



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

DEC 03 2013

Lynn Carlton, M.D.
Radiation Safety Officer
Nuclear Diagnosis, Inc.
P. O. Box 3371
Springfield, MO 65808

Dear Dr. Carlton:

Enclosed is Amendment No. 69 to your NRC Material License No. 24-17561-01 in accordance with your request. Please note that the major changes made to your license are printed in **bold** font.

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.

Please 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."

1. Please note that, at this time, we were unable to approve the request in your letter dated September 12, 2013, to decommission the hot lab at your Mt. Vernon, Missouri location because, as your letter states, it is still in active use. Therefore it cannot be decommissioned for release for unrestricted use until it is *permanently no longer in use*.

I have attached some information to assist you in providing appropriate information to prepare the decommissioning request.

2. Please also note that your requests to add hot lab rooms and areas to four locations of use were *minimally adequate*. We approved them at this time, but we must have additional information to complete your application for them and for our review.

Please base your response, diagrams and descriptions upon NUREG 1556, Vol. 9, Rev. 2, Sections 8.15 Item 9 and 8.16 Item 9 and Figure 9.1. Please do *not* send blueprints or copies of blueprints. They typically contain much information we do not need and

Enclosure 1 of this document contains sensitive security-related information.
Upon removal of Enclosure 1 this cover letter and Enclosure 2 is decontrolled.

L. Carlton

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very little information that we do need for our review. Please also include descriptions of shielding and the direction of north in your response.

Please submit a written response for the hot lab addition request within 30 days of the date of this letter (about the fourth week of December 2013). Please address your response to my attention as "additional information to control number 581668.)

If a different timeframe is necessary, please contact me at (630) 829-9841 to discuss alternative arrangements.

3. Please also note that we were unable to consider Michelle Gamble, CNMT, as a "second RSO" for this license, as requested in your letter dated August 15, 2013, because 10 CFR 35.24(b) limits each medical use licensee to one Radiation Safety Officer (RSO) for each license.

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

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 (Attachment 1) 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 and Attachment 2 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). 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.

L. Carlton

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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. 24-17561-01
Docket No. 030-12966

Enclosures:

1. Amendment No. 69
2. Decommissioning

Decommissioning

Attachment 2 – Decommissioning:

Please 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.*"

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; 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. 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, *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.

Enclosure 2

If your license historically authorized radioactive materials and/or 10 CFR Part 35 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, 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. Please only submit the last, or final, records for leak tests, DIS disposal, etc.

If you have any questions, please contact a staff reviewer by calling USNRC, Region III, the Materials Licensing Branch, (630) 829-9887.

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.

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.

- 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.