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

October 24, 2022

Samuel Rhoades, Ph.D.
Radiation Safety Officer
Mercy Hospital Joplin
100 Mercy Way
Joplin, MO 64804

Dear Dr. Rhoades:

Enclosed is Amendment No. 62 to your NRC Material License No. 24-01090-03 in accordance with your request.

If you have any questions or comments concerning this amendment, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 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 your letter dated August 29, 2022, requesting the expansion of authorization for Grzegorz Mariusz Szarnecki, M.D. to include materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries.

We were unable to approve this request because the information submitted was insufficient to complete our review. If you wish to pursue this request, please follow the instructions in this letter to provide additional information.

Please provide only one complete, written response that is currently dated and signed by a senior management official for this license. Your response must include a business-style transmittal letter that identifies this license and contains appropriate information about the unresolved issues below. This will greatly help ensure that your response is processed correctly in our offices.

Under no circumstances should you submit more than one, complete, written response, even by different means of transmission, such as email, regular mail, etc. To do so will introduce confusion and delay in the processing and review of your response.

Your written response should be addressed to my attention at the above address as "additional information to control number 631949."

The fastest and most reliable method of submitting your response is to scan it in and email it to R3DNMSMAIL.Resource@nrc.gov with a "cc" to me at colleen.casey@nrc.gov.
Upon receipt of your written response, we will then continue our review.

Concerning your request to expand Dr. Szarnecki's authorization to include materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131, we noted that your letter dated August 29, 2022, failed to support this request as his authorization for materials in 10 CFR 35.100 and 35.200 do not qualify him for this expanded use, which is in 10 CFR 35.392.

After several telephone discussions and email exchanges between you and me and Elizabeth Tindle-Englemann, my NRC Materials Inspector colleague, it appears that Dr. Szarnecki is unable to demonstrate his qualifications for the use of materials in 10 CFR 35.392 pursuant to 10 CFR 35.57.

10 CFR 35.57(b)(2)(i) states: "(2) **Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission** or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a Commission master material broad scope license **on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:**

(i) For uses authorized under § 35.100 or § 35.200, **or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005,** in nuclear medicine by the American Board of Nuclear Medicine; **diagnostic radiology by the American Board of Radiology**; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;"

Dr. Szarnecki does not meet the regulatory requirements above, despite his having been certified by the American Board of Radiology in diagnostic radiology before October 24, 2005.

This is because he was not identified as an authorized user for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a Commission master material broad scope license on or before October 24, 2005, for the oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes. Further, it follows that he did not perform these uses on or before October 24, 2005, as he was not authorized to do so.

Attached to an email on October 5, 2022, you sent us a copy of Dr. Szarnecki's specialty board certification. However, this submission lacked official status as it was an email with no signature. 10 CFR 35.12(a) requires an application to be signed by licensee's management. I am only including this statement to acknowledge the email transmission of the board certification. Even if it had been submitted properly it would not have changed our conclusions about Dr. Szarnecki's authorization.

If you wish to pursue this request, please provide appropriate documentation that supports expanding Dr. Szarnecki's authorization to include the oral administration of sodium iodide I-131 for imaging and localization purposes.

NUREG 1556 Vol. 9, Rev. 3, section 8.7.2 and Appendix D may be helpful, as well as the Forms NRC 313(a) series, which are available on our Medical Uses Licensee Toolkit webpage at: https://www.nrc.gov/materials/miau/med-use-toolkit.html.

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

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 24-01090-03
Docket No. 030-12728

Enclosure:
Amendment No. 62