



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

JUL 15 2021

Mark L. Gates, M.D.
Radiation Safety Officer
Saint Francis Medical Center
211 Saint Francis Dr.
Poplar Bluff, MO 63703

Dear Dr. Gates:

In letters dated June 20, 2019, July 16, 2019, August 27, 2019 and April 9, 2021, Black River Medical Center (BRMC), now known as Saint Francis Outpatient Center – Poplar Bluff, submitted to the U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to Direct License Transfer of NRC Materials License No. 24-32383-01.

BRMC erroneously included in these documents a request to merge its separately licensed location of use concurrently into the SFMC license, which was not possible. This is because no termination for BRMC was requested in these documents and an NRC licensed location can only be under one license at a time. As requested above, the BRMC licensed location would have been under two separate licenses at the same time, which was not possible.

NRC has consented to the change of ownership and control for NRC Materials License No. 24-32383-01 in separate correspondence.

No changes to the SFMC license resulted from this change of ownership so no amendment to your license was warranted or made at this time.

Our enclosed "Summary of Review" should explain what transpired and how it has been resolved.

We are in receipt of your request to change your Radiation Safety Officer (RSO) under control no. 624756. We expect to complete this review within 30 days of the date of this letter or by August 15, 2021.

Therefore, there is no amendment enclosed with this letter.

This letter serves to document our administrative closure of your request under control no. 613610, which has been voided (taken out of our pending amendment database) as no changes to your license were appropriate or possible.

We understand that BRMC, now known as "Saint Francis Outpatient Center – Poplar Bluff," has decided to terminate its NRC license. We are reviewing that under control no. 623315. This termination will also have no effect on the license for SFMC so the only pending request we will have after this is the proposed RSO change under control no. 624756, which is unaffected by the voiding of control no. 613610.

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.

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>.

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-c/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,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-00158-03
Docket No. 030-02269

Enclosure:

Summary of Review
For Change of Control
For BRMCI

**SUMMARY OF REVIEW
FOR CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
24-32383-01, BLACK RIVER MEDICAL CENTER AND NON-MERGER INTO MATERIALS
LICENSE NUMBER 24-00158-03, ST. FRANCIS MEDICAL CENTER**

DATE: July 15, 2021

DOCKET NOS.: 030-36211/030-02269

LICENSE NOS.: 24-32383-01/24-00158-03

CONTROL NOS.: 614077/613610

LICENSEE: Black River Medical Center/St. Francis Medical Center

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

Black River Medical Center (BRMC) is authorized by NRC License 24-32383-01 for the possession and use of sealed and unsealed forms of byproduct material for the medical diagnosis and treatment of humans. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed requests for consent to a complete and direct license transfer of control submitted by Black River Medical Center that resulted from the purchase of assets of Black River Medical Center St. Francis Medical Center (SFMC).

SFMC is authorized by NRC License 24-00158-03 for the possession and use of sealed and unsealed forms of byproduct material for the medical diagnosis and treatment of humans.

It should also be noted that this review was originally assigned to another reviewer previous to reviewer completing the licensees' requests.

The first correspondence received for this review were letters dated June 20, 2019 (ML19189A345) and July 16, 2019 (ML19198A103), given control no. 613610 for SFMC. The requests were for a change of control and ownership that BRMC planned for August 2019 stemming from the purchase of assets of BRMC by SFMC.

The letter dated June 20, 2019 (ML19189A345) was also controlled in for BRMC under 614077.

These letters requested that the BRMC location of use be merged into the SFMC license as a result of the sale of BRMC and acquisition into SFMC. Since each facility had separate licenses and no termination of the license for BRMC was requested at that time, either implicitly or explicitly, such a merger was not possible.

It was later learned by the reviewer that BRMC closed on August 9, 2019 and SFMC assumed ownership of it on August 12, 2019, the date of purchase.

The documents received by NRC contained incomplete information, incomplete or incorrect signatories and requested changes to the BRMC license that were not appropriate or possible.

Additional letters dated August 27, 2019 (ML19246A086), and April 9, 2021 (ML21102A199) were added to BRMC's request under 614077.

Many other email and telephone communications between the reviewer and licensee representatives took place on various dates between 2019 and 2021 to sort out this review. These dates and contacts included, but were not limited to, December 12, 2019, March 10, 2020, March 16, 2020, May 8, 2020, and April 5, 2021. Licensee representatives who communicated with the reviewer included Rebecca Eyler, Radiology Director for SFMC; Gwen Long, Lead Nuclear Medicine Technologist for SFMC; Gail Allen, QC Technologist and Regulatory Affairs for SFMC; Ginnie Ginathan, Director of Imaging, SFMC; Christie Derarrnan, Practice Manager, Imaging Center for Saint Francis Outpatient Center of Poplar Bluff (the new, temporary name given to BRMC in late 2019); Patricia Pyland, Assistant Manager, Imaging Center for Saint Francis Outpatient Center of Poplar Bluff; and Walter Kopecky, Ph.D., consultant for both BRMC and SFMC.

It should also be noted that some of the documents transmitted to NRC were mailed as hard copies and others were faxed. All documents referenced both NRC licenses and many contained duplicative information.

The reviewer noted that the correct way to have requested this change of ownership and control would have been to leave the license for SFMC out of consideration, as the separately licensed facility and program for BRMC could not be merged into the SFMC license. No licensing action should have been initiated for SFMC, given the information provided at that time.

In addition, the change of ownership affected the license for BRMC only. The only effect that SFMC should have had on the change of ownership request and process was as the new owner and its being a known entity, which negated the need for a pre-licensing site visit, which is discussed further below.

There was considerable confusion and misunderstanding among the licensees' representatives and the NRC reviewer regarding the licensee's intentions and expressed requests, which did not align well. Ultimately, these issues have been addressed and resolved, permitting NRC to consent to the change in ownership and control of the license for BRMC.

BRMC concluded that, by late 2019, it did not generate sufficient nuclear medicine business at the BRMC licensed location to justify continuation of the active practice and license there. Licensee representatives contacted NRC for discussions as to their options at that point. The reviewer sent BRMC representatives requested detailed information in an email on May 6, 2020, concerning the decommissioning for termination of their license for subsequent telephone discussions.

BRMC ultimately decided to terminate its NRC license, which is being reviewed under control no. 623315 for letters dated September 30, 2020 (ML20281A560) and April 9, 2021 (ML21102A199). The termination of the BRMC license will be finalized within 30 days of the date of this amendment changing the ownership and control.

The original change of ownership request for BRMC was posted to the NRC's website for comment on September 5, 2019, and taken down 30 days later on October 5, 2019, with no comments having been received.

As there was no impact of the change of ownership BRMC experienced on the license for SFMC, control no. 614077 was voided on July 15, 2021.

The change of ownership was consented to for BRMC, now named "Saint Francis Outpatient Center of Poplar Bluff," in Amendment No. 11 on July 15, 2021.

Although BRMC did not explicitly identify its requests as a direct transfer of ownership and control, NRC staff considered that the requests implicitly constituted a complete direct transfer of ownership and control.

The direct transfer of control is described in the Agency Documents Access and Management System (ADAMS) accession numbers provided throughout this document.

BRMC's requests and correspondence were reviewed by NRC staff and considered to constitute a request for consent to direct changes in control of a 10 CFR Part 30 license, using the guidance in NUREG 1556, Volume 15, Rev. 1, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016.

The NRC staff finds that the information submitted by Black River Medical Center sufficiently describes and documents the transactions that took place and the commitments made by Black River Medical Center

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the requests and correspondence identified throughout this document and finds that the direct change in control was in accordance with the Act.

The staff finds that Black River Medical Center remained qualified to use byproduct material for the purposes requested, and continued to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing System (WBL), and ADAMS, Black River Medical Center has been an NRC licensee since March 27, 2002. The NRC conducted an inspection of Black River Medical Center on May 17, 2018, and no violations were identified during this inspection. The commitments made by Black River Medical Center indicate and/or state that Black River Medical Center License No. 24-32383-01:

- A. would not change the radiation safety officer listed in the NRC license;
- B. would not change the personnel involved in licensed activities;
- C. would not change the location, facilities, and equipment authorized in the NRC license;
- D. would not change the radiation safety program authorized in the NRC license;
- E. has changed the organization's name listed in the NRC license; and

F. would keep regulatory required surveillance records and decommissioning records.

As a result of this transaction, SFMC owns and operates this facility. Since BRMC and SFMC are both active NRC licensees, SFMC is a known entity for security purposes, following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," January 1, 2019, revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants, or NRC licensees transferring control of licensed activities, that the licensed material will be used for its intended purpose and not for malevolent use.

Black River Medical Center is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 24-32383-01.

REGULATORY FRAMEWORK

Black River Medical Center's License No. 24-32383-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the change in control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15, Rev. 1, June 2016. As discussed in NUREG-1556, Volume 15, NRC is generally using the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed.

The Black River Medical Center's requests for consent describe a complete, direct change of control resulting from the SFMC's purchase of Black River Medical Center. As such, the transfer required NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in Agency Documents Access and Management System (ADAMS) accession numbers associated with the letters and correspondence referenced throughout this document. Since the transaction date of August 12, 2019, Black River Medical Center, has continued as the licensee and remains in control of all licensed activities under Materials License No. 24-32383-01, as described above. The NRC staff finds that the requests for consent adequately provide complete and clear descriptions of the transaction, and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15, Rev. 1, June 2016.

TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Black River Medical Center sufficiently describes and documents the commitments made by Black River Medical Center and SFMC and is consistent with the guidance in NUREG-1556, Volume 15, Rev. 1, June 2016.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(xi).

CONCLUSION

The staff has reviewed the requests for consent submitted by BRMC with regard to a complete direct change of control of byproduct materials license No. 24-32383-01 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the licensee and commitments; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they have and will maintain the existing records; and, in the future, will abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15, Rev. 1, June 2016.

Therefore, the staff concludes that the proposed change in control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.