



### CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU		DATE OF CONTACT	TYPE OF CONVERSATION	
Dennis J. Aurand, M.S., DABR/RSO		04/23/2019	<input type="checkbox"/> E-MAIL	
E-MAIL ADDRESS	TELEPHONE NUMBER		<input checked="" type="checkbox"/> TELEPHONE	<input type="checkbox"/> INCOMING
daurand@mhc.net	231-392-8612			<input type="checkbox"/> OUTGOING
ORGANIZATION	DOCKET NUMBER(S)			
Munson Medical Center	030-02074			
LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)			
Munson Medical Center	611664			
SUBJECT Request for Additional Information				
SUMMARY AND ACTION REQUIRED (IF ANY) On 4/23/19, M. Gryglak and D. Aurand discussed the additional information to authorize Dr. Allsopp for use of Y-90 TheraSpheres. See the attached list of items discussed.				
NAME OF PERSON DOCUMENTING CONVERSATION MAGDALENA R. GRYGLAK				
SIGNATURE 			DATE OF SIGNATURE 4/23/19	

1) Please clarify the requested authorization for Dr. Karczewski (10 CFR 35.100, 35.200 and 35.300 (limited to oral administration of sodium iodide I-131);

2) To authorize Dr. Allsopp for use if Y-90, please provide the following:

a) Clarify the request for Y-90 authorization (TheraSpheres);

b) Letter regarding the residency program (please review the attached NRC guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, dated 2/12/16):

"William Allsopp, D.O. successfully completed the Diagnostic Radiology Residency Training Program at NAME OF THE EDUCATIONAL FACILITY from MONTH/YEAR to MONTH/YEAR.

During the residency program, Dr. William Allsopp received 80 hours of classroom and laboratory training for byproduct material, including Y -90 microspheres. The classroom and laboratory training included radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology.

NAME/Residency Program Director

Signature

Printed name"

c) Letter regarding the supervised experience with the use of Y-90 microspheres:

"William Allsopp, D.O. successfully completed the Interventional Radiology Fellowship Program at the University of Chicago from July 1, 2017 to June 30, 2018.

During fellowship, Dr. Allsopp successfully completed supervised work experience for the medical use of yttrium-90 microspheres involving:

a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;

c) Evaluation of each patient or human research subject for the dose and activity of Y-90 microspheres to be administered to each treatment site;

d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;

e) Using administrative controls to prevent a medical event involving the use of byproduct material;

f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and

g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres.

Additionally, Dr. Allsopp has successfully completed training in the operation of the delivery system, safety procedures, and clinical use of Y-90 TheraSpheres. Dr. William Allsopp successfully administered (STATE NUMBER OF CASES OR "AT LEAST 3") Y-90 TheraSphere cases under the supervision of Authorized User/s (PROVIDE NAME/S).

NAME/Fellowship Program Director/supervising Authorized User  
Signature  
Printed name"

- d) Provide documentation regarding the Y-90 Authorized Users supervising Dr. Allsopp:
- Copy of the Agreement State/NRC license
  - If the Agreement State/NRC license is a broad scope license, please provide a letter from the RSO listed on the license attesting that the NAME is an AU on license no. XXX for the use of Y-90 TheraSpheres since DATE.

## **Gryglak, Magdalena**

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**From:** Gryglak, Magdalena  
**Sent:** Monday, April 22, 2019 10:53 AM  
**To:** daurand@mhc.net  
**Subject:** CN 611664 Request for Additional Information, NRC license no. 21-08317-01, Munson Medical Center  
**Attachments:** Y-90 guidance.pdf; Request for Additional Information.docx

Good morning Mr. Aurand,

I reviewed your request to authorize Dr. Allsopp for Y-90 and Dr. Karczewski for 10 CFR 35.100, 35.200, and 35.300 material. Please provide additional information as outlined in the attached request for additional information document and NRC guidance dated February 12, 2016.

Please provide the requested information in a signed and dated letter by May 15, 2019. You may email the information as a pdf document directly to me.

I would like to discuss the information needed before you respond. Please let me know the date and time when you would be available to discuss the information (preferably this week).

Please acknowledge receipt of this email.

Thank you  
Magdalena R. Gryglak  
US NRC Region III  
630-829-9875