



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 6, 2024

Bradley A. Ambs, R.Ph.
Radiation Safety Officer
RLS (USA) Inc.
12300 Hubbard Rd.
Livonia, MI 48150

Dear Bradley A. Ambs, R.Ph.:

This refers to the letter dated June 12, 2024, (the "letter"), signed by Glenn P. Sullivan, Ph.D., Director of Regulatory Affairs, requesting an amendment to your NRC license no. 21-24828-01MD to add two proposed authorized nuclear pharmacists (ANPs), Shelli Ann Newman and Jennifer Nicole McKenzie.

We are unable to complete our review of your request because the information submitted in the letter is insufficient.

Within 15 days of the date of this letter (by close of business on August 21, 2024) please provide only one written response to the items below.

Please only send us one complete, written, currently dated and legibly signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a.

Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us unless we direct you to do so. If you resubmit such information for the sake of adding context and other details to enhance its meaning, that is acceptable.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors, although emailing a PDF document is the least efficient mechanism for responding to me.

The most reliable and efficient method of responding is to email a PDF of your signed response to R3-DRSSMail.Resource@nrc.gov. You may "cc" me on that message, but only because I requested the additional information for this amendment request.

Please address your written response to my attention as "additional information to control number 641289" to facilitate proper handling in our offices.

You may consider scheduling a Teams call with me to discuss the items in this letter. Arranging the call by email is preferable. My email address is colleen.casey@nrc.gov. My telephone number is (630) 829-9841.

A. Shelli Ann Newman

A copy of an online verification of Ms. Newman's pharmacist license status was included in the letter. However, no terminal degree or other descriptive suffix was provided to support her as a pharmacist. Please specify a terminal degree and/or other descriptive suffix to support her a pharmacist.

The letter states that Ms. Newman was previously listed on NRC license no. 34-29200-01MD as an ANP and RSO and references an Attachment B to the letter.

Attachment B consists of a letter on Cardinal Health letterhead dated November 27, 2023, for NRC license no. 34-29200-01MD, addressed to Bryan Parker in the Materials Licensing Branch in the USNRC Region III office. Nothing about this letter, or its attached signatory list, objectively supports the assertion that Ms. Newman was previously listed on this license as either an ANP or RSO.

A copy of Amendment No. 77 for this Cardinal Health license is also in Attachment B which does not list ANP's by name on the license in Condition Nos. 12.A, 12.B and 12.C. Cardinal Health evaluates and names its ANPs internally. No list of ANPs is furnished to NRC.

Please provide appropriate documentation to support Ms. Newman as an ANP for your license.

B. Jennifer Nicole McKenzie

A copy of an online verification of Ms. McKenzie's pharmacist license status was included in the letter. A copy of the referenced radiopharmacy license she is named on as an ANP in the state of Ohio was also included.

However, no terminal degree or other descriptive suffix was provided; even on the Ohio radiopharmacy license, to support her as a pharmacist. Please specify a terminal degree and/or other descriptive suffix to support her a pharmacist.

C. We noticed that you are submitting your licensing requests only to specific people in our organization, such as Magdalena Gryglak, Tammy Tomczak, Bryan Parker and Robert Orlikowski. This is incorrect and inefficient This practice is causing delays in processing your requests and it is adding an unnecessary email burden to uninvolved persons.

For the past 4+ years, it has been our highly recommended practice to submit your licensing requests to R3-DRSSMail.Resource@nrc.gov only and not to other persons, unless you are already working with a specific reviewer on a specific request. Then you can "cc" that reviewer when you submit your written response. But all initial licensing requests should go to this monitored mailbox, R3-DRSSMail.Resource@nrc.gov.

If you continue to send your requests to specific individuals only, and if one or more of them are unavailable for one or more days, your request is not going to be processed until they return to work. Whereas, using the monitored mailbox gets your request processed more quickly upon receipt.

It is also greatly appreciated to minimize/eliminate unnecessary email burden to uninvolved persons.

Please note that, in Region III alone, we have approximately 850 materials licenses to administer. This results in a tremendous volume of communications. Modifying your communications to be more efficient and accommodating would be very much appreciated. Thank you for your help in this regard so we may better serve you and all of our licensees.

D. The following references may be useful in preparing your response.

“§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

(4) The applicant satisfies any special requirements contained in parts 32 through 37 and 39 of this chapter; and...”

Section 8.7.2 and Appendix C in the following guidance document should be helpful in preparing your response.

“Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses, Final Report,”

NUREG 1556 Vol. 13, Rev. 2, at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/> is the appropriate guidance document for your license.

In addition, Section 9 in the NUREG states:

“9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued.

Applicants for license amendment or renewal should do the following:

- ☐ Use the most recent guidance in preparing an amendment or renewal request.
- ☐ Submit either an NRC Form 313 or a letter requesting amendment or renewal.”

Please be reminded that 10 CFR 30.9(a) requires: “(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.”

A courtesy copy of this letter is being provided t via email to Dr. Sullivan, as well as to Innocent Tsorxe, Senior Health Physicist in your organization, per the “cc” email addresses below.

In accordance with 10 CFR 2.390 of the NRC's “Rules of Practice,” a copy of this letter 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 <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

Cc: glenn.sullivan@rls.bio,
innocent.tsorxe@rls.bio

License No. 21-24828-01MD
Docket No. 030-29642
Control No. 641302