



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

September 5, 2018

Christopher J. Conlin, M.D.
Radiation Safety Officer
McLaren - Flint
401 S Ballenger Hwy.
Flint, MI 48532

Dear Dr. Conlin:

In letter dated July 2, 2018, McLaren - Flint submitted to the U.S. Nuclear Regulatory Commission (NRC) a request to authorize the use of yttrium - 90 on NRC license no. 21-04171-04. After review of the request, we have noted that additional information is needed to complete our review. Specifically, as I and Ms. Tracy King discussed on September 4, 2018, please provide the following information:

- A. Please provide a commitment to follow all the requirements in Title 10 of the *Code of Federal Regulations* (CFR) Part 35 for brachytherapy sources and manual brachytherapy use as stated on page 7 of the NRC guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and Sir-Spheres Licensing Guidance", dated February 12, 2016, Revision 9.
- B. Please revise your commitment regarding Written Directives to contain information that the modifications to the written directive will include the reason for not administering the intended dose or activity, the date, and the signature of an Authorized User for yttrium-90 microspheres as stated on page 8 of the NRC guidance.
- C. In your letter dated July 2, 2018, you provided documentation of qualifications for Rod Golovoy, M.D. to use yttrium-90 TheraSpheres:
 1. During verification of the American Board of Radiology certification, we learned that Dr. Golovoy's certification in diagnostic radiology and interventional radiology is inactive. Please explain the discrepancy and provide current certifications.
 2. Please provide a statement that Dr. Golovoy completed 80 hours of classroom and laboratory training for byproduct material, including yttrium-90 microspheres (provide location and dates) in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity and radiation biology.

C. Conlin

- 2 -

- D. Please provide a statement that Christopher J. Conlin M.D. and Rod Golovoy, M.D. will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative. Additionally, please commit that you will submit the documentation from the manufacturer to the NRC Region III Office within 30 days of when these three patient cases have been satisfactorily completed. Please refer to page 5 of the guidance, "Training and Experience Documentation."
- E. Based on our discussion with Ms. Tracy King on September 4, 2018, we understand that you are requesting to remove Tomy Paul Kalapparambath, M.D. from license no. 21-04171-04 as an authorized user.

Please provide a written response to this letter by September 18, 2018. Your response should be signed and dated by an authorized personnel. You may submit your response via email to Magdalena.Gryglak@nrc.gov. Please reference control no. 609372 in your response.

We will resume our review once we receive your response. If you have any questions, please do not hesitate to contact me at 630-829-9875 or Magdalena.Gryglak@nrc.gov.

Sincerely,



Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 21-04171-04
Docket No. 030-02048
Control No. 609372

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Wednesday, September 05, 2018 8:24 AM
To: 'tking@mpcphysics.com'
Subject: Request for Additional Information, NRC license no. 21-04171-04, McLaren-Flint
Attachments: 609372 Request for Additional Information.pdf

Good morning Mr. King,

As we discussed yesterday, please see the attached Request For Information.

Thank you

Magdalena R. Gryglak
U.S. NRC Region III
630-829-9875