



## CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU		DATE OF CONTACT		TYPE OF CONVERSATION	
Julie Hanna, Lead Nuclear Medicine Technologist		10/22/2019		<input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE	
E-MAIL ADDRESS		TELEPHONE NUMBER		<input type="checkbox"/> INCOMING <input type="checkbox"/> OUTGOING	
Julie.Hanna@mymhc.com		816-617-7278			
ORGANIZATION		DOCKET NUMBER(S)			
Mosaic Life Care		030-14791			
LICENSE NAME AND NUMBER(S)		MAIL CONTROL NUMBER(S)			
Mosaic Life Care/24-18287-01		616113			
SUBJECT Request for Additional Information					
<p>SUMMARY AND ACTION REQUIRED (IF ANY)</p> <p>The licensee submitted letters dated 9/4/19 (ML19282D231) to add Y-90 program and 10/4/19 (ML19291D861) to change an area of use.</p> <p>On 10/22/19, M. Gryglak and J. Hanna discussed the information needed as listed in the attached document.</p>					
NAME OF PERSON DOCUMENTING CONVERSATION Magdalena Gryglak					
SIGNATURE 				DATE OF SIGNATURE 10/22/19	

Request for Additional Information/Control No. 616113

1. Provide a facility diagram in accordance with guidance in NUREG 1556, Volume 9, Revision 3, Section 8.9.1, if new areas/rooms will be used for administrations of Y-90 at 5325 Faraon St. Joseph, Missouri. If the material will be used in the same areas/rooms previously approved by the NRC, please state so.

If facility diagram is required, please include the following details:

- a. Indicate address on the diagram and the direction of north;
  - b. Describe areas/rooms where radioactive material will be used (e.g. injection room, hot lab, etc.);
  - c. Provide the dimensions/scale for the areas/rooms where material will be used;
  - d. Describe adjacent areas/rooms to the areas where radioactive material will be used (e.g. hallways, outside/exterior/ labs/ lounge/office etc.);
  - e. Describe the area above and below areas/rooms where radioactive material will be used;
  - f. Describe/label details such as sinks, material receipt area, material storage area, dose calibrator, waste storage inside the hot lab;
  - g. Describe measures to secure radioactive material (e.g. describe or label locked door, locked lead container etc.)
2. To name Silas H. Williams, M.D. as an Authorized User for Y-90 administrations, please provide the following:
    - a. Current/valid physician license no. 28864.
    - b. A copy of the State of Nebraska license nos. 01-88-01 and 01-50-01, the Nebraska Medical Center.
    - c. A signed and dated letter from the Radiation Safety Officer, license no. 01-88-01, attesting that Neil Hansen, M.D. is an Authorized User for 10 CFR 35.100, 35.200, and 35.300 material on license no. XX (provide the DATES).
    - d. A letter from the Radiation Safety Officer, license no. 01-88-01/01-50-01 (the license authorizing the use of Y-90), attesting that Adam Alli M.D. is an Authorized User for administrations of Y-90 SIR-Spheres on license no. XXX (provide the DATES).
  3. Please provide the required commitments, "Procedures for Administration," page 7, NRC guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices, TheraSphere and SIR-Spheres Licensing Guidance", dated February 12, 2016, revision 9.
  4. Please provide the required commitments, "Termination of Treatment due to Stasis," and "Emergent Patient Conditions," page 8, NRC guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices, TheraSphere and SIR-Spheres Licensing Guidance", dated February 12, 2016, revision 9.
  5. If you desire to make changes to your radiation protection program for Y-90 in the future, please provide the required statement and conditions that must be met listed on page 10, "Radiation Protection Program Changes," NRC guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices, TheraSphere and SIR-Spheres Licensing Guidance", dated February 12, 2016, revision 9.

6. Please resubmit the facility diagram for the new proposed injection room at 5325 Faraon Street, Saint Joseph, Missouri indicating:

- a) the direction of north,
- b) confirm that PET material is not used.

7) If you wish to release the current injection room for unrestricted use, please provide a final status radiation survey and contamination survey in accordance with 10 CFR 30.36 including the following information:

- a. A survey map providing contamination (in cpm and dpm) and radiation readings (mR/hr) keyed to specific locations within each room where radioactive material was used and stored (a diagram of the facility with cpm/dpm and mR/hr readings/points shown on the diagram with description of the reading/point such as floor, countertop etc.);
- b. Background contamination and radiation readings;
- c. Guidance/action levels for contamination and radiation readings;
- d. Instrumentation used to conduct the surveys including the manufacturer's names and model numbers;
- e. Calibration dates for survey meters;
- f. efficiency/correction factors for well counters;
- g. Date and name/s of individuals performing the status survey;
- h. Confirmation that all radioactive waste has been decayed to background or disposed of to an authorized recipient/ no waste was stored in the room.
- i. Confirmation that no radioactive material is present in the injection room.

## Gryglak, Magdalena

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**From:** Gryglak, Magdalena  
**Sent:** Tuesday, October 22, 2019 8:18 AM  
**To:** jack.bridges@mymhc.com; Hanna, Julie  
**Subject:** Request for Additional Information, License no. 24-18287-01, Mosaic Life Care, Control No. 616113  
**Attachments:** Request for Additional Information.docx; Y90 guidance.pdf

Good morning Dr. Bridges,

I have reviewed your requests dated September 4, 2019 and October 14, 2019. I will need additional information to proceed with the amendment.

Please address the questions in the attached Request for Additional Information document.

Please provide your response in a signed and dated letter by 11/16/19. You may provide your response directly to me via email.

Please acknowledge receipt of this email and let me know if you have any questions.

Thank you

Magdalena R. Gryglak  
Health Physicist  
U.S. NRC Region III  
630-829-9875