[redacted]

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

January 16, 2024

Heather Sutyak, CNMT, RT(N)
Radiation Safety Officer
Good Samaritan Hospital
520 S 7th St.
Vincennes, IN 47591

Dear Heather Sutyak:

Enclosed is Amendment No. 88 to your NRC Material License No. 13-01787-01 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) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions or comments, please contact me at colleen.casey@nrc.gov or at (630) 829-9841. Reaching me via email is the most reliable method. My fax no. is (630) 515-1078.

This also refers to your letter dated October 10, 2023, in which you requested, in part, that Jennifer Young, M.D. be added to your license as an authorized user for materials in 10 CFR 35.100, 35.200 and 35.300.

There were some issues with your request, as follows:

1. You submitted a medical specialty board certificate in support of Dr. Young's request that met our requirements in 10 CFR 35.290(a). Therefore, no preceptor attestation for this modality (includes 10 CFR 35.100 authorization) was needed or appropriate.

   However, a preceptor attestation was submitted for this request that you signed as the RSO. Since Dr. Young was applying to become an authorized user (AU), as defined in 10 CFR 35.2, then you, as the RSO, were not qualified to serve/sign as her preceptor in Part II, Second Section of the Forms NRC 313 A (AUD). Please also see the definition of "Preceptor" in 10 CFR 35.2. This is a "no response" item.

   We disregarded the inappropriate portions of this preceptor statement in our review.

2. We noted that there was insufficient supporting information provided in your letter to authorize Dr. Young for the use of materials in 10 CFR 35.300.

[redacted]

We authorized Dr. Young for materials in 10 CFR 35.100 and 35.200 only.

If you wish to pursue the request for Dr. Young to be authorized for 10 CFR 35.300, please provide the appropriate information to demonstrate that she meets the requirements in 10 CFR 35.300.

Please refer to your written response as “additional information to control no. 637490.” 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 313.

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.

You may submit your response as a PDF attached to an email that is addressed to R3-DRSSMail.Resource@nrc.gov. You may “cc” me on that email.

You may wish to schedule a Teams or telephone call with me to discuss the items we are requesting additional information on.

Such a discussion of these items may serve to clarify the information required by our regulations so that your response will be complete and accurate.

The Consolidated Guidance About Materials Licenses Program – Specific Guidance About Medical Use Licenses, Final Report (NUREG- 1556, Volume 9, Revision 3) should also be helpful, especially, but not limited to, Item 7, 8.7.2 and Appendices C, D and E.

In order to become authorized for materials in 10 CFR 35.300, training and experience is required that includes the use described in 10 CFR 35.390(b)(1)(ii)(G)(3), i.e., non-iodine-131, parenteral administration therapy.

Only training and experience for 10 CFR 35.390(b)(1)(ii)(G)(1) and 35.390(b)(1)(ii)(G)(2) was provided for Dr. Young. These authorizations correlate to 10 CFR 35.392 and 35.394 for iodine-131 usages, respectively.

In response, please either provide information to support your request for Dr. Young to meet the training and experience requirements in 10 CFR 35.390(b)(1)(ii)(G)(3) or modify your request to authorize Dr. Young for materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or greater than 33 millicuries, essentially 10 CFR 35.392 and 35.394.

3. In addition, we noted that your letter stated that Dr. Anthony Minotti signed off on Dr. Young's training and experience on the attached copies of NRC Form 313A (AUT). You identify Dr. Minotti as an authorized user on Broad Scope License No. "02110180045."

   This appears to be an Agreement State type A medical broad scope license that we do not have access to.

   Therefore, we cannot verify the validity of this license since the state of Ohio administers it, not NRC. Please provide a current, unredacted copy of this license.

   Also, as a Type A medical broad scope license, the license itself will not list the names of authorized persons, such as Dr. Minotti.

   As the above guidance document, NUREG 1556 Vol. 9, Rev. 3 states in Appendix D, Part V, in part: "To identify an individual who is authorized under a broad scope license or broad scope permit of a Master Materials License, provide a complete copy of the permit issued by the broad scope licensee/permittee. Alternatively, provide a statement signed by the RSO or chairperson of the RSC similar to the following: "_____ (name of individual) was authorized under _____ (name of licensee/permittee) broad scope license number_____ to use_____ (materials) during _____ (time frame)."

   Please provide this information for Dr. Minotti, Dr. Patel and Dr. Beytas as authorized users who supervised Dr. Young and to support Dr. Minotti as an appropriate preceptor.

4. Please have these forms corrected and please note that the correction/modification of the NRC Forms 313 A (AUT) will require the forms to be currently dated and signed.

   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."

5. We noted that your letter dated October 10, 2023, included two mentions of a request for an "expediated" amendment. We assumed these were typos and that "expedited" is what was intended.

   However, no justification or support was provided in this request.

   We noted that the criteria in NUREG 1556, Vol. 20, Rev. 1, Section 4.15, and especially 4.15.2, were not mentioned or met.

   Further, your license already lists many authorized users (AUs) for the use of materials in 10 CFR 35.200 and it lists 10 AUs for the use, in whole or in part, of materials in 10 CFR 35.300.
   Your license only lists one location of use so we presume that coverage for your patients' medical needs are adequate.

   There doesn't appear to be a reason or emergency to justify expediting your request.

In order to consider a future request to expedite an amendment, please provide a currently dated and signed (by a senior management official, not the proposed RSO), written response to the following so we can consider your request:

We have noted that many licensees often add the word “expedite” or similar wording to their licensing correspondence, some almost routinely, thus creating an expectation that we will automatically interrupt work on cases already in queue to begin work on the cases requesting non-specific, unjustified and unsupported “expedites.”

This is disruptive to our process and often such cases contain no other information to justify and support the “expedite” request, nor a date when it is needed by. In addition, these cases are often of poor quality and require more time to review than should be expected.

Therefore, to assist us in serving you better, and in order to serve all of our applicants and licensees fairly, please contact us by telephone ((630) 829-9500 (ask for a materials licensing reviewer or the materials licensing branch chief), or a specific reviewer, if known) if an emergent medical situation or compelling business situation arises after you have submitted an amendment request to your license or new license application and if you can justify and support the need for that particular amendment/new license to be moved up in our normal reviewing queue.

Having this information enables our management to best decide how to handle your expedite request.

Please note that we normally process all licensing actions, including amendment requests, new license applications and renewals, in the order in which they are received, i.e., “first come, first served.” We have conducted business in this manner for more than 30 years.

As stated in our acknowledgment card, sent to all who submit licensing applications for our review, the initial review for amendments and new license applications is normally completed within 90 days of receipt, as an internal goal only.

The initial review for renewals is normally completed within 180 days of receipt, again as an internal goal only.

The technical quality of your submission is a primary factor that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Preparing your new license and amendment requests carefully and in accordance with NRC’s regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at http://www.nrc.gov, will help ensure that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

If you know of a truly emergent medical situation that is unforeseen and beyond the circumstances of your control or a compelling business situation impacting your license and you need a licensing action completed by a certain specific date (not “stat” or “as soon as possible,” etc.), please advise us of the particulars of the situation, the specific date when the new license or amendment is needed and the specific justification and support for it, which should be briefly summarized.

Calling us directly is quickest, (630) 829-9500; depending on the situation, email may be useful.

Emailing your request to R3-DRSSMail.Resource@nrc.gov is usually the fastest and most reliable means of transmission; faxing your application/ request to us at 630-515-1078 is the second most reliable method of transmission.

But, very importantly, only send one, complete, signed and dated application/ request. Do not submit more than one copy or other copies by different means of transmission, as doing so introduces errors in processing, delays and confusion.

In addition, please briefly explain why your new license or amendment request was not completed and submitted to us at least 90 days prior to the date when you needed it by.

As the volume of non-specific “expedite” requests we receive is quite large, this information is important to determine whether a reasonable effort was, could or should have been made on your part to prepare and submit the request in a sufficiently timely manner to permit our review without passing over the licensing requests of others who made their submissions earlier.

NRC expects the first vetting of all incoming licensing requests to be performed by the requesting licensee/applicant to ensure that the application is complete and accurate in all material respects, which will enable us to more readily assess whether to “expedite” it and act uon it more quickly, with less interference and impact to the cases in queue ahead of it.

Please also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) signs and dates the new license application or amendment request letter. For expedite requests, it is preferable that a senior management official sign the request, as possible/appropriate.

Please include the name, best telephone numbers and email addresses of at least one knowledgeable contact person who is familiar with your new license application or amendment request, and a fax number, if necessary.

The contact person should be someone who already has standing with us on matters related to your license, such as your outgoing RSO or a senior management official. The license is issued to the ownership/senior-most management for the license, not to the RSO. This helps to protect the integrity of your license by ensuring that only appropriately authorized persons are allowed to make changes to your license and communicate with us about such changes.

Please address all licensing correspondence to: “ATTN: Materials Licensing Branch Chief” at the address shown below, unless you are directed to a specific, named reviewer for the immediate situation only.

In sum, if you have a genuine need to request an expedited review of your request, please do so and include the information above. If the situation is sudden, unforeseen, and imminently time-sensitive, please call a materials licensing reviewer or our supervisor.

If your amendment request does not meet the above criteria, please kindly refrain from requesting an expedited review unless it is really necessary.

Please also address the criteria in NUREG 1556, Vol. 20, Rev. 1, Section 4.15, including 4.15.1 and 4.15.2.

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.

NRC’s Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC’s electronic document system.

Pursuant to NRC’s RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system “Agencywide Documents Access and Management System” (ADAMS).

The NRC’s document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

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 C. Casey

Digitally signed by Colleen C. Casey
Date: 2024.01.16 12:27:08 -06'00'

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 13-01787-01
Docket No. 030-01600
Control. No. 637490

Enclosure:

Amendment No. 88