



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

NOV 29 2018

Liang (Larry) Wang, M.S.  
Radiation Safety Officer  
Elkhart General Hospital  
P.O. Box 1329  
Elkhart, IN 46515-1111

Dear Mr. Wang:

This refers to the letter dated November 14, 2018 ("the letter"), signed by you, in which you requested an amendment for NRC Material License No. 13-18879-01 to discontinue and remove your iridium-192 high dose rate (HDR) remote afterloading sealed source authorization and your cesium-137 manual brachytherapy sealed source authorization.

This also refers to the telephone discussion of your letter with me on November 28, 2018.

We have reviewed your request and find that we will need additional information in order to complete our review.

Please provide only one complete, written response that is currently dated and signed by a senior management official for this license, in accordance with 10 CFR 35.12(a). Your response must include a business-style transmittal letter that identifies this license appropriately and contains complete information about the unresolved issues below. This will help ensure that your response is processed correctly in our offices and may be reviewed.

Your written response should be addressed to my attention at the above address within 30 days of the date of this letter (December 30, 2018), as "additional information to control number 610538." If an alternative timeframe to respond is needed, please contact me at (630) 829-9841 or [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov) to make other arrangements. We will then continue our review.

Although your letter did not explicitly state that you intend to release for unrestricted use the areas where the HDR and Cs-137 sealed sources were authorized for receipt, use and storage, if you want us to remove these authorizations, you must also request specifically that we release these areas.

If you are currently using either or both of these areas for the receipt, use and storage of any other materials under this license, then please so state, as we will then permit these areas to remain as restricted areas of use covered by this license. They will not be released for unrestricted use of any kind.

If you elect to have these areas of use removed, please note that we cannot authorize licensees to release the "areas of use" from licenses for unrestricted use (even by other staff members) until we have received in our offices, reviewed a copy of the results of final status surveys, i.e.,

"decommissioning" and "close-out surveys," for the affected facilities, and amended your license to release them.

For the cesium-137 sealed sources that were transferred or disposed of, please state whether you want to release for unrestricted use which specific areas of use; please provide a copy of the final (only the final) leak test result for each sealed source, as required by 10 CFR 35.67 and 35.2067; 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, complete and unredacted copy of its license that clearly shows it was/is licensed to receive your sources.

For the removal of HDR sealed source(s) and device(s) from your license, if sources were transferred or disposed of, please provide a copy of the final (only the final) leak test result for the sealed source, as required by 10 CFR 35.67 and 35.2067; 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, complete and unredacted copy of its license that clearly shows it is licensed to receive your sources.

If the last 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 the vendor took the last source and did the final leak test, the result must still contain the information required by 10 CFR 35.2067.

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. Such documents are unacceptable as proof that licensed materials were transferred or disposed of to an appropriately licensed entity and accepted into its inventory.

An assumption of decay for relatively short-lived materials is insufficient to support a request for the removal of sources such as your HDR source, 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 or cesium-137 sources, among others.

The following references may assist you: 10 CFR 30.34(c); 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, at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>; and NUREG 1757, Vol. 1, Rev. 2 at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>.

Please also note that 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.”

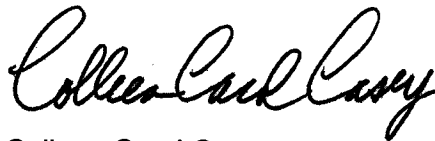
For medical/human use licensees, the following regulation describes appropriate signatories for licensing correspondence:

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.”

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 <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive, flowing style.

Colleen Carol Casey  
Materials Licensing Branch

License No. 13-18879-01  
Docket No. 030-17305  
Control No. 610538