Trinity Health

Trinity Health Muskegon Hospital

December 29, 2023

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Additional information for Amendment request, dated 12/6/2023, to License No. 21-02187-01, Trinity Health Muskegon Hospital.
MAIL CONTROL NUMBER: CN 638180

This letter is in response to your request, dated 12/21/2023, for additional information.

1. Team Approach
   We shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

2. Notification
   We request authorization to notify the NRC, in the future, that we are permitting an Authorized User (AU) to work at our facility without requesting an additional license amendment when the following conditions are met:
   a. the AU satisfies the T&E listed in this licensing guidance for Y-90 microspheres; and
   b. the AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master materials licensee, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master materials license broad scope permittee; and
   c. the licensee provides the NRC a copy of the license or permit on which the AU is listed for the specific Y-90 microsphere use; and
   d. the licensee provides the NRC documentation of the completion of three patient cases if previously not submitted to the NRC; and
   e. the licensee provides documentation of the above listed conditions to NRC for each AU no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of Y-90 microsphere.

3. Medical Event Reporting
   A medical event will be reported:
   a. when the total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed, even if the

administration of byproduct material does not result in a dose that that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; or

b. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

If you have any questions regarding this matter, please contact me at Dale.Schippers@trinity-health.org or 231-672-3339.

Sincerely,

Dale Schippers

Dale Schippers, MS, DABR
Radiation Safety Officer, Trinity Health Muskegon Hospital

Martha Pavon

From: Laura Cender
Sent: Wednesday, January 3, 2024 12:12 PM
To: Martha Pavon
Cc: Sandy Pavon; Tammy Tomczak
Subject: File for ADAMS - Trinity Health Muskegon Hospital, CN 638180
Attachments: 665 638180 Response to Request for Additional Information.pdf; 638180 Response to Request for Additional Information.pdf

Hello,

Please see the attached file to be added to ADAMS for CN 638180, Trinity Health Muskegon Hospital.

Thanks,
Laura

Laura Cender
Pronouns: She/Her
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
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Phone: (630) 829-9712