



October 26, 2023

Nuclear Regulatory Commission Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: NRC Materials License No. 21-26707-01MD
RLS (USA), Inc., 4380 Brockton SE., Suite 3, Kentwood, MI 49512

Licensing:

Please allow this letter to serve as notice that RLS (USA), Inc. wishes to amend the above referenced license as follows:

Please Add:

Radioisotope	Chemical or Physical Form	Maximum Activity	Authorized Use
Y-90	Microspheres – SIRTEX Medical, Model SIR-Spheres	1 Ci	Receipt, manipulate, storage, and redistribution of sealed sources initially distributed by a licensed manufacturer

RLS has received requests from customers to provide Y-90 microspheres that will be transferred from the shipping vial and are ready for use. RLS will receive a unit dose in a vial directly from SIRTEX Medical, an Authorized Nuclear Pharmacists (ANP) will draw-up amount of dose specific to written directives of requesting Physician using a syringe into another vial under clean room conditions. RLS has already established communication with SIRTEX medical and approved to manipulate dose and redistribute pending RAM license amendment approval.

RLS will also adhere to the following commitments:

1. (a). RLS has obtained a written authorization from the manufacturer to prepare and distribute the product.

(b). RLS will not be characterized as a distributor in the devices registry. RLS will not be selling Sirtex products. RLS will only deliver dose(s) drawn to authorized users

(c). RLS will ensure replacement of tamper evident seals.

(d). RLS will not make changes to the package inserts. The preparation of this product will be done in accordance with the package insert dose preparation procedures provided by the manufacturer.

(e). RLS will follow QA/QC requirements as a distributor of Y-90 microspheres. RLS maintains a high QA/QC standard for all our radiopharmaceuticals. RLS will go above and beyond to implement Sirtex QA/QC plan if applicable.

2. RLS will be shipping the dose in manufacturer's SIROs D-vials.
3. RLS will only ship in approved vials provided by the manufacturer. Sirtex has assessed the manufacturer's shipping vials.
4. RLS will dispense the dose at the proper volume per the manufacturer's instructions.
5. Although the dose will be ready for use once shipped to a customer, RLS will provide additional instruction to customers to follow routine procedures to verify dose receive.
6. All Pharmacists previously authorized by this license as Authorized Nuclear Pharmacists (ANP) will complete provided instructions and/or training on the manufacturer's procedures/recommendations. The training will be provided by SIRTEX designated trained representatives.
7. RLS will develop and utilize discrete dispensing procedures for the Y-90 microspheres.

All other aspects of our radiation program, policies on file, and SOP's remain unchanged currently. Should you have any additional questions or require additional information, please feel free to contact me personally at 773-318-2621 or by email at glenn.sullivan@rls.bio. Thank you in advance for your assistance in this matter.

Sincerely,



Glenn P. Sullivan, Ph.D.
Director Regulatory Affairs
Corporate Radiation Safety Officer
RLS (USA), Inc.

Attachment: Delegation of Authority for Glenn Sullivan

cc: Kentwood, MI No. 21-26707-01MD License File
Kentwood Pharmacy RSO

Attachment

Delegation of Authority

Glenn Sullivan



FROM: Trey Bankson, Chief Operating Officer, RLS
CC: All RLS Pharmacy Employees
DATE: June 2, 2023
SUBJECT: Corporate Radiation Safety Officer Delegation of Authority

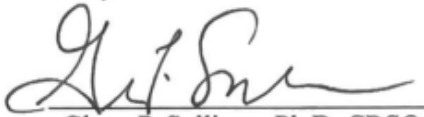
Glenn P. Sullivan, Director, Health Physics, Regulatory Affairs, has been appointed Corporate Radiation Safety Officer (CRSO) for RLS. The CRSO has the responsibility for:

- Managing the corporate radiation safety program
- Ensuring the safe use of radioactive materials within the company
- Identifying radiation safety problems through direct observation or through appointees
- Recommending corrective actions and verifying implementation of such actions; and
- Ensuring compliance with regulations and licensing conditions.

Glenn Sullivan is hereby delegated the authority necessary to meet the above-listed responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

- Make legally binding statements pertaining to radioactive materials licenses operated by RLS.
- Have unhampered access to all activities at any RLS facilities involving radioactive materials to identify radiation safety problems.
- Immediately stop, within coordination with management, any user that might result unsafe situation or a violation of license conditions.
- Recommend corrective actions; and,
- Verify the implementation of actions taken to correct radiation safety problems.

All of us have a critical responsibility in ensuring the safe use of radioactive materials, where safety is the center of our business.


Glenn P. Sullivan, Ph.D., CRSO

6/2/23
Date


Trey Bankson, COO

6/2/23
Date

Martha Pavon

From: Tammy Tomczak
Sent: Thursday, October 26, 2023 1:36 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: [External_Sender] Amendment Request to NRC Materials License No. 21-26707-01MD-Kentwood, MI
Attachments: GRR Sirspheres Amendment Request.pdf

Good morning, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>
Sent: Thursday, October 26, 2023 1:29 PM
To: Tammy Tomczak <Tammy.Tomczak@nrc.gov>
Cc: Bob Orlikowski <Robert.Orlikowski@nrc.gov>
Subject: FW: [External_Sender] Amendment Request to NRC Materials License No. 21-26707-01MD-Kentwood, MI

Hi Tammy,

This is a new request. If there is no pending action already assigned for the license, please assign to me.

Thank you
MG

From: Innocent Tsorxe <innocent.tsorxe@rls.bio>
Sent: Thursday, October 26, 2023 1:16 PM
To: Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>
Cc: Glenn Sullivan <glenn.sullivan@rls.bio>; RArequest <RArequest@rls.bio>; Timothy Burke <timothy.burke@rls.bio>; Stephen Williams <stephen.williams@rls.bio>
Subject: [External_Sender] Amendment Request to NRC Materials License No. 21-26707-01MD-Kentwood, MI

Hello Magdalena,

Please find attached herewith amendment request to NRC Materials License No. 21-26707-01MD-Kentwood, MI
RSO for Kentwood Pharmacy is cc'd herewith.

Let me know if you need any further information.

Innocent Y Tsorxe
Sr. Health Physicist

m: +1 224 602-2302

e: innocent.tsorxe@rls.bio
w: rls.bio

