

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE RD. SUITE 210 LISLE, IL 60532-4352

September 3, 2022

Ramon Raneses, M.D. Radiation Safety Officer Regional Cardiology Associates, P.L.C. 3399 Pollack Rd. Grand Blanc, MI 48439

## SUBJECT: REGIONAL CARDIOLOGY ASSOCIATES, P.L.C., REQUEST FOR WRITTEN CONSENT TO DIRECT LICENSE TRANSFER

Dear Dr. Raneses:

By letter dated April 11, 2022, signed by Vuong DuThinh, M.D., F.A.C.C., and Abdulfatah Osman, M.D., Medical Director, Genesys Heart Center, with additional and clarifying information being provided in the letter dated July 14, 2022, signed by Ramon Raneses, M.D., F.A.C.C., President; and Jennifer Cobb, V.P. Operations, Ascension Medical Group, Regional Cardiology Associates, P.L.C., submitted to the U.S. Nuclear Regulatory Commission (NRC) a request for written consent to an direct transfer of control of U.S. NRC Materials License Number 21-32298-01. In accordance with Section 184 of the Atomic Energy Act of 1954, as amended (AEA), and Title 10 Code of Federal Regulations (10 CFR) §30.34, the U.S. NRC consents to the transfer.

Regional Cardiology Associates, P.L.C., is authorized by the U.S. NRC to possess and use byproduct material under 10 CFR Part 30. By letter dated April 11, 2022, Regional Cardiology Associates, P.L.C., requested written consent to the direct transfer of control of its license from the U.S. NRC. Because the license was issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," the U.S. NRC must find that the transfer is in accordance with the provisions of the AEA and, if so, must give its consent in writing prior to the transfer, in accordance with Section 184 of the AEA and 10 CFR §30.34(b). Additionally, the U.S. NRC staff reviewed the direct transfer of control request using the guidance in U.S. NRC NUREG-1556, Volume 15, Revision 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.

10 CFR §30.34(b) states:

(1) No license issued or granted pursuant to the regulations in [parts 30] 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.

(2) An application for transfer of license must include:

- (i) The identity, technical and financial qualifications of the proposed transferee; and
- (ii) Financial assurance for decommissioning information required by [10 CFR] §30.35.

As described in ADAMS Accession Numbers ML22111A276 and ML22210A051, the direct transfer of control will result from an Asset Purchase Agreement as part of a practice acquisition. The acquired practice will operate as a subsidiary of Ascension Medical Group Michigan, d/b/a Ascension Medical Group, under the new legal name, Ascension Genesys Heart Center. Regional Cardiology Associates, P.L.C., will remain in existence with no changes in the membership or other ownership interests in Regional Cardiology Associates, P.L.C. The U.S. NRC staff finds that the licensee request adequately provides a complete and clear description of the proposed transaction, consistent with 10 CFR §30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1. The sufficiency of the description is evaluated below.

The request for a direct transfer of ownership was posted for public comment on the U.S. NRC website for 30 days in accordance with 10 CFR Part 2, Subpart M, and as described in the U.S. NRC's Regulatory Issue Summary 2014-08, Revision 1. No comments were received from members of the public.

In the request for a direct transfer of control, Regional Cardiology Associates, P.L.C., provided information regarding its current decommissioning funding plans. Based on the information provided, Regional Cardiology Associates, PLC, is not required to have financial assurance for decommissioning because of the types and amount of material authorized in its license. The U.S. NRC staff finds that the licensee's request adequately provided information for financial assurance for decommissioning, consistent with 10 CFR §30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1.

Further, the U.S. NRC conducted an inspection of Regional Cardiology Associates, P.L.C., on April 18, 2022, at the licensee's facility in Grand Blanc, Michigan, in which no violations were identified.

Additionally, as described in its request, Ascension Medical Group Michigan, d/b/a Ascension Medical Group, commits that it:

- A. will not change the radiation safety officer listed in the U.S. NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the U.S. NRC license;
- D. will not change the radiation safety program authorized in the U.S. NRC license; and
- E. will keep regulatory required surveillance records and decommissioning records.

Based on these commitments, the U.S. NRC staff finds that the licensee request adequately documents the constraints, license conditions, requirements, representations, and commitments made by the transferee, consistent with 10 CFR §30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1.

Ascension Medical Group Michigan, d/b/a Ascension Medical Group, is considered a known entity for security purposes. U.S. NRC staff used the guidance provided by the U.S. NRC's Office of Nuclear Material Safety and Safeguards' "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the application," January 29, 2019 revision. The purpose of this checklist is for the U.S. NRC to obtain reasonable assurance from new license applicants or U.S. NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use. Therefore, for security purposes, Ascension Medical Group Michigan, d/b/a Ascension Medical Group, is considered a known entity because it is the Parent Company of Eastside Cardiovascular Medicine, PC, which holds U.S. NRC Materials License No. 21-26263-01, authorizing the possession of byproduct material for diagnostic procedures.

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c)(21).

The staff has reviewed the request for a direct transfer of control of U.S. NRC Materials License Number 21-32298-01. The U.S. NRC staff finds that the direct transfer of control is in accordance with Section 184 of the AEA and 10 CFR §30.34(b) and consents to the transfer. Please note that you will need to notify us promptly, in writing, after the transaction has been finalized and include a signed copy of the merger agreement confirming completion of the transaction. If this planned merger has not been consummated within 30 days of the date of this letter, please notify us in writing.

Future changes in the licensee's name, licensed use, licensed materials, licensed location, persons responsible for licensed material, or other changes to the corporate organizational structure require submission of a request to amend the license or a request to transfer the license. U.S. NRC approval must be received prior to implementation of any such proposed change.

In accordance with 10 CFR §2.390, a copy of this letter will be available electronically for public inspection in the U.S. NRC's Public Document Room or from the Publicly Available Records component of the U.S. NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the U.S. NRC website at: <u>https://www.nrc.gov/reading-rm/adams.html</u>. If you have any questions regarding this letter, you may contact Jason M. Kelly, MPH, Health Physicist, at (630) 829-9737 or via electronic mail at Jason.Kelly@nrc.gov.

Sincerely,

Jason M. Kelly, MPH Health Physicist Materials Licensing Branch

License No. 21-32298-01 Docket No. 030-35626 Control No. 630748