



June 20, 2023

U.S NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352
630-829-9500

RE: Response to Request Additional Information for NRC Materials License No. 13-18845-01

Below is the response as regards the email request (dated 6/2/23) for additional information regarding the request for Y-90 Therasphere AU additions and policy and procedure updates.

1. In place of 10 CFR 35.3045(a), we, the licensee, shall commit to report any event, except for an event that is caused by shunting as described in the criteria below, or as a result of patient intervention, as defined in 10 CFR 35.2 as an actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration. The criteria for event reporting is:
 - the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and
 - an administration of the wrong radionuclide or type of microsphere; or
 - an administration to the wrong individual or human research subject; or
 - an administration by the wrong route of administration; or
 - an administration by the wrong mode of treatment; or
 - 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; or
 - 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 as defined in Section 6.1 when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

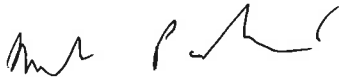
Additionally, we, the licensee, shall comply with the medical event reporting and notification

requirements as described in 10 C=FR 35.3045(b)-(g).

2. We commit that Charles Bower, M.D. and Justin J. Lightburn, M..D. will complete at least the first three hands-on patient cases with Y-90 microspheres TheraSphere in the physical presence of an authorized user (AU) who is authorized for TheraSphere permitted by 10 CFR 35.1000. The licensee will submit the written attestation that the proposed AU has satisfactorily completed the requirements in criteria A and B of the licensing guidance and is able to independently fulfill the radiation safety-related duties as an AU for Y-90 microsphere TheraSphere. The attestation will be obtained from an AU for Y-90 microsphere TheraSphere.

Please contact us with any questions or concerns.

Sincerely,



Mark Podgorski
Vice President - Operations
Goshen Health
RAML #13-18845-01

Martha Pavon

From: Frank Tran
Sent: Thursday, June 22, 2023 1:45 PM
To: Martha Pavon
Cc: Tammy Tomczak
Subject: FW: RE: Request additional information for NRC Materials License No. 13-18845-01
Attachments: Response to requested additional information for the NRC ML No. 13-18845-01.pdf; 635435 Additional information 665.pdf

Dear Martha,

Please add the attachment to ADAMS as additional information for CN 635435. Let me know if you have any question.

Thank you,

Frank

From: Lowden, John <jlowden@goshenhealth.com>
Sent: Thursday, June 22, 2023 9:28 AM
To: Frank Tran <Frank.Tran@nrc.gov>
Cc: Kelly Stoneberg <kstoneberg@ohiomedphys.com>
Subject: [External_Sender] RE: Request additional information for NRC Materials License No. 13-18845-01

Dear Frank Tran,

I have attached the additional requested information for Goshen Health, NRC Materials License No. 13-18845-01. If you have any questions, please feel free to contact me by email or by phone listed below.

Thank you

John P. Lowden
Senior Medical Physicist | Goshen Health
(574) 364-2968
200 High Park Ave., Goshen, IN 46526
GoshenHealth.com

