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

MAR 0 6 2018

Nita Gerig, M.D.
Radiation Safety Officer
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601

Dear Dr. Gerig:

We have reviewed your letter dated January 22, 2018, requesting the release for unrestricted use of the areas where materials in 10 CFR 31.11 were used at your facilities and find that we will need additional information to complete our review.

Please prepare a written response that completely and concisely covers all of the items below, as appropriate, and submit it within 15 days of the date of this letter, by March 21, 2018, or contact me to make alternative response time arrangements. Please mark your written response to my attention at the address shown at the top of this letter and reference it as "additional information to control number 602283."

Please submit this information as one complete, written response that is currently dated and signed by a senior management official for this license. This will help ensure that your response is processed correctly in our offices. Please explicitly identify your license with the information contained in an NRC Form 3 or an equivalent "business-style" letter, as you would for any amendment request.

We are sending this letter in regular mail to you, Dr. Gerig, and we are also transmitting a copy to your designated point of contact for this request, Brett L. Colter, at bcolter@sbmf.org.

Mr. Colter signed the original amendment request letter dated January 22, 2018, as "Asst. to the Radiation Safety Officer," which is a position we are unfamiliar with for your license.

10 CFR 35.12(a) requires that a senior management official sign all licensing correspondence (at least the initial request). In that request, a point of contact may be named for us to reach out to for additional information, as needed.

If this is what you intended for this request, please have a senior management official sign your response letter to this request for additional information letter (RFAI) and state that you want Mr. Colter to serve as the point of contact. His contact information is already given in the January 22, 2018, letter and need not be resubmitted in this instance.

If you have any questions or comments concerning this amendment, please contact me at (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov but please do not transmit your response via email or PDF. Faxing it directly to the number above is quickest. Do not email your response to me and do not transmit your response by more than one means of transmission as doing so will create delays and inhibit our processing of the response.

As you know, we cannot authorize licensees to release the "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

Your license amendment must be completed first before you can be approved to release the "areas of use" from licenses for unrestricted use (even by other staff members).

The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc. and unsealed materials, spills, and contamination.

When your remaining unsealed iodine-125 in vitro kit waste materials reach their disposition date please include the final records for any waste materials transferred or disposed of, pursuant to 10 CFR 35.2092.

Do not submit all historical records of waste disposal; only submit the final records for transfer or disposal, to support the assertion that the facilities contain no residual radioactive materials in any form.

Your letter indicates that you are holding for decay-in-storage remaining iodine-125 in vitro kit waste materials until they reach their final disposition date of July 6, 2019. However, your letter does not indicate where these materials are being stored, what the shielding and security of the materials are. Please provide this information in your response also.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; and NUREG 1757, Vol. 1, Rev. 2 at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/.

The final status surveys that you submit to us should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. We noted that some of the information below was provided in your letter but some of it was not.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/

Please submit the following information with your close-out survey:

a. Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate. Specify type of surface surveyed (floor, countertop, doorhandle, sink, etc.) and at what distance, if exposure rate surveys.

   Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Please use traditional units only. Gross results and/or net results should be stated and described appropriately. Please do not use "counts per minute" as units as they are meaningless for the purposes of this survey.

b. The name of the person(s) performing the survey.

c. The date(s) the survey was performed.

d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. Include manufacturer's names and model numbers to ensure clarity.

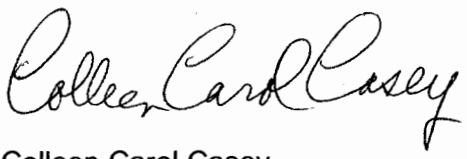
e. Background measurements for both exposure rate surveys and wipe test surveys and each instrument's efficiency or correction factor.

f. The date(s) that the survey instrument(s) were last calibrated. Please do not state when the instrument(s) are "due" to be calibrated in the future as this is not meaningful information. Please do state when the instrument(s) were last calibrated.

g. The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken, including re-testing results. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-00670-04
Docket No. 030-01582
Control No. 602283

Cc:

Brett L. Colter
bcolter@sbmf.org