



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

JUN 20 2016

David E. Sieffert, M.S.  
Radiation Safety Officer  
Lakeland Medical Center, St. Joseph  
1234 Napier Avenue  
St. Joseph, MI 49085

Dear Mr. Sieffert:

Enclosed is Amendment No. 97 to your NRC Material License No. 21-04177-01 in accordance with your request.

Please note that significant changes to your license may appear in **bold** font, such as format changes resulting from requests you made and updates that we have implemented at this time. We deleted Condition No. 13 from your license, as it appeared on Amendment No. 96, because we added the regulations it covered in 10 CFR part 71 to the Preamble that appears at the top of page 1 of your license. Subsequent Condition(s) may be renumbered as a result.

Please note that we were unable to delete the authorization for gadolinium-153 in Subitem Nos. 6 through 9.I. of your license at this time because the information in your letter dated April 5, 2016, was insufficient to complete our review.

In order to pursue this request, please submit a written response to the information requested and referenced below, addressing it to my attention as "additional information to 590662." We will continue our review at that time.

If you would like to discuss this issue with me before preparing your response, please contact me to do so at my telephone number or email address below. Scheduling a call via email beforehand may be most expeditious.

We were unable to complete our review of your request to remove the authorization for gadolinium-153 for several reasons.

The documents supporting your request consisted mostly of copies of bills of lading/shipment manifests (see section below about these also). The copies submitted were in such a tiny font and of such a poor print quality that they could not be read.

You also submitted a document from ADCO Services, Inc. about your shipment. It is our understanding that this company is no longer licensed to accept radioactive materials waste shipments. If our understanding is incorrect, please provide a complete current copy of this company's license to accept radioactive materials waste shipments.

The page showing "Wipe test analysis" with a graph that was blank, did not provide meaningful information. Please see our advice below about leak tests, raw data, records, etc. when preparing your response.

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

~~Official Use Only - Security-Related Information~~

We noted that you, as RSO, signed the letter above. Please also see the advice below about signatories for licensing requests. The following is information I have assembled and used in similar circumstances such as yours before. Please note that you may find all of it useful but especially the sections that appear in **bold** font, for this particular issue.

**Removing authorizations for materials, areas/locations of use from licenses, terminating licenses, etc.**

Please 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.*"

**We cannot authorize licensees to release the "locations/addresses of use" or "areas 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.**

**In addition you must submit this information to us, explicitly identifying your license with the information contained in an NRC Form 3 or equivalent "business-style" letter, as an amendment request.**

**Your license amendment must be completed first before you can be approved to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members).**

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 this license, please provide a copy of the final leak test 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; 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 sources.**

**For the final leak test, please do not submit the raw data and associated print-outs generated by radiation detection and/or counting devices.**

**For medical licensees, please submit the final leak test information in accordance with the requirements in 10 CFR 35.67 and the record requirements in 10 CFR 35.2067.**

**If sealed or unsealed materials, including waste streams or waste materials (including those under 10 CFR 35.92, if applicable) were transferred or disposed of as part of the close-out of this license, 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.**

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For waste materials transferred, include the final records for any waste materials transferred or disposed of, pursuant to 10 CFR 35.2092.

Do not submit all records of waste disposal; only submit the final records for transfer or disposal, to support the assertion that the facilities contain no residual radioactive materials in any form.

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.

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 and only if you are terminating the license; 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/>.

Your complete historical review should specify when and where all licensed materials, including materials in 10 CFR 31.11, *were actually possessed* under the license, beginning with the original issuance of 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.

If your license historically authorized radioactive materials and/or modalities that you never used, then please so state specifically. Please be mindful that NRC will review your inspection history.

Please respond by stating exactly which licensed materials were used at the affected location historically and please submit final status survey information covering those radioactive materials.

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

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. Specify type of surface surveyed (floor, countertop, doorhandle, sink, etc.) and at what distance, if exposure rate surveys.

Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately.

- b. The name of the person(s) performing the survey.

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- c. The date(s) the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. Include manufacturer's names and model numbers to ensure clarity.
- e. Background readings and each instrument's efficiency or correction factor.
- f. The date(s) that the survey instrument(s) were last calibrated. Please *do not* state when the instrument(s) are "due" to be calibrated in the future as this is not meaningful information. Please *do* state when the instrument(s) were last calibrated.
- g. The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken, including re-testing results. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.
- h. **If sealed sources were used in the affected areas/locations, please include a copy of the most recent leak test results for each source. If sources were transferred, please provide the license number (if a current Region III NRC licensee) or a copy of the license for the transferee, or a copy of the license and/or permit for the broad scope licensee who took possession of the sources. Appropriate acknowledgment(s) of receipt should be submitted for "cradle to grave" accountability.**

**Also, please always include the telephone number and fax number of at least one person who serves as a point of contact for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.**

**Signatures required for Materials Licensing Correspondence and Best Practices**

**To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.**

**An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.**

**As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all initial requests for licensing requests must be signed, in order to comply with the regulatory requirements listed below.**

**If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.**

**All subsequent "new/initial" licensing requests must then be signed appropriately.**

**Please always sign every licensing document and communication submitted, even if you sign an email and transmit it to us via email/PDF or fax.**

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Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, will likely delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:

"(a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,

"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 requires the typed or printed name and signature of a certifying officer. The NRC Form 313 can be found at:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf>

If the NRC Form 313 is not used, then a standard "business-style" letter *containing all of the information on the NRC Form 313* may be used instead. The letter may or may not be on "letterhead stationery."

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:

"(a) An application must be signed by the applicant's or licensee's management."

10 CFR 35.2, "Definitions" states, in part:

"*Management* means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates."

Please address all initial licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown at the top of the first page of this letter.

If you have made prior arrangements with a specific reviewer or if you are responding to a specific reviewer about an issue currently under review, then please address your written response to the attention of that reviewer, including the control number for the licensing action pending.

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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 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.**

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 (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).

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.

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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,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive style with a large initial "C".

Colleen Carol Casey  
Materials Licensing Branch

License No. 21-04177-01

Docket No. 030-02049

Enclosure:

Amendment 97