



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

JAN 27 2020

Laura T. Smith, M.S.
Radiation Safety Officer
Ascension Macomb Oakland Hospital,
Warren Campus
11800 East 12 Mile Road
Macomb Center
Warren, MI 48093

Dear Ms. Smith:

Enclosed is Amendment No. 80 to your NRC Material License No. 21-01190-05 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.

1. Please note that, in this amendment, we were unable to approve Jeffrey Neil Adams, M.S. as an Associate Radiation Safety Officer (ARSO) for the materials listed in Subitem Nos. 6. through 9.K. and L. on the license.

It was not made clear to us from your letter dated October 21, 2019, that you wanted Mr. Adams to be named ARSO for all materials on the license and he did not present qualifications for these specific materials.

This is because you did not provide documentation that he met the requirements in 10 CFR 35.50(c)(2), 35.50(c)(3) and 35.50(d), as it pertains to the yttrium-90 microspheres permitted by 10 CFR 35.1000.

If you wish to pursue this request, please follow the instructions given below in Item 6 to provide an appropriate written response.

Additionally, we noted that, contrary to the assertion made in your letter October 21, 2019, Mr. Adams is no longer the RSO for license number 21-15638-01 and has not been RSO for several months. We also noted that license did not authorize yttrium-90 microspheres permitted by 10 CFR 35.1000.

Your letter dated October 21, 2019, also requested that Mr. Adams be named an Authorized Medical Physicist (AMP) for "35.400," in part. However, no materials requiring an AMP under 10 CFR 35.400, i.e., 10 CFR 35.433, are authorized by this license. So Mr. Adams has not been named an AMP for materials in 10 CFR 35.400.

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

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We further noted that the effective date printed on Mr. Adams specialty board certification was cut off and rendered illegible. Please check your future submissions to ensure that all necessary information is legible in your documents.

2. In the course of this review, we noted that Subitem No. 6.J. authorizes gadolinium-153 sealed sources for "storage only incident to disposal."

However, please be cautioned that this authorization was not expected to be in effect for an indefinite period of time.

It is expected that you are actively arranging the final transfer and disposal of this material.

This is because 10 CFR 35.92 restricts the disposal of licensed material for "decay -in-storage" (DIS) to only those materials with a half- life of 120 days or less, provided that those materials meet the other requirements in 10 CFR 35.92.

Gadolinium-153 has a half- life of 242 days, which excludes it from DIS and 10 CFR 35.92.

Please submit a written response, following the instructions in Item 6 below, within 30 days of the date of this letter (by March 1, 2020) to describe the measures you are taking to dispose of the gadolinium-153 materials on your license that are currently authorized only for "storage incident to disposal." If a reasonable, alternate timeframe to respond is needed, please contact me at colleen.casey@nrc.gov or 630-829-9841 to make arrangements.

Please also include a reasonable, approximate near- term timeframe when you expect to have these materials disposed of to an appropriately licensed entity. It appears that these materials have already been in "storage incident to disposal" for more than 3 years.

3. We also noted that no specific radionuclides are listed in Subitem No. 6.G. on your license, pursuant to 10 CFR 35.49. Although the sealed source manufacturers' names and model numbers are listed in Subitem No. 7.G., the radionuclides are not listed in Subitem No. 6.G. and you are responsible for providing this information.

Please list the specific radionuclides for each of the sealed sources listed in Subitem Nos. 6. and 7.G., following the instructions in Item 6 below.

4. In the course of this review, we noticed that Subitem No. 9.J. authorizes you for two different high dose rate remote (HDR) afterloading brachytherapy devices when it appears that you are only using one such device at one location of use.

Please explain why you are authorized for two different HDR devices and if one of the devices authorized should no longer be listed on the license, please explain and direct us to remove the device.

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Please state when the device was removed from your location of use and by whom, i.e., which licensed entity took possession of it. Please follow the instructions in Item 6 below for your response.

5. On December 15, 2019, we unexpectedly received a duplicate fax from you of the October 21, 2019, letter originating this amendment and its attachments. The fax transmission sheet stated "Comments: I believe this was previously sent in, but cannot tell as have not received a letter of receipt." No name is on the fax transmission sheet but it appears to have come from you, Ms. Speer Smith, according to the information at the very top of the page.

This fax was mis-processed initially because it was a duplicate of what we already had under control number 616859. Our standard acknowledgement of correspondence document was sent to your attention at the mailing address of record for this license for the original October 21, 2019, letter.

It was incorrect to assume that, since you had not located the acknowledgement of correspondence document, you should just send in another duplicate fax of the original without checking with us first.

A telephone call to our Licensing Assistant, Ms. Tammy Tomczak, at 630-829-9564, or an email to her at Tammy.Tomczak@nrc.gov should have been sufficient to corroborate our possession and processing of the original amendment request.

If you are having difficulties receiving mail from us as the RSO for this licensee, it might be useful to address the problem with the licensee directly. Or, if the mailing address itself is incorrect somehow, request an amendment to change the mailing address.

We have not received "returned mail" from you. If we do receive "returned mail," we always follow up promptly with a telephone call and/or email contact to resolve the problem.

Sending us an unexpected duplicate amendment request like this introduces delay and confusion to our processes and wastes resources. Please kindly refrain from this type of communication in the future. We appreciate your assistance.

6. In order to submit your written responses to the above items, where we have asked for them (and/or if you choose to pursue them, for item 1), please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) response correspondence document, including either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a that permits us to identify your license.

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. If you resubmit such information only for the sake of adding context and other details to enhance its meaning, that is acceptable.

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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 a fax of one complete copy only to me at (630) 515-1078. Please do not email your written response to me.

Please address your written response to my attention as "additional information to control number 616859" to facilitate proper handling in our offices.

Please also 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."

If you have any questions concerning this amendment please contact me at either (630) 829-9841. 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

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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,

A handwritten signature in black ink, appearing to read "Colleen Carol Casey". The signature is fluid and cursive, with the first name "Colleen" being the most prominent.

Colleen Carol Casey
Materials Licensing Branch

License No. 21-01190-05
Docket No. 030-02005

Enclosure:

Amendment No. 80