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

MAY 12 2016

John J. Chorzel, M.S.
Radiation Safety Officer
Christian Hospital
11133 Dunn Road
Dept. of Nuclear Medicine
St. Louis, MO 63136

Dear Mr. Chorzel:

Enclosed is Amendment No. 63 to your NRC Material License No. 24-13383-01 in accordance with your request.

Please note that the major changes made to your license are printed in **bold** font, which now includes the designation of ADAMS accession numbers for the documents listed in Condition No. 14. Minor updates and reformatting in Condition No. 12 are also included.

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 we were unable to approve Amir J. Momtahen, M.D. as an authorized user (AU) for the use of materials in 10 CFR 35.100 and 35.200 because the information provided in your letter dated March 14, 2016, was insufficient to complete our review for all modalities requested.

Specifically, the documentation in support of Dr. Momtahen's application failed to include completed preceptor forms NRC Form 313 (AUD) for the use of materials in 10 CFR 35.100 and 35.200, as required by 10 CFR 35.290(c)(2).

Only NRC Form 313 (AUT) was completed and submitted so we only authorized Dr. Momtahen for the use of materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries.

If you wish to pursue this matter, please provide a complete, written response, that is currently dated and legibly hand-signed by a senior management official for this license, pursuant to 10 CFR 35.12(a).

It should be addressed to my attention at the above address, as "additional information to control number 590394." We will then continue our review.

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

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Please refer to the regulatory requirements in 10 CFR 35.190 and 35.290 and section 8.12, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response In particular, sections III, V, and IX in NUREG 1556, Vol. 9, Rev. 2, Appendix D, should be useful.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

In addition, we noted that the facsimile transmittal sheet used for your March 14, 2016, letter stated, "PLEASE EXPEDITE (if possible): REQUEST FOR ADDITION OF AU." The facsimile form making this request was unsigned, although the document transmitted was signed.

As we receive a great many such requests in this manner, I have developed the following information to assist licensees making such requests, to facilitate a better mutual understanding of expectations, our process and priorities, to enable us to serve you, and all of our licensees, better and more fairly. I also included information to assist and clarify appropriate and necessary signatures for licensing correspondence.

"Expedite" Requests:

To assist us in serving you more efficiently, it would be helpful to contact us by telephone if an emergent medical situation or compelling business situation arises preferably before or, if appropriate, after you have submitted an amendment request to your license or new license application and if you can justify and support the need for that particular amendment to be moved up in our normal reviewing queue.

Having this information enables our management to best decide how to handle your expedite request.

Please note that we normally process all licensing actions, including amendment requests, new license applications and renewals, in the order in which they are received, i.e., "first come, first served."

As stated in our acknowledgment card, sent to all who submit correspondence for our review, the initial review for amendments and new license applications is normally completed within 90 days of receipt, as an internal goal only.

The initial review for renewals, as an internal goal only, is normally completed within 180 days of receipt. The technical quality of your submission is a primary factor that only you can control in order to enable us to help you more promptly and minimize or eliminate delays in the reviewing process.

Preparing your new license and amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at http://www.nrc.gov, will greatly help ensure that your

correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

Ideally, if you know of an emergent medical situation or compelling business situation impacting your license and you need a licensing action completed by a certain specific date (not "stat" or "as soon as possible," etc.), please advise us of the particulars of the situation, the specific date when the new license or amendment is needed and the specific justification and support for it, which should be briefly summarized.

Please also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) and/or your Radiation Safety Officer signs and dates the new license application or amendment request letter.

Please include the name of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances.

Please address all licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below, unless you have been specifically directed, by pre-arrangement, to address it to a specific reviewer.

"Please also 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."

You may also wish to review NRC Information Notice 2007 – 38, "Ensuring Complete and Accurate Information In The Documentation Of Training and Experience For Individuals Seeking Approval As Medical Authorized Users," which is available on our website.

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 licensing requests and subsequently provided information 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.

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, may 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 business - style letter containing all of the information on the NRC Form 313 may be used instead.

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."

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.

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.

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

Colleen Carol Casey
Materials Licensing Branch

License No. 24-13383-01
Docket No. 030-02382

Enclosure:

Amendment No. 64