



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. STE 210  
LISLE, IL 60532-4352

November 24, 2021

Nizar A. Assi, M.D.  
Radiation Safety Officer  
Gateway Cardiology, P.C.  
10004 Kennerly Rd.  
Ste. 185B  
St. Louis, MO 63128

Dear Dr. Assi:

Enclosed is Amendment No. 13 to your NRC Material License No. 24-32202-01 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.

This also refers to the telephone discussion between Muharem Sumic, CNMT of your staff and me on November 24, 2021, regarding the change to your mailing address and location of use described in the letter dated September 7, 2021 ("the letter").

We determined that the information in the letter was lacking certain details but was minimally adequate to permit you to relocate on schedule on December 3, 2021, as Mr. Sumic stated.

Once you have completed your relocation to the new facility and you prepare an amendment request to remove the old facility from the license, please include an updated diagram that addresses the following concerns:

A.

1. Item 2 of your letter refers to "tentative RAM storage locations," as annotated on the diagram. Please explain what is meant by "tentative" and indicate where the radioactive materials storage locations will be for incoming materials, dosages awaiting use and radioactive waste.
2. The nuclear imaging diagram attached to the letter appears in a tiny font that is very hard to read even with PDF zoom employed. Please submit a clearer, revised facility diagram that conforms to the parameters in NUREG 1556 Vol. 9 Rev. 3, Section 8.9, Item 9; Section 8.9.1; and Figure 8-3. This guidance document is available on our medical licensing toolkit website. Simple, non-elaborate hand drawn diagrams are preferred.

The enclosed documents contain sensitive security-related information.  
When separated from this cover letter this letter is uncontrolled.

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Blueprints and copies of blueprints or other schematics are strongly discouraged as they tend to show much of what we do not need and relatively little of what we do need.

3. Items 1, 3 and 5 on your diagram use the term "(self shielded)" in what appear to be inappropriate uses for that term. Please describe what you mean by "self shielded" for each use of this term and if other language can better illustrate your meaning, please do so.
4. It isn't clear from your diagram where the injection area will be and the places where supportive shielding materials will be employed. Please specify where the injection area will be and describe the types and thicknesses of supportive shielding materials and where they will be used.

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 send your response/amendment request to my attention at the address shown above and reference it as "additional information to control no.628587."

Please ensure that only one correspondence letter is used that shows both the date and the signature of the senior management official, in contrast to the two separate, incomplete correspondence letters initiating this request.

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.

- B. To remove a location of use from your license, such as when you want to delete the old hospital's address from the license after you have completely moved into the new hospital (for future reference):
  1. Start with a master list of every authorization that has ever been authorized for the location of use, i.e., the old hospital, even those authorizations that have already been taken off before. This is an historical review.
  2. State explicitly which of these authorizations you ever actually used (as in possessed, stored, handled, used, etc.) and if you used an authorization or more than one, when did you stop using the authorization, as in a date (month and year minimum).

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If you did not use a specific authorization(s), tell us that explicitly also. Bear in mind that we will corroborate your responses with your inspection and enforcement history in our records.

3. For those authorizations that you used, you must account for each "from cradle to grave." In other words, you have to describe what you used and where (locations of use, areas of use, storage, etc.); prove that there is no residual leakage, if sealed sources were involved; prove that there is no residual, removable contamination; prove that all materials have been decayed, if allowed; prove that all materials have been disposed of to authorized/licensed entities, received by them and acknowledged by them; and provide copies of Agreement State license(s) for those recipient entities licensed by Agreement States, as NRC does not have access to these licenses to verify their licensure.
4. We cannot authorize licensees to release the "locations/addresses of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc., including sealed sources and unsealed materials, spills, and contamination.

If sealed sources were transferred or disposed of as part of the close-out of the location of use, please provide a copy of the final leak test result for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current, complete, unredacted copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials (such as in 10 CFR 35.100, 35.200, 35.300, 31.11 and carbon-14, hydrogen-3, etc.) were transferred or disposed of as part of the close-out of this location of use, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

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An assumption of decay for relatively short-lived materials is insufficient to support a termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

Please also be reminded that the "decay-in-storage (DIS)" provisions in 10 CFR 35.92 only apply to materials with a half-life of 120 days or less. For example, this provision may not be used for cobalt-57 sources, among others.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; 10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities," (if you have a medical program; check the "Termination of Activities" section in other volume(s) in the NUREG 1556 series for other than medical programs at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>); "NRC Form 314" at <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf>; and NUREG 1757, Vol. 1, Rev. 2 at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>.

5. Your complete historical review should specify when and where all licensed materials (such as in 10 CFR 35.100, 35.200 and 35.300 (please note these are the correct ways to designate subsections in 10 CFR Part 35, not "Part 100, Part 200, etc.") were actually possessed under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

For licensed materials and waste that were "decayed - in - storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license, such as 10 CFR 35.92 and 10 CFR 2092.

For other licensed material waste streams (only if appropriate), such as incineration (volume reduction), animal carcasses, shipment for burial, compaction, vial disposal, and so on, provide copies of appropriate records to demonstrate "cradle to grave accountability."

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present. For example, please only submit the last, or final, records for leak tests, DIS disposal, etc.

6. The final status surveys should consist of: exposure rate measurements to show that all sources of radioactive material have been removed; and, contamination checks (wipe tests) of areas where radioactive materials were used or stored.

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Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>

Please submit the following information with your close-out survey:

- a. Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately. "Counts per minute (cpm)" and similar units are unacceptable.

- b. The name of the person(s) performing the survey.
- c. The date(s) the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. It is expected that instruments used will be appropriate for the types of radiation being detected; the exposure rate levels and sensitivity anticipated; and the removable contamination levels and sensitivity anticipated.
- e. Background readings and each instruments' efficiency or correction factor.
- f. The date(s) that the survey instrument(s) were last calibrated and the radionuclide(s) each was calibrated with. Please do not state when the instrument(s) are "due" to be calibrated in the future. Please do state when the instrument(s) were last calibrated.
- g. The action levels for exposure rate measurements and the action levels and efficiency (cies) for wipe test measurements. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.

If you have any questions or detect any errors in this amendment, please contact me at (630) 829-9841. My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov) and my fax number is (630) 515-1078. During the pandemic, reaching me by email is probably the quickest and most efficient way to contact me.

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.

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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).

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>.

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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,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Health Physicist  
Materials Licensing Branch

License No. 24-32202-01  
Docket No. 030-35167