



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 13, 2024

Louisa I. Ritchlin
Radiation Safety Officer
Premier Cardiovascular Consultants
of Michigan
1257 N. Main St.
Lapeer, MI 48446

Dear Louisa I. Ritchlin::

Enclosed is Amendment No. 1o your NRC Material License No. 21-35663-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions.

In your correspondence to us dated January 3, 2024, received in our offices on January 24, 2024, and in the letter dated March 1, 2024, you indicated that you wished to release for unrestricted use your former location of use at 1739 N. Saginaw St., Suite 101, Lapeer, Michigan.

The NRC staff has reviewed your final status surveys. Based on its review, the staff has concluded that all licensable radioactive material has been removed from within your former location of use and residual radioactive material attributable to licensed activities does not exceed current NRC criteria.

Based on these conclusions no further remediation or actions with respect to NRC regulated material is required for your former location of use and it is suitable for unrestricted use.

In the documents supporting the request dated March 1, 2024, for the release for unrestricted use of your former location, you included an inventory and leak test report for sealed sources dated January 8, 2024.

We noted that the model numbers of the sealed sources listed were not included, as required by 10 CFR 35.2067(a) and (b). Please correct your inventory and leak test report for sealed sources accordingly.

This amendment also approves your new location of use, although the diagrams submitted were incomplete and minimally acceptable.

In my February 16, 2024, email to Lyndsay Rohlman, Office Manager of your practice, I stated, in part: "Please consult NUREG 1556 Vol. 9 Rev. 3 on our website for the Materials Licensing Toolkit.

We need a complete close out survey for the former location. Your new location must conform with the section on Facilities and Equipment in the above NUREG."

In Item 8.9.1 in the NUREG 1556 Vol. 9, Rev. 3 guidance document, under:

"Response from Applicant: All medical use applicants, including broad scope medical use applicants, are required to provide facility diagrams.

Provide the following:

- Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
- Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
- Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET).
- Doors should be indicated, and specify which doors are access controlled (i.e., locked)."

The elements highlighted in **yellow** above are missing from your new facility diagrams.

Within 30 calendar days of the date of this letter (by close of business on April 13, 2024) please provide only one complete, written, currently dated and signed response to the items below.

Please address your written response to my attention as "additional information to control no. 638983."

Please include the name, direct phone number and direct email address for at least one point of contact knowledgeable in matters concerning your NRC license, apart from phone numbers and email addresses for outside physics consultants for this practice.

Note that, for the past 4 years, we only issue licensing actions via electronic transmission and we no longer send hardcopy, paper documents.

Having the direct email address for a senior manager/owner of the practice helps us to transmit the licensing documents to the correct, licensed recipient.

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.

Please do not send your response to me only as that will incur a delay in processing it in our offices.

Your letters dated January 3, 2024 (received in our offices on January 24, 2024) and March 1, 2024, requested an expedited review of your license changes. In my email to Dr. Mostafa on February 20, 2024, I explained our processing practices, especially as they relate to the numerous requests we receive for "expedited" reviews.

Your letter dated March 1, 2024, also stated that "we are unable to care for patients until our license has been amended." This is untrue.

We never stated or implied that you had to stop patient care while the amendment for the new location was pending. If you had a question or concern about that, you should have asked me about it but, to the best of my recollection and in my notes and email records, it does not appear that you did so. If you have such questions in the future, you should contact us to ensure that your understanding is correct.

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

We have noted that many licensees often add the word "expedite" or similar wording to their incoming 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. We have not conducted an in-depth review of your amendment request yet so its quality is not yet known to us.

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) 829-9887, 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.

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 important, 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 upon 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 of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances. 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.

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 concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov. Contacting me via email is the most reliable method of reaching me.

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. 24-35663-01
Docket No. 030-39299

Enclosure:

Amendment No. 1