

## UNITED STATES NUCLEAR REGULATORY COMMISSION

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

OCT 28 2019

Emily J. Chasteen, M.S. Radiation Safety Officer Barnes-Jewish West County Hospital 12634 Olive Blvd. St. Louis. MO 63141

Dear Ms. Stollard:

Enclosed is Amendment No. 17 to your NRC Material License No. 24-26243-01 in accordance with your request.

 This amendment authorizes the changed location of use for your newly built hospital, adjacent to the existing hospital, although both hospitals have the exact same mailing address.

You can move the nuclear medicine department from the existing hospital into the nuclear medicine department in the new hospital with this amendment.

After the move is complete, you must decommission the old nuclear medicine department and request and receive an amendment to the license before it may be released for unrestricted use.

We cannot authorize licensees to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc., including sealed sources and unsealed materials, spills, and contamination.

If sealed sources were transferred or disposed of as part of the close-out of this facility, please provide a copy of the final leak test for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials were transferred or disposed of as part of the close-out of this license, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for

shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; NUREG 1556 Vol. 9, Rev. 3, section 9, "License Amendments and Renewals;" and NUREG 1757, Vol. 1, Rev. 2 at <a href="http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/">http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/</a>.

Your complete historical review should specify when and where all licensed materials, including materials in 10 CFR 31.11, were actually possessed under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

If your license historically authorized radioactive materials and/or modalities that you never used, then please so state specifically. Please be mindful that NRC will review your inspection history.

Please respond by stating exactly which licensed materials were used at this location historically and please submit final status survey information covering those radioactive materials.

For licensed materials and waste that were "decayed - in - storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license.

Please be mindful that the regulations for DIS only apply to those materials with a half-life less than or equal to 120 days, pursuant to 10 CFR 35.92. Therefore, materials including, but not limited to, cobalt-57, gadolinium-153, cesium-137, and barium-133.

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present.

Please only submit the last, or final, records for leak tests, DIS disposal, etc.

The final status surveys should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: <a href="http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/">http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/</a>

Please submit the following information with your close-out survey:

a. Always specify each location/address of use (see Condition No. 10 on your license) that corresponds to the areas of use you are requesting to release for unrestricted use.

b. Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

Do not submit blueprints or copies of blueprints. The diagrams you used to add the affected areas of use to the license; the diagrams you used for routine exposure rate surveys and wipe tests; and/or diagrams prepared in accordance with NUREG 1556 Vol. 9, Rev. 3, Figure 9.1 (add the direction of north) are examples of diagrams that will facilitate our understanding of the areas you wish to release for unrestricted use.

Submitting diagrams of only certain components/fragments of the areas you are requesting be released for unrestricted use, such as certain walls, hoods, sinks, floors, etc. without the full context of each entire affected area is unacceptable and leads to delays and confusion in processing your request.

Meaningful traditional units (milliroentgen, millirem, dpm, etc.) are best and should be stated, either in addition to SI units or as "stand alone" units. Gross results and/or net results should be identified as such and described appropriately.

- c. The name and position of the person(s) performing the survey.
- d. The last date(s) of use for each radioactive material possessed, used or stored in the areas of use you are requesting to release for unrestricted use. This includes sealed and unsealed materials.
- e. The date(s) when the surveys were performed.
- f. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- g. Background readings and each instruments' efficiency or correction factor. Include the energy level(s) and energy level "windows" you counted for.
- h. The date(s) that the survey instrument(s) were last calibrated. Please do not state when the instrument(s) are "due" to be calibrated in the future. Please do state when the instrument(s) were last calibrated.
- i. The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken. Specify whether and where previous spills occurred and how they were remediated.
- i. If sealed sources were used in the affected areas/locations, please include a copy of the most recent inventory and leak test results for each source. These records must include all of the information required by 10 CFR 35.2067(b) and 35.2067(a) for inventories and leak tests, respectively. If sources were transferred please provide the license number (if a current Region III NRC licensee) or a copy of the license for the transferee, or a copy of the license and/or permit for the broad scope licensee who took possession of the sources. Appropriate acknowledgment(s) of receipt should be submitted for "cradle to grave" accountability.

Also, please always include the telephone number and fax number of at least one person who serves as a point of contact and is knowledgeable in the licensed activites for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.

Please ensure that a senior management representative signs the amendment request. Please ensure that a management representative signs the amendment request, in accordance with 10 CFR 35.12(a), as appropriate, for medical programs.

2. In the course of this review, you contacted us several times to hasten our review when it became apparent to you that your previous attempt to request this amendment had not been successfully received by us.

The following is some general information, compiled from deficiency correspondence I've prepared over the years, to assist you in preparing not only this response, but also any future licensing actions, to minimize or eliminate requests we must make for additional information. This can greatly lessen the workload for you and for us and permit us to serve you better.

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

This is <u>not</u> 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.

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.

In preparing your response, 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."

## "Expedite" Requests:

[For medical licensees only, please take special note of the definitions in 10 CFR 35.2; and the provisions in 10 CFR 35.13 and 35.14; 35.26; 35.24(c); 35.24(d); and, for Type A broad scope medical licenses, 10 CFR 35.49. If your request meets the requirements and/or criteria in these sections, it may be acceptable for you or your Radiation Safety Committee to internally evaluate and approve certain changes to your license and then use the notification processes described in these regulations, as appropriate.

For example, if a medical licensee wants to name an Authorized User (AU) physician to its license who is currently named to another NRC license for the exact same use, the licensee can allow that AU to begin work and utilize the notification process, as permitted by 10 CFR 35.13(b) and (c) and 35.14(a).]

We have noted that many licensees often add the word "expedite" or similar wording to their incoming correspondence, some almost routinely, thus creating an expectation that we will automatically interrupt work on cases already in queue to begin work on the cases requesting non-specific, unjustified and unsupported "expedites."

This is disruptive to our process and often such cases contain no other information to justify and support the "expedite" request, nor a date when it is needed by. In addition, these cases are often of poor quality and require more time to review than should be expected.

Therefore, to assist us in serving you better, and in order to serve all of our applicants and licensees fairly, please contact us by telephone ((630) 829-9887, or a specific reviewer, if known) if an emergent medical situation or compelling business situation arises 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/new license 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." We have conducted business in this manner for more than 26 years, as of 2019.

As stated in our acknowledgment card, sent to all within 10 - 14 days of receipt in our offices, who submit licensing applications 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 is normally completed within 180 days of receipt, again as an internal goal only.

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

If you know of a truly emergent medical situation that is unforeseen and beyond the circumstances of your control or a 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.

Calling us directly is quickest, (630) 829-9500; depending on the situation, email may be useful.

Faxing your application/ request to us at 630-515-1078 is usually the most quick and reliable method of transmission.

Only send one, complete, signed and dated application/ request.

Do not submit more than one copy or other copies by different means of transmission, as doing so introduces errors in processing, delays and confusion.

In addition, please briefly explain why your new license or amendment was not completed and submitted to us at least 90 days prior to the date when you needed it by.

As the volume of non-specific "expedite" requests we receive is quite large, this information is important to determine whether a reasonable effort was, could or should have been made on your part to prepare and submit the request in a sufficiently timely manner to permit our review without passing over the licensing requests of others who made their submissions earlier.

NRC expects the first vetting of all incoming licensing requests to be performed by the requesting licensee/applicant to ensure that the application is complete and accurate in all material respects, which will enable us to more readily assess whether to "expedite" it and act upon it more quickly, with less interference and impact to the cases in queue ahead of it.

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. For expedite requests, it is preferable that a senior management official sign the request, as possible/appropriate.

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 are directed to a specific, named reviewer for the immediate situation only.

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.

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. My email address is colleen.casey@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

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 <a href="http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html">http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</a>.

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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely.

Colleen Carol Casey Materials Licensing Branch

Docket No.: 030-31901 License No.: 24-26243-01

Enclosure:

Amendment No. 17