



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

Richard L. Dobben, M.D.
Radiation Safety Officer
Franciscan Health Michigan City
301 W. Homer St.
Michigan City, IN 46360

MAY 21 2019

Dear Dr. Dobben:

Enclosed is Amendment No. 51 to your NRC Material License No. 13-13144-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This also refers to the letter dated March 4, 2019, ("the letter"), signed by Dean Mazzoni, President and CEO of Franciscan Health Michigan City. Item 3 of the letter requested the removal of the location at 301 W. Homer Street from your license.

We were unable to approve the removal of 301 W. Homer Street, Michigan City, Indiana from your license because the information in the letter was insufficient to complete our review.

If you wish to pursue this request, please provide only one response to the items below.

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a.

Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors. The most reliable and fastest way to respond is to send a fax to me at (630) 515-1078.

Please address your written response to my attention as "additional information to control number 611550" to facilitate proper handling in our offices.

Please always provide the name, direct telephone number, fax number and email address for at least one individual knowledgeable in the amendment being requested. The letter provides the name and phone number of your Nuclear Medicine Supervisor, Amy Johns-Carter, CNMT, but it does not provide her fax number and email address.

Please consider scheduling a telephone call with me, or have Ms. Johns-Carter schedule a telephone call with me, to discuss the items in this letter. Arranging the call by email is preferable. My email address is colleen.casey@nrc.gov. My telephone number is (630) 829-9841.

A telephone discussion of these items may serve to clarify the information required by our regulations so that your response will be complete and accurate. Please also note that 10 CFR 30.41 and 30.51 may be of assistance to you, in addition to the regulations mentioned below.

Please be reminded that 10 CFR 30.9(a) requires: "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

1. Item 3 in the letter directs us to "remove the address 301 W. Homer Street from our license." 301 W. Homer Street, Michigan City, Indiana is also your mailing address. Your instruction was not specific and did not include the city and state of the address. Please respond by specifying the full address that you want removed from the license and whether you only want it removed from Condition No. 10 or if you want the mailing address changed also.

If you also want the mailing address changed, please so state and provide a new, complete mailing address.

2. The historical review provided in the letter was incomplete. Please specify what you meant by "The last date of service was January 11, 2019." Which licensed modalities were last used on this date?
3. The letter states "The last date of I-131 usage was October 24, 2018." But this license also authorizes the use of materials other than iodine-131 under 10 CFR 35.300. Please state whether you ever used materials other than iodine-131 under 10 CFR 35.300 and if so, which radionuclides, when was the last use of each and provide appropriate final disposal records for each that comply with 10 CFR 35.92 and 10 CFR 35.2092.
4. On what appears as page 2 in the letter there is a list of areas that were wipe tested and surveyed for exposure rates. Please explain what is meant in the listing for areas 25, 26, 27 28 and 29 as they all have the word "background" in them. Normally, a single background measurement is taken in what is expected to a radiologically "clean" area and it is then compared to measurements taken in the areas that are radiologically questionable.
5. For DIS disposal of waste materials, please note that 10 CFR 35.92 does not apply to cobalt-57 and gadolinium-153, because each has a half-life that exceeds 120 days. These materials may not be stored for decay and subsequent disposal.

It appears that you disposed of some sealed sources containing cobalt-57 and gadolinium-153 but you did not provide us with copies of acknowledgements of receipt from the entities who received these sources and the NRC license number or current,

un - redacted Agreement State license for each entity who took possession of these sources from you.

Please provide this information in response.

Please also include a copy of the most recent leak test results for each of the sealed sources that you transferred for disposal. Your leak test results must include all the information required by 10 CFR 35.2067(a).

6. The "inventory" page in the letter, dated January 25, 2019, was incomplete because many of the sources shown did not have all the information required by 10 CFR 35.2067(b).

Also, the second column of this page, dated January 25, 2019, has a header of "source description and lot number." 10 CFR 35.2067 does not mention "lot numbers" for sealed source records. Please explain what is meant by "lot numbers" and provide instead the information required, i.e., model numbers, serial numbers, etc.

7. Please also include a copy of the most recent leak test results for each of the sealed sources that you transferred to one of your other licensed facilities. Leak tests should be taken prior to such transfers to ensure that removable contamination, if found, is not spread. Your leak test results must include all the information required by 10 CFR 35.2067(a).
8. Please provide a copy of the final waste disposal records that page 1 of your letter states is documented in your "Syntrac Hot lab Management System" for "old radioactive waste sharps and non-sharps." These records must include all the information required by 10 CFR 35.2092. Please only send the final waste disposal records.

Your final disposal of short-lived materials in 10 CFR 35.100 and 35.200 should be included, as well as your final disposal of materials in 10 CFR 35.300, including, but not necessarily limited to, iodine-131.

9. Please specify what your action levels were for each type of survey performed, wipe tests and exposure rates. Please specify whether there were any spills, lost sources or contamination identified at this location historically.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 13-13144-02
Docket No. 030-09928

Enclosure:

Amendment No. 51