Community Healthcare System

COMMUNITY Hospital

July 15, 2015

Materials Licensing Branch
USNRC Region III
2443 Warrenville Road
Lisle, IL 60532-4351

RE: Amendment Request License # 13-15882-01
Mail Control No. 583899

In response to your email of July 9, 2014 regarding our request for Y-90 authorization, here is the additional information requested:

1. Ramana Yedavalli, MD and Thomas Shin, MD will each individually complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which we are requesting authorization.

Byproduct Material	**Form or Manf / Model #**	**Max. Quantity**	**Purpose of Use**
Yittrium-90	SirSpheres Sirtx	2 Ci Total	per 10 CFR 35.1000

2. The licensee will administer the Y-90 microspheres in accordance with the written directive.

   a. We confirm that pre-administration our written directive will include the patient's name as well as the date, the signature of the AU, the treatment site, the radionuclide to specifically note the physical form (Y-90 microspheres), the prescribed total dose (rad or Gy) / activity (mCi or GBq) or the statement "or dose/activity delivered at stasis" if appropriate. Additionally we will specify the maximum dose/activity that will be acceptable to the specified site(s) outside the primary treatment site due to shunting.

   b. We confirm that manufacturer's procedures will be followed:
      i. For all calculation and documentation of dose / activity to treatment site and other sites
      ii. For preparation of dosage to be administered
      iii. for performance of pre / post vial dosage measurement

   c. We confirm that post-administration, but before the patient leaves the post-procedural recovery area, the date, the signature of the AU, the total dose/activity delivered to the treatment site and other sites. If the administration was terminated because of stasis then the total dose/activity delivered to the treatment site when stasis occurred will be noted. Additionally the dose/activity delivered to the specified site(s) outside of the primary treatment site due to shunting will be noted.

3. If the Y-90 microspheres are to be placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, the licensee will:

   a) Label vials and vial radiation shields with radionuclide and form, for example, Y-90 microspheres.

   b) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure, for example, Y-90 microspheres, brachytherapy.

Please direct any questions regarding this matter to either me at 219-836-7351, email jpkatz@comhs.org.

Sincerely,

Jacqueline Katz, RT, MBA

Jacqueline Katz, RT, MBA
Director of Medical Physics
Community Healthcare System

Jacqueline P. Katz

From: Tran, Frank <Frank.Tran@nrc.gov>
Sent: Wednesday, July 09, 2014 7:42 AM
To: Santosh K. Kar
Cc: Jacqueline P. Katz
Subject: Request for additional information re: Y-90 authorization

Dear Mr. Kar:

We have reviewed your amendment request with regard to adding Y-90 microsphere's use to your license. In order to continue our review, please provide the following:

1) A statement that Ramana Yedavalli, M.D. and Thomas Shin, M.D. will individually complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought.
2) A statement that the licensee will administer Y-90 microspheres in accordance with the written directive.
3) A statement that if the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, the licensee will:
   a) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
   b) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Please provide a response in writing with an authorized signature by July 18, 2014. Please refer Mail Control No. 583899 in your response to facilitate proper handling in our office. You could scan and email the response to frank.tran@nrc.gov or fax it to 630-515-1078 (you should keep the original response for your record).

If you have any questions, please do not hesitate to contact me at 630-892-9887.

Thank you,

Frank Tran
License Reviewer
NRC Region 3/Division of Nuclear Materials Safety
Phone: 630-829-9623
Fax: 630-515-1078
Email: Frank.Tran@nrc.gov

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Copy of Email

Tran, Frank

From: Jacqueline P. Katz <Jacqueline.P.Katz@comhs.org>
Sent: Tuesday, July 15, 2014 11:05 AM
To: Tran, Frank
Subject: RE: Request for additional information re: Y-90 authorization Mail control number 583899
Attachments: NRC response Mail Control 583899 Y-90 amendment request July 2014.pdf

Mr. Tran,

Attached is our response to the request for additional information for our Y-90 authorization, mail control number 583899. Please advise if we need to provide you with any additional statements or clarification.

Thank you,

Jackie Katz
Director Radiation Oncology and Medical Physics
Community Hospital
Munster, IN
Office: 219-836-7351
Fax: 219-852-6476

From: Tran, Frank [mailto:Frank.Tran@nrc.gov]
Sent: Tuesday, July 15, 2014 8:11 AM
To: Jacqueline P. Katz
Subject: RE: Request for additional information re: Y-90 authorization

Dear Ms. Katz:

You could scan and email the response to frank.tran@nrc.gov or fax it to 630-515-1078 (you should keep the original response for your record). Please refer Mail Control No. 583899 in your response to facilitate proper handling in our office.

Thank you,

Frank Tran

From: Jacqueline P. Katz [mailto:Jacqueline.P.Katz@comhs.org]
Sent: Tuesday, July 15, 2014 7:28 AM
To: Tran, Frank
Subject: RE: Request for additional information re: Y-90 authorization

Mr. Tran,

I will get these out right away. I returned to work to day and in order to meet the deadline, can this be faxed?