

Request for Additional Information
Prime Healthcare Services – Kansas City, LLC d/b/a St. Joseph Medical Center Renewal
(CN 589393)

This RAI follows a call conducted on April 21, 2016.

NOTE: In the items below, all references to the "application" refer to St. Joseph's renewal application (ML15323A045) dated November 12, 2015, and all references to "letter" refer to St. Joseph's additional information letter dated December 22, 2015 and received via facsimile on December 23, 2015, unless otherwise indicated.

Participants:

NRC: Sara Forster, Health Physicist, Materials Licensing Branch, Region III

Applicant: Sebastiano Anzalone, Consultant Regional Health Physics Specialist, Cardinal Health, on behalf of St. Joseph's

DISCUSSION ITEMS

As discussed, we expect to receive your written response on or before May 5, 2016, under a signed and dated cover letter.

AUTHORIZED USERS:

1. As discussed, Ronald R. Weis, M.D., is currently listed on the license but not in the application. Please confirm that you wish to remove Dr. Weis from the list of Authorized Users on the above referenced license.

USE OF YTTRIUM-90 MICROSPHERES:

2. Generally, your letter referenced statements related to the use of Y-90 microspheres, as provided in the 2012 revision to NRC's guidance. As discussed, the Y-90 microspheres guidance was updated in February 2016 and is available at <http://www.nrc.gov/docs/ML1535/ML15350A099.pdf>. Please refer to that update for the current commitments suggested by the NRC for Y-90 microsphere licensees. Please either update statements made in your letter based on the 2012 guidance with the 2016 guidance or, at a minimum, add the information requested in Item 3, below.
3. Please add additional statements as discussed and as noted below and revise statements in the letter to commitments (i.e. using the term shall where unclear, etc.). Added statements should confirm the following:
 - **Concerning Training:** *[The licensee shall] 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.*
 - **Concerning Written Directives:** *If prescribed activity is used in lieu of prescribed dose [in the written directive], then activity will be used for all documentation and evaluations.*

Forster, Sara

From: Forster, Sara
Sent: Friday, April 22, 2016 2:19 PM
To: 'Anzalone, Sebastiano'
Subject: Additional Information Request re Prime Healthcare Services - Kansas City, LLC d/b/a St. Joseph Medical Center, NRC Lic. No. 24-02704-01, CN 589393
Attachments: 02240.589393.24-02704-01 RAI from 04 21 2016 call.docx

Dear Mr. Anzalone:

As discussed, please see the attached conversation record.

Please refer to NUREG 1556, Vol. 9, rev. 2, "Program-Specific Guidance About Medical Use Licenses," when preparing your response. The volume may be found at the website:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>.

Please provide additional requested information within 14 days of our conversation (on or before May 5, 2016), via a signed and dated cover letter. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely yours,

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
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