



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

JUN 18 2014

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

Dear Ms. Smith:

Enclosed is a Corrected Copy to Amendment No. 63 to your NRC Material License No. 21-03210-01 which adds a single total possession limit to your authorization of materials in 10 CFR 35.300.

Amendment No. 63 was issued on January 28, 2014, and, in our transmittal letter, we included a second request for the following:

"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."

We requested a written response within 30 days, or by late February 2014. We also requested that you contact us to make alternative arrangements to respond if necessary.

Also, in our letter to you dated July 31, 2013, transmitting an amendment, we included the same request:

"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."

We requested a written response within 30 days or by late August. We also requested that you contact us to make alternative arrangements to respond if necessary.

In your letter dated October 28, 2013, you committed to providing this information at a later date. As of January 28, 2014, we had not received any correspondence addressing the one total possession limit you wished to have for all materials in 10 CFR 35.300.

On January 29, 2014, you and I spoke about this matter by telephone and we agreed that you would respond as soon as you received our letter or that you would contact me to

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

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make alternative arrangements. Your correspondence to us requests email contact only and we have strived to contact you as requested. You have also told us that it is difficult to contact you by telephone and that mail to you at this licensed address often takes extra time to be delivered to you.

On seven dates between March 11, 2014, and June 4, 2014, we sent email messages to you requesting this information to resolve the 10 CFR 35.300 total possession limit issue.

In four email messages between January 29, 2014, and May 15, 2014, you committed to providing us with this information.

As of June 17, 2014, we have not received the requested possession limit.

We also noted that you submitted an amendment request dated April 5, 2014, which was assigned to another reviewer. This amendment request does not contain the requested possession limit either.

Therefore, we have issued this Corrected Copy to Amendment No. 63 to include a total possession limit of four curies for all materials in 10 CFR 35.300. We based this possession limit upon a review of your enforcement history, to get a sense of your usage of materials in 10 CFR 300.

However, if this possession limit is insufficient, please contact us immediately to request a different total possession limit for all materials in 10 CFR 35.300.

Please note that your possession limit should not restrict you from obtaining the necessary quantities of licensed materials to carry out licensed activities authorized by 10 CFR 35.300. This is because your possession limit request should be sufficient to permit possession, use, storage, waste streams and growth.

If you would like to discuss this Corrected Copy, please contact me to ensure our mutual understanding is clear.

Since we decided to issue this Corrected Copy to resolve the possession limit issue, another change has taken effect that resulted in a change to your license, described as follows.

The regulations specified in Title 10 of the Code of Federal Regulations Part 37 (Part 37) "Physical Protection of Byproduct Material," impose physical security requirements for the possession and use of the most risk significant radioactive materials. The most risk significant radioactive materials are referred to as Category 1 and Category 2, based on quantities, and are listed in Appendix A of 10 CFR Part 37.

The list is based on the International Atomic Energy Agency's rankings of radiation sources (Category 1 and Category 2 quantities of radioactive material). The final rule was published in the Federal Register on March 19, 2013, with an effective date of May 20, 2013, and a compliance date of March 19, 2014. NRC licensees were required to fully

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implement the new regulation by March 19, 2014. The requirements of Part 37 supersede the requirements of the "Order Imposing Increased Controls" and the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials."

Please note that we have amended your license to remove License Condition No. 20, as it appeared on Amendment No. 63, which required implementation of the Orders listed above. Accordingly, you are now required to comply with the security requirements of Part 37.

The new rule is available on NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part037/>. NRC has also created a web page on Part 37 that can be found at <http://www.nrc.gov/security/byproduct/10-cfr-part-37.html>.

This page contains helpful information, such as hyperlinks to the final rule language as published in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2013-03-19/pdf/2013-05895.pdf>), types of Licensees that may be subject to Part 37 requirements, related Implementation Guidance – NUREG-2155 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2155/>), as well as some Frequently Asked Questions that have been developed during the implementation process.

In addition, the NRC issued a Regulatory Issue Summary (RIS) 2014-03 "Notice of 10 CFR Part 37 Implementation Deadline for NRC Licenses on March 13, 2014." This RIS can be found on our website at: <http://pbadupws.nrc.gov/docs/ML1405/ML14052A157.pdf>.

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. Please note that the major changes made to your license are printed in bold font.

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.

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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.

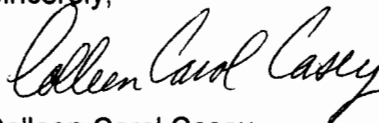
Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC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

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:
Corrected Copy to
Amendment No. 63