



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

December 6, 2021

Patrick J. Morello, M.D.
Radiation Safety Officer
Capital Region Physicians –
Central Missouri Cardiology
3501 A West Truman Blvd
Jefferson City, MO 65109

Dear Dr. Morello:

Enclosed is Amendment No. 11 to your NRC Material License No. 24-00158-03 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.

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.

By letters dated November 23, 2020 (ML20339A448), December 28, 2020 (ML21006A224) and April 8, 2020 (ML21099A232), Central Missouri Cardiology, P.C. (CMC), now known as "Capital Region Physicians – Central Missouri Cardiology," submitted to the U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to Direct License Transfer of NRC Materials License No. 24-32441-01.

Based on the information you provided, we understand that, as a result of the sale of the assets of CMC to Capital Region Medical Center, control of CMC was directly transferred on December 31, 2020. We further understand that this transfer has not resulted in any change to the licensed materials, persons using the licensed material, location of use of licensed material, or persons responsible for the licensee's radiation safety program. The licensee's name has now changed from "Central Missouri Cardiology, P.C." to "Capital Region Physicians – Central Missouri Cardiology."

Based on the above understandings and, as more fully detailed in the enclosed NRC staff's Summary of Review for Change of Control, which documents the NRC staff's review of the request, we have no objection to the transfer.

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-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,

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

Colleen Carol Casey
Materials Licensing Branch

License No. 24-32441-01
Docket No. 030-36211

Enclosure:

Summary of Review
For Change of Control
For CMCI

**SUMMARY OF REVIEW
FOR CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
24-32441-01, CENTRAL MISSOURI CARDIOLOGY, P.C.**

DATE: December 6, 2021

DOCKET NO.: 030-36211

LICENSE NO.: 24-32441-01

CONTROL NO.: 623927

LICENSEE: Central Missouri Cardiology, P.C.

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

Central Missouri Cardiology, P.C. is authorized by NRC License 24-32441-01 for the possession and use of sealed and unsealed forms of byproduct material for the medical diagnosis 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 Central Missouri Cardiology, P.C. ("CMC") that resulted from the purchase of assets of CMC by Capital Region Medical Center (CRMC).

CRMC is authorized by NRC License 24-12699-01 for the possession and use of sealed and unsealed forms of byproduct material for the medical diagnosis and treatment of humans.

The first correspondence received for this review was a letter dated November 23, 2020, (ML20339A448) under control no. 623927. The letter stated that it was requesting a name change for the license only and the proposed name included the full name of CRMC.

The reviewer contacted the licensee in a letter requesting additional information dated December 16, 2020. The licensee's response stated that a change in ownership/control was, in fact, taking place. The response letter dated December 28, 2020 (ML21006A224) expanded on the planned transaction and added some details. The proposed new name was changed to "Capital Region Physicians – Central Missouri Cardiology ("CRP-CMC")," and CRMC's name was removed. The change in ownership was scheduled to take place on December 31, 2020.

A third letter dated April 8, 2020 (ML21099A232) contained additional information about the transferor, CMC, and the transferee, CRMC – CRP.

There were several telephone calls and emails exchanged between Ms. Arla Qualls, RN-Director, Capital Region Physicians – Central Missouri Cardiology and the reviewer to discuss and clarify some questions concerning the transaction. These issues have been addressed and resolved, permitting NRC to consent to the change in ownership and control of the license for CRP-CMC.

The original change of ownership request for CMC was posted to the NRC's website for comment on January 6, 2021, and taken down 30 days later on February 6, 2021, with no comments having been received.

Although CMC 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.

CMC's requests 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 Central Missouri Cardiology, P.C. sufficiently describes and documents the transactions that took place and the commitments made by Central Missouri Cardiology, P.C., as well as by CRMC.

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 CMC 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, CMC has been an NRC licensee since February 20, 2003. The NRC conducted an inspection of CMC on October 12, 2018, and no violations were identified during this inspection, excepting violations of 10 CFR 35.60 and 35.63, which were non-cited due to discretion afforded by Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages."

The commitments made by CMC indicate and/or state that CMC License No. 24-32441-01:

- 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 to "Capital Region Physicians – Central Missouri Cardiology"; and

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

As a result of this transaction, CRMC owns and operates this facility. Since CRMC and CMC are both active NRC licensees, CRMC 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.

CMC is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 24-32441-01.

REGULATORY FRAMEWORK

CMC's License No. 24-32441-01 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 CMC's requests for consent describe a complete, direct change of control resulting from the CRMC's purchase of CMC. 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 December 31, 2020, CMC has continued as the licensee and remains in control of all licensed activities under Materials License No. 24-32441-01, as described above. The NRC staff finds that the requests for consent adequately provide complete and clear descriptions of the transaction and are 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 CMC sufficiently describes and documents the commitments made by CMC and CRMC 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 CMC with regard to a complete direct change of control of byproduct materials license No. 24-32441-01 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.