



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

June 29, 2023

Carmen R. Kmety-Stevenson, Ph.D.
Radiation Safety Officer
Methodist Hospital of Gary, Inc.
8701 Broadway
Merrillville, IN 46410

SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED DECEMBER 19,
2022, FOR METHODIST HOSPITAL OF GARY – INC., NRC LICENSE NO.
13-16558-01

Dear Carmen R. Kmety – Stevenson, Ph.D.:

This letter concerns the request in a letter dated December 19, 2022 (ML22354A228) to amend your U.S. Nuclear Regulatory Commission (NRC) License No. 13-16558-01 to add Sudheer Paruchuri, M.D. as an Authorized User for iodine-131 therapy; authorization for Lutetium-177 Pluvicto; and authorization for Germanium-68/Gallium-68 generators. The requests in this letter were assigned control no. 633911.

On January 31, 2023, I sent you a detailed email stating that the referenced license provided for Dr. Paruchuri did not authorize him, or the license at all, for the use of sodium iodide I-131 therapy under 10 CFR 35.300; I was checking into whether the Lu-177 Pluvicto was already authorized under 10 CFR 35.300; and there was no supporting information provided for the Ge-68/Ga-68 generators to be added, as per 10 CFR 35.1000, Emerging Medical Technologies and guidance for same.

We had a telephone call on January 31, 2022, to discuss the items above and you asked if you could add another proposed Authorized Use (AU) for the use of Ra-223 Xofigo only. We discussed what would be required to add a new AU for Xofigo and I requested a written response by March 3, 2023.

On March 6, 2023, we received your letter dated March 3, 2023. You submitted a copy of a different license to support Dr. Paruchuri's request to use I-131; I had confirmed for you that Lu-177 Pluvicto was already authorized under 10 CFR 35.300 so no amendment was needed for that; you stated that you did not want to pursue obtaining the Ge-68/Ga-68 generators anymore; and you provided the name and medical specialty board certificate for the proposed Xofigo AU but directed us to not consider it at this time as more information was needed.

On March 9, 2023, I sent you an email requesting additional information for Dr. Paruchuri because, although the referenced license authorized him for the I-131 use requested, it was from 2015, more than 7 years prior to the date of your amendment request. So I asked for

C. Kmety-Stevenson

documentation to support the request that complied with 10 CFR 35.59, "Recentness of Training."

On March 23, 2023, you emailed me that Dr. Paruchuri was not able to provide the requested documentation so you were withdrawing that last piece of your original request.

We have withdrawn this amendment request and subsequent responses without prejudice to resubmission at a later date.

This amendment request letters are available electronically from the Agencywide Documents Access and Management System (ADAMS).

This letter only serves to advise you that we have administratively closed out control no. 633911.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room (PDR) or from ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact me at 630-829-9841 or colleen.casey@nrc.gov.

Sincerely,

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 13-16558-01
Docket No. 030-11234
Control No. 633911