



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

July 7, 2022

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

Dear Dr. Raneses:

I have reviewed the 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, providing notification of a pending transfer of control of licensed operations under U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-32298-01.

The U.S. NRC's guidance document applicable to your request, which I refer to as "the guidance" elsewhere in this document is 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. This guidance is available on the U.S. NRC's website at:

<https://www.nrc.gov/docs/ML1618/ML16181A003.pdf>

1. Appendix E, "Information Needed for Transfer of Control Application," of the guidance identifies the information needed to evaluate a proposed transfer of control application. Your application provided much of the information from this appendix.

The following items were either not addressed or lacked adequate detail:

- Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.
- Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.
- Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
- Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.

Additional items in this letter provide additional detail about the information needed to support the evaluation of the proposed change of control. Further information regarding completion of the license application may be found in Section 5, "Change of Control," of the guidance.

2. Section 5.1, "Description of Transaction," of the guidance specifies that a complete and clear description of the transaction must be provided.

The description should include all of the following as applicable:

- Identification of any changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members of Board of Directors, etc.;
- The new legal name of the licensed organization;
- New licensee contact and telephone number(s) to facilitate communications; and
- Pre- and post-transaction organizational chart showing the corporate structure of the license holder and its parent companies, if any.

Upon review of the description of the proposed transaction, it appears that *REGIONAL CARDIOLOGY ASSOCIATES, PLC*, (transferor) will be purchased by *ASCENSION MEDICAL GROUP MICHIGAN d/b/a Ascension Medical Group* (transferee) and will operate under the auspices of its subsidiary *ASCENSION GENESYS HEART INSTITUTE* under the legal name of *ASCENSION MEDICAL GROUP GENESYS HEART CENTER*.

A check with the Michigan Licensing and Regulatory Affairs' Corporations Division was not successful in verifying the active registration of *ASCENSION MEDICAL GROUP GENESYS HEART CENTER*. Please indicate when *ASCENSION MEDICAL GROUP GENESYS HEART CENTER* will be registered.

In addition, please provide a pre- and post-transaction organizational chart showing the corporate structure of the license holder and its parent companies, if any. If there are any changes in the reporting relationship of the Radiation Safety Officer to management, please also illustrate those changes and provide an updated Delegation of Authority as applicable.

3. Section 5.3, "Changes of Location, Equipment and Procedures," and Section 5.4, "Surveillance Records," of the guidance identify that the transfer of control consent request should also provide the status of the following:
 - licensee's facilities, equipment, and radiation safety program; and
 - all applicable surveillance requirements and records.

The request identified that there will be no changes in location, equipment and procedures and that the surveillance program is in compliance with the regulations and requirements and all programs will remain the same at the time the control is transferred.

Your response did not provide adequate detail. Please also describe the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records as applicable.

4. Section 5.5, "Decommissioning and Related Records Transfers," of the guidance identifies that prior to approval of a transfer of control, licensees must arrange for the transfer and maintenance of records important to the decommissioning of facilities involved in licensed activities (e.g., leak test results and transfer/disposal records). Further, the transferee must confirm, in writing, that they accept full responsibility for the decommissioning of the site, including any contaminated facilities and equipment.

While the request indicates that licensed operations will continue following proposed corporate transaction, this is not an adequate description because it does not describe the transfer and maintenance of records important to decommissioning.

As a minimum, the request should address the following:

- the statement, "Pursuant to 10 CFR §30.35(g), we shall maintain drawings and records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred; or we will transfer the records to the appropriate NRC regional office before the license is terminated;"
- description of the method and proposed timetable for the transfer of required records,
- a commitment by the transferee to maintain the records received from the transferor; and
- an agreement to perform a survey confirming that the facility is free of contamination or an agreement by the transferee to accept the facility "as is" on the date of transfer.

Please resubmit your request addressing all applicable items from Section 5.5 of the guidance, including those identified above. For additional information and guidance, please refer to Section 5.5 and Appendix E, "Information Needed for Transfer of Control Application," of the guidance.

5. Section 5.6, "Transferee's Commitment to Abide by the Transferor's Commitments," must either commit to abide by all constraints, license conditions, requirements, representations and commitments identified in and attributed to the existing license or provide a description of its own program to comply with the license and all applicable regulations.

The request identified that Genesys Heart Center will abide by all constraints, conditions, requirements, and commitments of the licensed program.

Please confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions. Further, please confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made 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 <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your application, please submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if no response is received within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at (630) 829-9737 or Jason.Kelly@nrc.gov.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

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