



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 27, 2024

Nanci A. Burchell, MBA, CNMT
Radiation Safety Officer
Children's Mercy Hospital
2401 Gillham Rd.
Kansas City, MO 64108

Dear Nanci A. Burchell:

Enclosed is Amendment No. 56 to your NRC Material License No. 24-15513-01 in accordance with your request.

If you have any questions or comments concerning this amendment, please contact me at colleen.casey@nrc.gov, which is the most reliable and efficient method of reaching me. My phone number is (630) 829-9841. My fax number is 630-515-1078.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This also refers to the letter dated April 10, 2024, signed only by you, in which you requested to change the Radiation Safety Officer (RSO) from you to Dillon Steppe, CNMT and the removal of Dan Heruth, Ph.D. as a non-medical authorized user of phosphorus-32 for in vitro research and development, per 10 CFR 30.4.

These requests were in addition to adding Viet Thien Le, M.D. as an Authorized User for the use of materials in 10 CFR 35.100 and 35.200, which we approved in this amendment.

If you wish to pursue the requests we were unable to approve, because the information submitted was insufficient to complete our review, please provide only one complete, written, currently dated and signed (by a senior management representative, per 10 CFR 35.12(a)) response to the items below.

Please address your written response to my attention as "additional information to control no. 640445."

Please only send us one complete, written, currently dated and legibly, physically 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 fastest way to respond is to send an email to R3-DRSSMail.Resource@nrc.gov and "cc" me at colleen.casey@nrc.gov.

Our guidance in NUREG 1556 Vol. 9, Rev. 3, section 8.7.1, Appendix D, Appendix E, and Appendix I should be helpful in preparing your written response. It is on our Medical Licensing Toolkit website at: <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf>.

1. As you are requesting to change the RSO for this license, a senior management representative must sign the amendment request. Having the outgoing RSO as the sole signatory is unacceptable. The license is issued to the ownership/senior management of the hospital, not to the RSO. Please ensure that an appropriate senior manager signs the updated, written response.
2. 10 CFR 35.24(b) requires, in part, that "A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements."

Please review NUREG 1556 Vol. 9, Rev. 3, especially section 8.7.1 and Appendix I. One of the last pages in Appendix I is a Model Delegation of Authority (DoA) for a new RSO. Please prepare and submit a DoA for Dillon Steppe that contains appropriate, current dates and signatures.

3. 10 CFR 35.50(d) requires that a proposed RSO "Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval."

This license includes authorization for all uses of unsealed byproduct material for which a written directive is required under 10 CFR 35.300.

However, Dillon Steppe only provided training in the radiation safety, regulatory issues, and emergency procedures for the use of sodium iodide I-131 in quantities less than or equal to 33 millicuries, which is equivalent to 10 CFR 35.392.

The required training in the radiation safety, regulatory issues, and emergency procedures for the rest of the authorizations under 10 CFR 35.300, which include the equivalent of 10 CFR 35.394 and 35.396, was not described for Dillon Steppe.

Please respond by advising us as to whether Dillon Steppe has had the rest of the required training to satisfy 10 CFR 35.50(d), 35.394 and 35.396 and provide appropriate documentation and a revised, updated and re-signed preceptor attestation.

4. 10 CFR 30.33(a)(3) states, in part, that an application for a specific license will be approved if 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.

Your requests to remove Dan Heruth, Ph.D. as a non-medical authorized user for unsealed phosphorus-32 (P-32) and to add Dillon Steppe as the new RSO present some problems.

First, you must have at least one qualified authorized user for every radioactive material on your license. Removing Dan Heruth, Ph.D. without replacing him with another qualified authorized user means the authorization for P-32 must be either modified to possession only in storage or removed from the license, after appropriate decommissioning activities have taken place, been documented, submitted and approved by NRC.

You also must have an RSO whose training and experience qualifies him or her in the radiation safety, regulatory issues and emergency procedures for the P-32, whether it is in storage or active use. Please respond by describing how you intend to address these problems.

I suggest that you contact me at my email address above to schedule a Teams call to discuss these matters before you attempt to formulate a written response.

5. 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.”

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>.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 24-15513-01
Docket No. 030-09259
Control No. 640445

Enclosure:
Amendment No. 56