



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

NOV 03 2016

Patrick J. Byrne
Radiation Safety Officer
Hannibal Clinic Operations, LLC
100 Medical Drive
Hannibal, MO 63401

Dear Mr. Byrne:

Enclosed is Amendment No. 11 renewing your NRC Material License No. 24-32619-01 in accordance with your request. Your license has been renewed for a term of ten years and will not expire until November 30, 2026.

Please note the following issues that remain with your renewal. Please respond to issues 3, 4 and 6 within 30 days of the date of this letter. In the alternative, please call me to make other response timeframe arrangements.

1. At this time, we also deleted Condition No. 14, as it appeared on Amendment No. 10, in favor of adding reference to 10 CFR Part 71 in the Preamble language at the top of page 1 of your license. We deleted Condition No. 13, as it appeared on Amendment No. 10, because the regulations in 10 CFR 30.35(d) render the condition no longer necessary. We also adjusted the documents listed in Condition No. 13, which has been reordered as a result of the deletion of your former Condition Nos. 13 and 14. No response required.
2. This also refers to your application dated May 6, 2016, which requests, in part, authorization for Chester Harrison, M.D. as an authorized user for materials in 10 CFR 35.200.

We were unable to approve Dr. Harrison at this time because the information provided in your application dated May 6, 2016 was insufficient to complete our review.

If you wish to pursue this matter, please provide a complete, written response that is currently dated and 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 590859." We will then continue our review.

Dr. Harrison's request to become an authorized user for materials in 10 CFR 35.200 must be fully supported by the documents you submitted. The only reference you provided for Dr. Harrison consisted of excerpted pages from an unsigned copy of a license issued by the Agreement state of Illinois. This was unacceptable to support Dr. Harrison's application.

Please submit a complete, current, signed and un-redacted copy of the license for Memorial & St. Elizabeth's Healthcare Services, LLP that shows it is authorized for

materials in 10 CFR 35.200 (or the Illinois equivalent) that Dr. Harrison is an authorized user for the use of materials in 10 CFR 35.200 (or the Illinois equivalent) on this license.

Please refer to the regulatory requirements in 10 CFR 35.290, 35.13, 35.14, 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. The following links may help you:

<http://www.nrc.gov/materials/miau/med-use-toolkit.html>

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>

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.

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.*"

3. In your response, please also include the direct telephone numbers, fax numbers and email addresses of at least the RSO and, if possible, one other person who can be responsive to licensing matters at the Hannibal Clinic, LLC directly. Our records in these regards are incomplete at this time and we are trying to bring them current to serve you better.
4. Please also specify the actual first name for the physician identified on your license as "C. Neal, M.D."
5. We were unable to approve the removal of authorization for materials in 10 CFR 35.500 at this time because the information provided in your application dated May 6, 2016, failed to support this request.

We cannot authorize the removal of materials from licenses until we have received and reviewed the results of each material's final status and disposition.

The final status and disposition must include a complete historical review of all *actual licensed materials possessed, used, stored, under that authorization*, including sealed sources and unsealed materials, spills, and contamination. In the present circumstance, please address the final status and disposition of sources you possessed under 10 CFR 35.500.

As sealed sources may have been transferred or disposed of, please provide a copy of the final leak test result for the last, most recent sealed sources under 10 CFR 35.500; 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.

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 for purposes of establishing the final status and disposition of your materials under 10 CFR 35.500.

An assumption of decay for relatively short-lived materials is also insufficient to support a final status and disposition/removal request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

The following references may assist you, if/as applicable: 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 these licensed materials, *were actually possessed* under the license and used, when the last use was for the most recent, last sources and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, etc.) or transferred.

If your license historically authorized radioactive materials under 10 CFR 35.500 that you never used, please so state specifically. Please be mindful that NRC will review your inspection history.

If licensed materials and waste 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 of the DIS restrictions in 10 CFR 35.92.

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 in order to demonstrate "cradle to grave accountability."

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.

If you have any questions, please contact me directly. If the final leak tests for your sealed sources are no longer available, please contact me to discuss alternative "close our survey" information that we will need instead.

6. We noted that you are listed as the RSO on several other NRC licenses. Therefore, in order to complete your authorization as RSO, please provide additional information as follows, in accordance with the response instructions above:
 - A. It appears that you are already named RSO on many other NRC licenses presently. Please advise us of the exact number of licenses on which you are currently named RSO.
 - B. Please describe how you will be able to devote sufficient time to this license to carry out the RSO duties, given your other RSO responsibilities.
 - C. Please describe the minimum amount of time you expect to spend serving as RSO for this license over a specified time period, such as "per week" or "per month."
 - D. Please specify what your typical response timeframe would be if you should be needed for emergency response for this license.

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.

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 <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.

P. Byrne

- 5 -

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. 24-32619-01
Docket No. 030-37200

Enclosure:

Amendment No. 11