 5, Radioactive Material – Your application dated March 22, 2022, requested the removal of the authorization for possession and utilization of byproduct materials previously used for activities under 10 CFR 35.400. Additionally, your application included the waste manifests for the disposal of various sources and associated November 19, 2021, cover letters. Your letter dated September 7, 2022, confirmed that all sources previously possessed under 10 CFR 35.400 had been disposed. Additionally, your letter dated September 7, 2022, included a document dated November 11, 2021, serving as the final closeout survey of the Radiation Oncology Hot Lab. Please provide the following information:

   a. Please provide the following with respect to the November 11, 2021, letter serving as the final closeout survey of the Radiation Oncology Hot Lab:
      i. Confirm whether only sealed sources were ever possessed in the Radiation Oncology Hot Lab.
      ii. Provide the results of the latest leak tests for each sealed source possessed, stored in the Radiation Oncology Hot Lab, and disposed.
      iii. Confirm that no sources stored in the Radiation Oncology Hot Lab have ever been identified to be leaking.

   b. With respect to the radiation oncology hot lab close out document, please

confirm that the "packaged sources" and "disposal paperwork" referred to in the November 11, 2021, final closeout survey letter are referring to, and limited to, the sources included on the waste manifests dated November 10, 2021, as provided in your March 22, 2022, renewal request. If there were other sources packaged at the time of the close out, please provide a list of those sources.

c. The renewal application dated March 22, 2022, contained a letter dated November 19, 2021, from Stan A. Huber Consultants, Inc. which confirmed the disposal of I-125 seeds that had been held for decay-in-storage. Additionally, you confirmed that the Sr-90 source included in the waste manifest was a brachytherapy source. However, the possession and use of Ir-192 and Cs-137 under 10 CFR 35.400 was not addressed.

   Therefore, please provide the following:

   i. Confirm whether Ir-192 and/or Cs-137 sources permitted by 10 CFR 35.400 were ever possessed under this license.
   ii. Provide the dates of final use for the Ir-192 and/or Cs-137 sources permitted by 10 CFR 35.400, if applicable.
   iii. Records of disposal for Ir-192 and/or Cs-137 permitted by 10 CFR 35.400 sources possessed under this license, if applicable.
   iv. Confirmation that the Ir-192 and/or Cs-137 permitted by 10 CFR 35.400 were found to be not leaking, if applicable.

4. 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. Your September 7, 2022, confirmed Mr. Godlewski is a consultant RSO and not a member of the licensee's organization. As such, please provide the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program) and expected offsite time dedicated to oversight and program support specifically for this license.

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 14 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: 2022.09.22 08:52:00 -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 SEPTEMBER 22, 2022

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SUNSI Review Complete: Jonathan Pfingsten

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