



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

MAR 17 2017

Edward J. Maas, M.D.
Radiation Safety Officer
Holland Community Hospital
602 Michigan Avenue
Holland, MI 49423-4999

Dear Dr. Maas:

Enclosed is Amendment No. 43 to your NRC Material License No. 21-18502-01 in accordance with your request.

Please note that we have prepared your license in our new Web Based Licensing (WBL) system at this time. As a result, changes to your license have been made so 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.

We deleted Condition No. 13 from your license, as it appeared on Amendment No. 42, in favor of referencing 10 CFR Part 71 in the Preamble at the top of page one of your license. Your subsequent Condition has been renumbered as a result.

We also adjusted the wording identifying the document in Condition No. 13.A. to more correctly reflect it as a letter dated August 13, 2014.

If you have any other 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.

In the course of this review we encountered issues regarding the full context of the training that Drs. DeLeeuw and Dykstra received for the localization of non-palpable lesions authorization and for signatures on the response letter.

The following is intended to prevent the recurrence of such issues, which will increase our ability to help you and serve you better. This is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence.

Please be reminded that USNRC is an independent and objective federal government regulator.

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

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This is not intended to be “all-inclusive”, nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

Signatures Required for Materials Licensing Correspondence and Best Practices

The following information is provided for future reference “as needed.”

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 physically and legibly hand-sign every licensing document and communication submitted. Electronic signatures, signature stamps, signatures or initials applied on behalf of someone else are not acceptable.

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. Sending us identical information by more than one means of transmission should never be done, as it increases the likelihood of mis-processing and subsequent delays.

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 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:

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“(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 business-style letter containing all of the “licensee-identifying” information on the NRC Form 313 may be used instead.

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.”**

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 above.

If you are directed to respond to a specific, named reviewer during the review process for a particular action only, then direct your written response to that reviewer by name.

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. 21-18502-01
Docket No. 030-13801

Enclosure:
Amendment No. 43