NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 03/01/2018

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Laura Luna	03/01/2018	☐ E-MAIL ☑ TELEPHONE
E-MAIL ADDRESS: lluna@mpcphysics.com	TELEPHONE NUMBER: (734) 662-3197	☐ INCOMING ☑ OUTGOING

ORGANIZATION	DOCKET NUMBER(S)
McLaren Oakland	030-02041
LICENSE NUMBER(S)	**CONTROL NUMBER(S)**
21-04081-03	602079

SUBJECT

Additional Information Request

SUMMARY

The following additional information will be needed to approve your request for the use of yttrium-90 SIR-Spheres, permitted by 10 CFR 35.1000, because the information in your letter dated December 14, 2017, was insufficient to complete our review.

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

2. 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.

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ACTION REQUIRED (IF ANY)

Please submit your response by March 16, 2018 and reference it to my attention as "additional information to control number 602079" 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

Jennifer L Bishop

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

3. For the request to add Dr. Adler for 10 CFR 35.1000 uses, the board certificate provide is only valid through 2010. Please provide a more current board certificate or documentation of recentness of training and experience.

4. The following commitments were incomplete. In your written response please provide the following commitments:

a. Procedures for Administration: The licensee shall commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods.

Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

b. Written Directives: 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.

The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

Termination of Treatment Due to Stasis - If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Emergent Patient Conditions - If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

c. Medical Event Reporting: The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

- 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 from the use of the wrong radionuclide; or
- the administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or
- the total dose or activity administered 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
- the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

CONVERSATION RECORD (continued)

ACTION REQUIRED (Continued from page 1)

d. In your application, you have requested an exemption to the semi-annual physical inventory requirement based on the draft guidance that is currently available for public comment. Since the guidance is still draft, we are not able to approve that request at this time. Also, it appears that some of the information provided in this section may have been inadvertently left off. Please provide the following commitment:

The semi-annual physical inventory of microsphere aggregates (e.g., vials) should include:

- the radionuclide and physical form; and
- unique identification of each vial in which the microspheres are contained; and
- the total activity contained in each of the vial(s); and
- the location(s) of the vial(s).

The licensee shall retain each semi-annual physical inventory record for three years.

e. In your request, your commitment on Patient Release appears to provide information on your procedures for how you will be in compliance with the regulations, which could be more restrictive. Please provide the following commitment:

The licensee should commit 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.

f. Radiation Safety Program Revisions- Please confirm that the most current revision of the NRC's guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use as posted on the NRC Medical Uses Licensee Toolkit will be used when making changes to your program.