



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210

LISLE, IL 60532-4352

JUN 19 2018

Yuenian (Neal) Zhang, Ph.D.
Radiation Safety Officer
Parkview Health
11141 Parkview Plaza Drive
Fort Wayne, IN 46845

Dear Dr. Zhang:

Enclosed is Amendment No. 126 to your NRC Material License No. 13-01284-02 in accordance with your request.

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 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.

- A. In the telephone discussion held on June 11, 2018, between you and Shelly Hire and me, it became evident that the authorized materials on your license did not actually match up with the locations of use (and potentially areas of use within locations of use) authorized in Condition No.10.

As this was an incidental finding in the course of our licensing review, you agreed to conduct an in-depth review of every material authorized on the license and evaluate what its correct location/area(s) of use should be. Where discrepancies are found, you agreed to submit a request to amend the license to correct them, with appropriate supporting information attached. Your understanding was briefly summarized in your letter dated June 14, 2018.

You agreed to submit this amendment request no later than 30 days after the telephone conversation where the discrepancies were discovered, July 11, 2018.

- B. In your letter dated June 12, 2018, you requested that we remove the location of use at 11141 Parkview Plaza Drive, Fort Wayne, Indiana for unrestricted use. However, you provided no supporting documents or information to justify the completion of this request. Please see the information below to prepare an appropriate amendment request to remove this location of use.

Also, please note that we have not removed the high dose rate (HDR) remote afterloading brachytherapy authorization from the location at 11141 Parkview Plaza

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

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Drive, Fort Wayne, Indiana. This is because you failed to provide a copy of the most recent leak test for the sealed source used in the device. Please provide a copy of the most recent leak test for the last sealed source used in the device.

In addition, the copy of paperwork you submitted from Elekta, Inc. showing that the vendor's representative took possession of the source was too faint to read. Please submit a legible copy that clearly shows the vendor took possession of the last sealed source in the HDR device.

- C. It is unclear why Subitem No. 9.I. of your license authorizes two different models of HDR devices, the Nucletron 105.999 and the 106.990. Please explain this discrepancy and advise us which model is correct; which model is incorrect; and support your request.
- D. Please be reminded that USNRC is an independent and objective federal government regulator. This is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence.

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.

To remove a location of use from a license, in overview:

1. Start with a master list of every radioactive material/type of use that has ever been authorized for the location of use in question, even those that have already been taken off before, if any. This is an historical review.
 2. Tell us explicitly which of these authorizations you ever actually used (as in possessed, stored, handled, used, etc.) and if you used an authorization or more than one, when did you stop using the authorization, as in a date (month and year minimum).
 3. If you did not use any authorization(s), tell us that explicitly also. Bear in mind that we will corroborate your responses with your inspection and enforcement history in our records.
 4. For those authorizations that you used, you must account for each "from cradle to grave." In other words, you have to describe what you used and where (locations of use, areas of use, storage, etc.); prove that there is no residual leakage, if sealed sources were involved; prove that there is no residual, removable contamination; prove that all materials have been decayed, if allowed; prove that all materials have been disposed of to authorized/licensed entities, received by them and acknowledged by them; provide copies of Agreement State license(s) for those recipient entities licensed by Agreement States, as NRC does not have access to these licenses to verify their licensure.
- E. You must have an authorized location of use for each material listed on your license. You must also keep your license current.

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The information we would need to support a request to remove each authorized material from the license:

1. If you did not use this authorization, i.e., you never possessed, used and/or stored this material, tell us that explicitly. Bear in mind that we will corroborate your responses with your inspection and enforcement history in our records.
2. If you did use this authorization, i.e., possess, use and/or store, you must account for it "from cradle to grave." In other words, you have to describe what you used and where (locations of use, areas of use, storage, etc.); prove that there is no residual leakage, if sealed sources were involved; prove that there is no residual, removable contamination; prove that all materials have been decayed, if allowed; prove that all materials have been disposed of to authorized/licensed entities, received by them and acknowledged by them; and provide copies of Agreement State license(s) for those recipient entities licensed by Agreement States, as NRC does not have access to these licenses to verify their licensure, appropriate.

F. Submit the information requested, above and below, as an amendment request, to my attention at the address above as "additional information to control number 602693." We will then continue our review.

Greater detail and expansion follows:

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.

For the removal of HDR sealed source(s) and/or device(s) from your license, if sources were transferred or disposed of please provide a copy of the final leak test result for the sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of the 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 and complete, unredacted copy of its license that clearly shows it is licensed to receive your sources.

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If the HDR sealed source was transferred to another appropriately licensed entity or transferred for disposal, and if the HDR source transfer took place within 6 months of the source's receipt under your license, you may be able to use the leak test provided by the vendor that accompanied the source initially. If the transfer took place 6 months or more after it was initially received by you, then a leak test must be performed. Please use 10 CFR 35.67 to conduct the leak test and 10 CFR 35.2067 to prepare the leak test record to be submitted to us.]

If unsealed materials (such as in 10 CFR 35.100, 35.200, 35.300, materials in 10 CFR 31.11, etc.) 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 facility removal and/or license termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

Please also be reminded that the "decay-in-storage (DIS)" provisions in 10 CFR 35.92 only apply to materials with a half-life of 120 days or less. For example, this provision may not be used for cobalt-57 sources, among others.

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 (such as in 10 CFR 35.100, 35.200 and 35.300 (please note these are the correct ways to designate subsections in 10 CFR Part 35, not "Part 100, Part 200, etc.") *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 to corroborate your information.

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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, such as 10 CFR 35.92 and 10 CFR 2092.

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.

Very important - unless you are specifically directed to do so, please do not submit “all” records from the beginning of the license to the present. For example, please only submit the last, or final, records for leak tests, DIS disposal, etc.

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 (wipe tests) 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; the exposure rate levels and sensitivity anticipated; and the removable contamination levels and sensitivity anticipated.

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- e. Background readings and each instruments' efficiency or correction factor.
- f. The date(s) that the survey instrument(s) were last calibrated and the radionuclide(s) each was calibrated with. 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 exposure rate measurements and the action levels and efficiency (cies) for wipe test measurements. 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 knowledgeable 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.

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).

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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. 13-01284-02
Docket No. 030-01593

Enclosure:

Amendment No. 126