



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

**MAR 29 2013**

Brian Davidson  
Radiation Safety Officer  
Covance Central Laboratory Services, Inc.  
8211 SciCor Drive  
Indianapolis, IN 46214

Dear Mr. Davidson:

Enclosed is Amendment No. 16 to your NRC Material License No. 13-26058-01 in accordance with your request. Please note that the 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.

**This also refers to the telephone discussion between you and me on March 28, 2013, concerning additional information needed to complete the requests made in your letter dated January 9, 2013.**

**You informed me that only iodine-125 at very low activity levels in dry, solid forms would be stored in the new room, as that was the only material stored in the present room.**

**You agreed that adding the new room now, as a "bridge," would be useful so you could transfer stored items and conduct a close-out survey in the present room. The new room has been added in this amendment and the present room remains authorized as well.**

**The close-out survey for the present room would be submitted to us, as additional information to control number 579725, addressed to my attention, at the address above.**

**I advised you that your letter dated January 9, 2013, was very minimally adequate to support adding the new room, because it had not been fully prepared in accordance with NUREG 1556, Vol. 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers," at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/sr1556v7.pdf>**

**This guidance document should be used for all licensing correspondence.**

**In this guidance document, sections 8.9 Item 9 and 8.11, Item 11, Appendix K and Appendix T should be responded to, as appropriate, for the new room. Details for the new room such as the direction of north, the functional identity of each space surrounding it, including above and below the room, its elevation, the address of the building it is in, shielding considerations, presence or absence of windows, etc. should be included.**

The close-out survey for the present room is needed for our review in order for us to authorize the release of room for unrestricted use (even by other members of your staff).

The survey 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. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in the guidance document above, as appropriate.

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

- a. A diagram of the facility with actual dose rate survey measurements and wipe test results keyed to specific locations.
- b. The name of the person performing the survey.
- c. The date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- e. Background readings and each instruments' efficiency or correction factor, including the radionuclides used as standards to determine instrument efficiency/correction factors (should be of sufficient energy ranges to capture all radionuclides used over the course of licensed activities.) Units used should be expressed as "millirem per hour" and "disintegrations per minute," respectively, for exposure rate measurements and wipe tests.
- f. The action level for each instrument used and whether the action levels were exceeded for both the wipe test results and the dose rate survey measurements.
- g. The date(s) that the survey instruments were last calibrated.

Please refer to NUREG 1556, Vol. 7, if you have questions about these matters. Another way to navigate to NUREG 556, Vol. 7 is to go to our website at <http://www.nrc.gov>. Then click on the "Nuclear Materials" toolbar key and the "Medical, Industrial and Academic" option on the Quick List. Follow the "Academic" and "guidance" links to NUREG 1556, Vol. 7.

In this amendment I also reformatted Condition No. 11; added a new Condition 15, that was missing from the license; and modified Condition No. 17.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. Our fax number is (630) 515-1078. My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov).

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

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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.

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>.

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. 13-26058-01  
Docket No. 030-31150

Enclosure:

Amendment No. 16