



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

MAR 11 2019

Brian Davidson  
Radiation Safety Officer  
Covance Laboratories, Inc.  
8211 Scicor Drive  
Indianapolis, IN 46214

Dear Mr. Davidson:

This refers to the renewal application dated December 18, 2018 for NRC Materials License No. 13-32713-01 and the telephone conference with you on March 8, 2019. Below are the summary of the discussion and the request for additional information.

1. You provided that the licensee name has not been changed and you would like to keep the licensee name as currently listed on Amendment No. 08; however, the mailing address will be changed to 8211 Scicor Drive, Indianapolis, Indiana where your office is located.
2. Provide an organizational chart that describes the management structure, reporting path, and the flow of authority between the General Manager - the senior management on site and the Radiation Safety Officer (RSO).
3. Provide a description of the animal handling and housing facilities. For your reference, NUREG-1556, Volume 7, Rev. 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," provides guidance on the information that should be addressed concerning the use of radioactive materials in animals. Also, provide a brief description of the use of animals in research and development including how animals will be handled after the completion of the studies. In addition, please confirm that the licensee will only use licensed material within the approved facilities and will not perform any field studies where licensed material will be released.
4. Based on NUREG-1556, Volume 11, Rev. 1, Section 8.5.2., please provide the following statement "Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office." In addition, based on your current financial assurance certificate please confirm that the licensee will ensure the possession of unsealed licensed material will be limited to less than or equal to  $10^4$  times the applicable quantities of appendix B to 10 CFR part 30 (for a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by  $10^4$  is less than or equal to 1.)

5. Item 8 "Training for Individuals Working in or Frequenting Restricted Areas" states that radiation workers will be trained by the RSO and/or other qualified individual. Please provide a description of the training and experience in radiation safety for "other qualified individual" related to your radiation safety program.
6. In Item 9, the licensee requests authorization to approve new animal rooms or laboratories for use and storage of licensed material without submitting amendment requests to the NRC. The request is not clear whether the new areas of use will be within the approved buildings or not. Please provide a brief description of all proposed locations of use (such as building A – about 70' wide x 120' long and four stories height, building B ...) and the facility diagrams showing the locations of the decay-in-storage room and the Extended Interim Storage. In addition, provide where (in what buildings) the new animal rooms or laboratories will be.
7. With regards to Item 10.2, please confirm that a) the licensee will only use calibrated radiation monitoring instrument to demonstrate compliances with the NRC regulations specified in 10 CFR part 20, b) the licensee will operate and maintain the radiation monitoring instrument in accordance with the manufacturer or vendor instructions, and c) radiation monitoring instrument will be calibrated by individuals authorized by the NRC or an Agreement State license at the frequency recommended by the manufacturer or vendor.
8. For Item 10.3, provide the following statement "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."
9. In Item 10.4, the licensee briefly discussed the bioassay requirement when working with certain radionuclides. Please provide a description of the bioassay program including the baseline bioassay measurement, periodic measurement, and termination bioassay measurement, if applicable.
10. In Item 10.7, the licensee referenced to an outdated licensing guidance in its commitments. Please provide the following "We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix L of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."" (Note: based on Table L-2 in Appendix L to NUREG-1556, Volume 11, Rev. 1, the acceptable surface contamination for I-125 is different than I-126, I-131, and I-133. It is about 10 times lower.)
11. In addition, in the licensee commitment to perform leak test in Item 10.7 the licensee referenced to an outdated guidance (Appendix T to NUREG-1556, Volume 1). Please provide the following statement "As an alternative, we will implement the model leak test program published in Appendix M of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""
12. In Item 11.1, the licensee requests the flexibility to establish alternate waste storage locations without submitting amendment requests to the NRC. Section 8.9 to the NUREG-1556, Volume 11, Rev. 1 considers storing radioactive waste (including decay-in-storage) as a special application and should be described. Therefore, the licensee should provide an amendment request to the NRC when a new radioactive waste

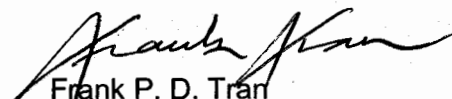
storage is proposed. Please confirm that a) the licensee will submit an amendment request for a new radioactive waste storage when needed, b) the licensee will follow the guidance provided in Appendix O, "Model Waste Management Procedures", to NUREG-1556, Volume 11, Rev. 1, to dispose low-level radioactive waste (LLRW) into sanitary sewerage or store in decay-in-storage, and c) the licensee will provide controls to ensure that radioactive waste containing tritium or carbon-14 disposing in accordance with 10 CFR 20.2005 will not be available for human or animal consumption.

13. Additionally, the licensee proposed an extended interim waste storage in Section 11.1. Based on the Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008, the extended interim storage of LLRW by materials licensees may be necessary if there is a loss of permanent disposal capacity for some classes of LLRW or there is uncertainty in the availability of access to LLRW disposal facilities. As discussed with you on March 8, 2019, you provided that your company has access to a LLRW site and your LLRW is currently disposed through Bionomics, Inc., a radioactive waste broker in Oak Ridge, Tennessee. Please confirm that the licensee has access to a LLRW disposal site and therefore its waste storage areas are not Extended Interim Storage, the licensee may store their LLRW in the proposed storage areas and will dispose them as early as possible.
14. The licensee was approved to use an incinerator in Building 240 to incinerate their LLRW (containing tritium and/or carbon-14) and dispose them as ash, in accordance with 10 CFR 20.2004. During the discussion, you provided that the licensee is no longer using the incinerator for LLRW and that LLRW will be disposed in accordance with the NRC regulations by discharging into sanitary sewerage or storing in decay-in-storage or transferring to other authorized licenses.

Please provide the response with a cover letter dated and signed by an authorized representative by April 8, 2019. To facilitate proper mail handling in our office, please reference Mail Control No. 610913 in your response. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact Frank Tran at 630-829-9630 or [frank.tran@nrc.gov](mailto:frank.tran@nrc.gov). For your reference, NUREG-1556, Volume 11, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope" can be found on the NRC's web page at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/>.

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>.

Sincerely,

  
Frank P. D. Tran  
Health Physicist  
Materials Licensing Branch