

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

JUL 31 2013



Laura T. Smith, M.S.
Radiation Safety Officer
St. John Hospital and Medical Center
22101 Moross Road
Detroit, MI 48236

Dear Ms. Smith:

Enclosed is Amendment No. 63 to your NRC Material License No. 21-03210-01 in accordance with your request. Please note that the major changes made to your license are printed in **bold font**.

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.

- A. **This also refers to your letter dated May 1, 2013, which requests authorization for iodine-125 seeds for the localization of non-palpable lesions, a use permitted by 10 CFR 35.1000.**

Guidance implementing this authorization is on our website at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html>

We noted that your letter dated May 1, 2013, failed to address most of the information in this guidance. Therefore, we were unable to complete our review.

If you wish to pursue this matter, please provide complete, written responses making clear, explicit representations and commitments, as described in the entirety of this guidance.

Please submit a currently dated and signed written response, addressed to my attention at the above address, as "additional information to control number 580880." We will then continue our review.

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

L. Smith

- 2 -

In your response please also note the following:

1. Please confirm that your Radiation Safety Committee will use the licensing guidance for iodine-125 seeds for the localization of non-palpable lesions, a use permitted by 10 CFR 35.1000, when evaluating proposed authorized users for this modality.
2. We noted that the request in your letter to "add" another facility address to your license for this modality is not entirely appropriate. This is because the address mentioned is already on your license for another use.

Please clarify the addresses where materials will be used for this modality, in the context of your license and in the context of our guidance document.

3. Please provide the manufacturer's name and model number for the sealed sources you will be using for this modality.
4. Please describe the calibration frequency for the survey instruments you will use to support this modality. Please confirm that survey instruments will be calibrated by appropriately licensed persons.

- B. Please note that, at this time, we adjusted the authorizations in Subitem Nos. 6 through 9 D, E and F to separate out your authorizations for materials in 10 CFR 35.400 by radionuclide. In making this format change, we retained the possession limit you had previously for all three radionuclides, 300 millicuries, and applied it to each separate authorization. If you would prefer to change your possession limits, please advise us of this in a future amendment request.

Your authorizations for materials listed in Subitem Nos. 6 through 9 E and F, as they appeared on Amendment No. 62, have been moved to Subitem Nos. 6 through 9, L and M.

- C. Please note that, at this time, we must change the possession limit in Subitem No. 8.C. from "As needed (not to exceed 2 curies of iodine-131)" to one all-inclusive limit. We can no longer continue "As needed" possession limits for materials in 10 CFR 35.300.

Please use the procedure described in section A. above when responding with your modified possession limit. Please respond, in writing and under current date and signature, within 30 days of the date of this letter. In the alternative, please contact me to make other response timeframe arrangements.

- D. This also refers to your facsimile transmittal cover sheet dated May 22, 2013, (copy attached) which was used to transmit amendment request letters for two different licensees. The first was for St. John Macomb - Oakland Hospital and the second was for St. John Hospital and Medical Center.

L. Smith

- 3 -

Although we understand that you serve as Radiation Safety Officer (RSO) for both licenses, 21-01190-05 and 21-03210-01, they are licensed separately and are located at different places.

On July 26, 2013, I happened to discover the second amendment for 21-03210-01 "piggy-backed" onto the amendment request for this license. I arranged to incorporate it into my review of another amendment request, a letter dated May 1, 2013, for St. John Hospital and Medical Center under control number 580880. No delay in review will occur this time, although that could happen in the future if multiple requests for different licenses are transmitted to us in this manner.

Therefore, to prevent confusion and potential for delays in review, please kindly refrain from sending us more than one amendment per facsimile transmittal sheet, as it greatly increases the likelihood that the additional requests will not become obvious to the reviewing staff until the technical review is underway. That was the case here.

Submitting one amendment request correspondence for a licensee per transmittal helps ensure we can best serve your licensing needs in a timely fashion.

- E. Please also note that we deleted Condition No. 14, as it appeared on Amendment No. 62, because this condition was no longer necessary.

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).

L. Smith

- 4 -

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.

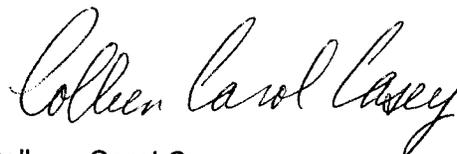
Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC 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
Materials Licensing Branch

License No. 21-03210-01
Docket No. 030-02028

Enclosure:
Amendment No. 63 |