



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

SEP 01 2016

Mark Gates, M.D.
Radiation Safety Officer
St. Francis Medical Center
211 St. Francis Drive
Cape Girardeau, MO 63703

Dear Dr. Gates:

Enclosed is Amendment No. 71 to your NRC Material License No. 24-00158-03 in accordance with your request. Please note the change in format of ADAMS accession numbers for all documents listed in Condition No. 13.

At this time, we also deleted Condition No. 13, as it appeared on Amendment No. 70, in favor of adding reference to 10 CFR Part 71 in the Preamble language at the top of page 1 of your license. The Condition after the deleted Condition has now been renumbered.

Please note that we were unable to approve your request for "termination for 35.500 authorization" at this time because the information in your letter dated June 14, 2016, was insufficient to complete our review.

If you wish to pursue this request, please submit a written response to the information below, addressed to my attention at the address above as "additional information to control number 591143." We will then continue our review.

Your request to remove authorization for 10 CFR 35.500 materials was not approved because the justification you provided for this request stated, "The brachytherapy program was initially set up for prostate seed implants. To date, we have not done a single procedure, nor were any radioactive sources ever on site."

The authorization for materials in 10 CFR 35.500 is for sealed sources used for diagnostic purposes only and has nothing to do with brachytherapy, which is authorized by 10 CFR 35.400. Your authorization for materials in 10 CFR 35.400 was already removed from your license previously. So you need to provide justification and support for your request to remove the authorization for materials in 10 CFR 35.500.

The following is information that can help licensees who wish to delete "locations/addresses of use" and/or "areas of use," that, depending on the circumstances, may be related to your request. Please review this information to determine what is most appropriate for you to submit in justifying and supporting your request in a future amendment. If you have questions about this matter, please contact me at (630) 829-9841.

"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 location of use, area of use or license, please provide a copy of the final leak test result 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; the NRC license number or license copy of the recipient/transferee; 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.

An assumption of decay for relatively short-lived materials is insufficient to support a termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; 10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities," (if you have a medical program; check the "Termination of Activities" section in other volume(s) in the NUREG 1556 series for other than medical programs at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>); "NRC Form 314" at <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf>; and NUREG 1757, Vol. 1, Rev. 2 at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>.

Your complete historical review should specify when and where all licensed materials, including materials in 10 CFR 31.11 (only if appropriate), *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.

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.

For other licensed material waste streams (only if appropriate), such as incineration (volume reduction), animal carcasses, shipment for burial, compaction, vial disposal, and so on, provide copies of appropriate records to demonstrate "cradle to grave accountability."

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

If you have any questions, please contact me directly.

Alternately, you may contact a staff reviewer by calling USNRC, Region III, the Materials Licensing Branch, (630) 829-9887 during normal business hours and ask to speak with the "Materials Reviewer on call."

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

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:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>

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

- a. 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.

Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately. "Counts per minute (cpm)" and similar units are unacceptable.

- b. The name of the person(s) performing the survey.
- c. The date(s) the survey was performed.

- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. It is expected that instruments used will be appropriate for the types of radiation being detected.
- e. Background readings and each instruments' efficiency or correction factor.
- f. 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.
- g. 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.
- h. If sealed sources were used in the affected areas/locations, please include a copy of the most recent leak test results for each source. 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.

Please always include the telephone number and fax number of at least one person who serves as a point of contact 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."

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.

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>.

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,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 24-00158-03
Docket No. 030-02269

Enclosure:
Amendment No. 71