



CONVERSATION RECORD

04/10/2018

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Sharon Updike, RSO		DATE OF CONTACT 04/10/2018	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS supdike@mpcphysics.com		TELEPHONE NUMBER (734) 662-3197	

ORGANIZATION Saint Joseph Regional Medical Center	DOCKET NUMBER(S) 030-13685
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LICENSE NUMBER(S) 13-02650-02	CONTROL NUMBER(S) 602290
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SUBJECT
Additional Information Needed for Amendment Request

SUMMARY
The following additional information will be needed to approve your request for the use of yttrium-90 Theraspheres, permitted by 10 CFR 35.1000, because the information in your letter dated January 11, 2018, was insufficient to complete our review.

a. In your request you did not indicate a location where the material will be used. Please provide a written response indicating the address of the location of use where you intend to use and store the material.

b. Please include in your written response documentation the RSO has obtained the requisite training in the radiation safety, regulatory issues and emergency procedures for the proposed new type of use for which you are seeking approval. This is similar to the training described in 10 CFR 35.50(e), as modified for the emerging technology permitted by 10 CFR 35.1000, and will require a preceptor attestation.

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ACTION REQUIRED (IF ANY)
Please submit your response by April 20, 2018, and reference it to my attention as "additional information to control number 602290" to facilitate proper handling in our office. Your response must be currently dated and signed. If you have any questions or require clarification of any of the information stated above, please do not hesitate to contact me at 630-829-9607

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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NAME OF PERSON DOCUMENTING CONVERSATION
Jennifer L. Bishop

SIGNATURE

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

c. In your request, you did not provide a complete commitment on written directives. Specifically, you did not provide the following commitment:

“For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, “prescribed dose” means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity should be used for all documentation and evaluations.”

In order to complete our review, you will need to provide this commitment in writing

d. In your request, the information provided for patient release was inadequate in that it did not include a commitment to develop procedures to ensure patients are released in accordance with 10 CFR 35.75. In order to complete our review, you will need to provide the following commitment:

“The licensee commits to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.”