



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

June 12, 2023

Dawn M. Edwards, M.S.  
Radiation Safety Officer  
University of Michigan Health-West  
5900 Byron Center Ave. SW  
Wyoming, MI 49519

Dear Dawn M. Edwards:

Enclosed is Amendment No. 74 to your NRC Material License No. 21-12829-01 in accordance with your request.

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) 829-9807 so that we can provide appropriate corrections and answers.

This also refers to your letter dated April 7, 2023, ("the letter") which requests that Michael D. Koets, M.D. be approved as an authorized user (AU) for the use of materials in 10 CFR 35.100, 35.200, 35.300 (limited to the oral administration of sodium iodide I-131, and 35.1000 (limited to yttrium-90 as TheraSpheres.

We approved Dr. Koets as an AU for the use of the materials in 10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131).

We were unable to approve Dr. Koets for the use of materials in 10 CFR 35.1000 (limited to yttrium-90 as TheraSpheres. This is because the information in your letter was insufficient to complete our review.

If you wish to pursue this authorization, please provide only one 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. Please do not email a PDF document to us, 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.

Please address your written response to my attention as "additional information to control number 635276" to facilitate proper handling in our offices.

You may submit your response as a PDF attached to an email that is addressed to [R3-DRSSMail.Resource@nrc.gov](mailto:R3-DRSSMail.Resource@nrc.gov). You may "cc" me on that email. My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov). My office telephone number is 630-829-9841. Please note that it is best to contact me via email as I telework at least half of the time.

My fax number is 630-515-1078.

Dr. Koet's application in your letter included a letter dated June 13, 2022, signed by Jared A. Christensen, who appears to be affiliated with the University of Michigan Cardiovascular Center.

However, no NRC license number was provided to identify this licensee. It is unclear if this is a limited scope license or a Type A medical broad scope license. If it is a limited scope license, please submit either the license number or a copy of the license that shows Dr. Christensen as an AU for the use of materials in 10 CFR 35.1000, limited to yttrium-90 TheraSpheres.

If Dr. Christensen is an AU under a Type A medical broad scope license, then that license does not include the names of AUs on the license itself. The licensee's internal Radiation Safety Committee (RSC) evaluates and approves or disapproves of AUs and maintains records of AUs. No information was provided to support that Dr. Christensen was an AU under a Type A medical broad scope license and qualified to serve as a preceptor for Dr. Koets..

Please submit appropriate documentation to identify the license that Dr. Christensen is an AU on to support Dr. Koets' application for the use of materials in 10 CFR 35.1000, limited to yttrium-90 TheraSpheres.

Please also include the dates of Dr. Koets' training under Dr. Christensen.

Please refer to the regulatory requirements stated above and the appropriate sections in NUREG 1556, Vol. 9, Rev. 2, especially Appendices B, D and E, for assistance in preparing your written response. In particular, Part II on page D-6, paragraph one and Section V. on page D-3, second paragraph in Appendix D reference some of the information we are requesting and describe preceptor statements and supporting licenses for preceptors. The following links may be helpful:

<http://www.nrc.gov/materials/miau/med-use-toolkit.html>

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(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."

You may also find it beneficial to review NRC Information Notice 2007 – 38: "Ensuring Complete And Accurate Information in the Documentation of Training and Experience For individuals Seeking Approval As Medical Authorized Users," which is located on our website at:

<http://pbadupws.nrc.gov/docs/ML0722/ML072270127.pdf>

This IN explains the importance and necessity of compliance with 10 CFR 30.9 and the potential consequences of non-compliance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website 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  
Region III

Docket No.: 030-02134  
License No.: 21-12829-01

Enclosure:  
Amendment No. 74