

PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
56	4/12/17	Changed the RSO

The inspectors reminded the licensee that on September 30, 2018, their NRC license expires. The licensee is planning to submit a timely application for renewal.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on March 14-16, 2016. The following violations were identified:

Non-Cited Violation: Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501 pertinent to 10 CFR 20.1201 and 20.1301: In the fall of 2015, the licensee identified that, due to oversight, previous in-vivo bioassays for iodine-125 did not consider attenuation incident to neck tissue resulting in doses that were about 50 times lower than the correct doses. In addition, the licensee identified a calculation error involving use of 5 rem as the thyroid dose limit that resulted in the dose calculation being 10 times lower than the correct dose.

During this inspection, the inspectors verified that the licensee continued to implement corrective action for this Non-Cited Violation (NCV) by using a thyroid phantom to account for attenuation incident to neck tissue for their bioassay calculations. In addition, the licensee corrected the calculation error involving the use of 5 rem as the thyroid dose limit that resulted in the dose calculation being ten times lower than the correct dose and updated applicable dose records.

Severity Level IV Violation: Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. Contrary to the above, since approximately October 2014, the licensee did not conduct adequate surveys to assure compliance with 10 CFR 20.1201 and 20.1301, which limit radiation exposure to radiation workers and members of the public, respectively. Specifically, the inspectors used an NRC owned, calibrated survey instrument affixed to a pancake probe to measure 34,330 disintegrations per minute at a single point over a combination keypad lock for an exterior door that opened from an outdoor, unrestricted area to Building 300.

Condition 22 of Amendment No. 54 of the licensee's NRC license includes a letter dated June 29, 2012, which states that individuals shall survey their hands anytime they exit the laboratory. The aforementioned inspectors' survey results are an example of the licensee not conducting an adequate survey of an individual's hands when the individual exited the laboratory. In addition, the inspectors identified that the licensee did not make adequate surveys to assure compliance with 10 CFR 20.1201, which limits radiation exposure to radiation workers. Title 10 CFR 20.1201(c) requires that the assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square

centimeters of the skin receiving the highest exposure. The licensee conducted ambient count rate surveys of radiation workers' skin that was contaminated with licensed material and used the survey results to calculate the shallow-dose equivalent; however, due to licensee oversight, the licensee's dose calculation results were dose per 100 square centimeters rather than the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure, resulting in the licensee's calculated dose being one tenth of what it should have been.

The inspectors reviewed calculations for skin exposures and determined that the licensee had appropriately assigned shallow-dose equivalent averaged over the 10 square centimeters of skin receiving the highest dose. However, since the last inspection, there were several occasions in which the licensee failed to perform adequate surveys to prevent the spread of radioactive material. Those occurrences are described in detail under Part II-Section 4 of this report. Due to the recurrence of the licensee's violation of 10 CFR 20.1501, this violation remains open.

The previous inspection of this licensee was on October 7-9, 2014. The following violation was identified:

Severity Level IV Violation: Title 10 CFR 20.1003 defines "survey" as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. Contrary to the above, on October 7, 2014, the licensee did not make surveys to assure compliance with 10 CFR 20.1201 and 20.1301, which limits occupational dose to individual adults and individual members of the public, respectively. Specifically, two survey instruments were used to conduct personal surveys of individuals exiting the Building 300 Lab and they read 3000 counts per minute (CPM) and 1750 CPM, respectively; and two survey instruments were used to conduct personal surveys of individuals exiting the Building 100 Lab and they read 900 CPM due to radioactive contamination on the survey instrument probes which did not allow individuals to detect radioactive contamination on themselves prior to exiting the labs. The inspectors subsequently identified radioactive contamination on a lunchroom chair and identified that the occupational worker who had just used the chair had radioactive contamination on several areas of his personal clothing, forearms, hands, and vehicle. The inspectors observed the licensee decontaminate the aforementioned areas and conduct post decontamination surveys. The licensee conducted daily surveys of the individual for several days to obtain results that were used to determine that the individual received 30 millirad to the skin as a result of the contamination.

During the inspection, the inspectors used an NRC owned, calibrated survey instrument that was affixed to a pancake probe and measured no counts above low background.

3. INCIDENT/EVENT HISTORY:

There were no open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee manufactured and synthesized radiolabeled chemicals for distribution to authorized persons. The licensee possessed approximately 6,700 Curies of hydrogen-3 (H-3) and 145 Curies of carbon-14 (C-14). Nearly 100 percent of the licensee's radioactive material was H-3 and C-14. Radiolabeled chemical synthesis involved use of high-specific-activity H-3 and C-14 labeled organic chemicals. A Health Physics Technician reported to the licensee's RSO. The RSO reported to the licensee's president who also served as the Chairman of the Radiation Safety Committee (RSC) and an authorized user. Three additional authorized users reported to the licensee's president.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87125

Focus Areas Evaluated: All

The inspectors: (1) observed authorized users donning and doffing personal protective equipment (PPE) as required; (2) observed authorized users wash and survey their hands every time they exited restricted areas; (3) observed no cosmetics applications in restricted areas; (4) observed no food or drink in restricted areas; (5) observed no pipetting by mouth; (6) observed licensed material used and stored on work surfaces covered with absorbent, disposable materials; (7) observed an authorized user demonstrate how he had transferred licensed material between buildings, including use of a suitable secondary containment; (8) observed an authorized user use a round-bottom container to hold licensed material, and that round-bottom container was contained in a beaker to prevent radioactive spills; (9) observed an authorized user measure the face velocity of a fume hood where licensed material was used, and the face velocity was as required; (10) observed that the licensee had transferred many Surface Contaminated Objects (SCO) from its premises since the last inspection; (11) noted that the RSO committed to continue transferring SCOs off of the licensee's premises; (12) reviewed selected reports of area removable contamination surveys; (13) noted that the RSO has direct access to corporate management and authority to perform RSO duties; (14) reviewed internal dosimetry records; (15) observed that licensed material was not used in field applications or for human use; (16) observed that the licensee was in compliance with possession limits; (17) observed the licensee still used motion and entry point alarms to identify unauthorized access to restricted areas; (18) interviewed an authorized user regarding use of ring dosimeter badges during use of P-32 and noted that the authorized user wore the badge correctly; and (19) reviewed several survey instruments and noted that all of them were in calibration.

The inspectors reviewed the radiation protection program audit record done in December 2016 for calendar year 2016, by the RSO. The RSO identified that licensee personnel are challenged to be encouraged to pursue improvement of the Radiation Protection Program and implementation due to low staffing levels. As a result, the licensee added 2.2 full-time equivalents. The RSO used interviews and observations to verify if licensed material was used safely and that required actions were taken. The RSO identified that there were not enough survey instruments available as backup; therefore, the licensee acquired more survey instruments resulting in having enough survey instruments. In addition, the RSO conducted daily constancy checks on survey instruments. The RSO also checked environmental monitoring, licensed material

security, licensed material transportation, the ALARA program, and physical inventory of licensed material.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors used NRC-owned, calibrated survey instruments to conduct independent surveys of selected areas of the licensee's facilities. The inspectors measured low background counts on several exterior doorknobs, keypad locks, doorbell buttons, and licensee pancake probes affixed to survey meters that were used to conduct personal ambient count rate surveys when exiting restricted areas and noted that the results showed no radioactive contamination.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Radiation Safety Officer

Donald Lite III was the licensee's RSO in June 2016, and he worked with Jeffrey S. Vollmer. At that time, Vollmer was technically qualified to serve as the licensee's RSO. From June 20, 2016 to November 2, 2016, (the day that Lite stopped being the licensee's RSO), Vollmer provided oversight of the radiation protection program and provided Lite with technical health physics expertise. In addition, Vollmer helped with auditing the radiation protection program once per week for 6 hours on Fridays (e.g., looking for problems, identifying actions that had not been completed, and finding problems or issues that need correction). In September 2016, Vollmer audited the radiation protection program biweekly until December 2016. After December 2016, Vollmer worked 20 hours per week auditing the radiation protection program, including oversight of the licensee's bioassay program, until the licensee designated Vollmer as the licensee's RSO on March 28, 2017. After Lite stopped being the RSO, the licensee contracted Lite for remote consultation to support Vollmer as the RSO, and the contract ends on December 1, 2017. As a result, Lite consulted Vollmer three times since about January 2017. The inspectors reviewed Lite's contract that included availability by telephone and email to communicate with licensee staff members about any health physics or related issue to the best of his ability and knowledge.

As the RSO, Vollmer observed authorized users using and handling licensed material including new licensed material syntheses, provided on-the-job radiation protection training such as PPE use, and reviewed the bioassay program and the air effluents program. In addition, he was aware that he has stop work authority if there is a dangerous action involving licensed material.

Condition 12. of Amendment No. 55 of the licensee's NRC License No. 24-21362-01 (license) dated January 20, 2015, states the name of the individual (i.e., Donald Lite III) who is the licensee's RSO. On November 2, 2016, Lite left the licensee's employ, and, although still available as a consultant, did not perform the duties and responsibilities of RSO. On March 10, 2017, the licensee submitted a letter requesting that the license be amended to add Vollmer as the RSO. License Amendment No. 56 was issued on April 12, 2017, adding Vollmer as the RSO. From November 2, 2016 to April 12, 2017, the individual named as the licensee's RSO in Condition 12 of Amendment No. 55 of the license did not perform the duties and responsibilities of RSO, resulting in a violation of Condition 12 of Amendment No. 55 of the license.

As long-term corrective action to prevent a similar violation, the licensee committed to revise its Radiation Protection Program (RPP) to: (1) inform the NRC whenever an individual notifies the licensee that he/she announces the date when he/she will stop

being the RSO; (2) start the process of hiring a new RSO; and (3) notify the NRC if there are any problems with the process of naming the new RSO on the license.

Personal Radiation Surveys & Radioactive Contamination Control

Contamination Event on November 15, 2016

On November 15, 2016, the licensee identified removable contamination of H-3 and C-14 in a lunchroom in Building 100. The licensee's "Contamination Investigation Report" reported that the causes of the event were: (1) decontamination of the Sea Land container last week; and (2) staff came into the building numerous times during the process and some loose contamination remained in the lunchroom. For action to prevent recurrence of the event, the report included, "The staff responsible for decontamination of the Sea Land container has been briefed on proper techniques to prevent recurrences." As such, the report's documented action to prevent recurrence of the event did not provide sufficient detail, such as the specific actions needed to prevent recurrences.

In order to get those details, the inspectors interviewed a licensee employee who had those details. The staff were told to put Sea Land container contaminated objects in 3 millimeter (mm) plastic bags that will be weighed, dated, surveyed for removable radioactive contamination, and surveyed for ambient count rate. In addition, the staff were told to don PPE when they are in the Sea Land container including jackets, gloves, shoe covers, and booties. The staff were also told to use a change area including use of 6 mm bags for the ground pad to prevent radioactive contamination spread to unrestricted areas, and to conduct "head-to-toe" personal ambient count rate surveys to identify C-14 contamination.

The inspectors noted that the licensee's investigation revealed that the licensee's method for identifying the cause of events was not high quality, and the actions to prevent recurrence did not provide enough detail to understand how to implement the action. The inspectors determined that the contamination event was evidence that authorized users were not conducting adequate personal radiation surveys when leaving restricted areas.

Contamination Event January 9, 2017

On January 9, 2017, the licensee identified removable contamination of H-3 and C-14 on the floor outside of the changing area in Building 100. The licensee's "Contamination Investigation Report" stated that the causes of the event were: (1) that contamination was tracked out from the changing area; (2) maybe the contamination happened when transporting chemicals between buildings; and (3) the area provides potential contamination on the floors and someone may have walked on a contaminated surface and tracked it out. For action to prevent recurrence of the event, the report included, "Recommend a shoe survey and further scans of area to detect spreading."

The inspectors noted that the licensee's investigation revealed that the licensee's method for identifying the cause of events was not high quality. The inspectors determined that the contamination event was evidence that authorized users were not conducting adequate personal radiation surveys when leaving restricted areas.

Personal Radiation Surveys

The inspectors observed an authorized user demonstrate how he had conducted full body frisks with a survey meter at the end of the workday. The inspectors noted that the individual had not surveyed the bottom of his shoes, which could have resulted in licensed material not being identified on the soles of his shoes that may have spread from a restricted area to an unrestricted area.

Title 10 CFR 20.1501(a) states, in part, that each licensee shall make or cause to be made, surveys of areas, including the subsurface, that: (1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate: (i) The magnitude and extent of radiation levels; and (ii) concentrations or quantities of residual radioactivity; and (iii) the potential radiological hazards of the radiation levels and residual radioactivity detected.

Condition 22. of Amendment No. 55 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated June 29, 2012 that includes the licensee's Radiation Protection Program (RPP). Section 5.2.3.1 of the RPP states, in part, "Individuals shall survey their hands every time they exit the laboratory. At the end of the workday, a full body frisk with the survey meter is required."

The aforementioned radioactive contamination events and the inspectors' identification of an authorized user not surveying the soles of his shoes is evidence that personal radiation surveys were inadequate to show compliance with 10 CFR 20.1201 and 10 CFR 20.1301 and Condition 22. of Amendment No. 55 of the license. As such, a violation of 10 CFR 20.1501(a) and Condition 22. of Amendment No. 55 of the license occurred.

As immediate corrective action after the onsite inspection, the licensee had managers and health physics staff members observe authorized users conduct personal surveys/full body frisks with a survey meter to confirm that the surveys are done as required. In addition, the licensee continued that practice as of October 26, 2017. The licensee also required that individuals shall survey their hands and feet every time they exit the laboratory. As long term corrective action, the licensee generated a root cause evaluation plan (plan) to prevent and reduce contamination outside of restricted areas that was approved by the licensee's president during the onsite inspection. The inspectors reviewed the plan that included, in part: (1) the purpose is to perform causal evaluation to determine corrective actions to prevent and reduce contamination outside of restricted areas; (2) use of a four member team of individuals led by a team leader that was trained in Root Cause Evaluations; (3) weekly team meetings beginning on October 9, 2017; (4) an evaluation that is expected to be completed and reported by November 24, 2017, with recommendations to reduce contamination events; (5) after the initial report is created, an effectiveness review of the corrective actions will be conducted monthly; and (6) the effectiveness reviews and evaluation and ensuing plans will be shared with all of the staff.

For years, the licensee has had the authorized users use two pairs of shoes to prevent events involving radioactive contamination being tracked from restricted areas to unrestricted areas. One pair of shoes is worn and stored only in the unrestricted areas. The other pair of shoes is worn and stored only in the restricted areas. The inspectors determined that the aforementioned radioactive contamination events are evidence that the licensee's having authorized users use two pairs of shoes has not prevented

radioactive contamination in unrestricted areas, however, it may have reduced the number of those events.

Surface Contamination Objects

Determination of Future Usefulness

Condition 22. of Amendment No. 55 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated September 30, 2014, that includes a commitment to follow the licensee's Standard Operation Procedure-29 (SOP-29) titled "Storage of Surface Contaminated Objects (SCO)."

Paragraph 1.1 of SOP-29 states, when no longer being used, SCOs are transferred to Building 200 for temporary storage or storage for future use, and a decision is made by the Senior Chemist and the RSO prior to movement of the item.

Contrary to the above, between October 1, 2014, and February 18, 2015, the licensee moved approximately 100 SCOs into temporary storage without a decision regarding their future usefulness. Movement of those items prior to a decision being made on their future usefulness constitutes a violation of Condition 22. of Amendment No. 55 of the license. The inspectors determined that it is important that a decision be made on the future usefulness of each SCO prior to its movement to storage because it directly affects how long the item may remain in temporary storage.

The root cause of this violation was a lack of management oversight regarding the SCO inventory process. As corrective action, the RSO updated the licensee's inventory of SCOs such that all SCOs have an indication of future usefulness. In addition, the RSO reviewed SOP-29 with the Senior Chemist and pertinent maintenance staff to ensure that a determination of future usefulness is made for all newly generated SCOs prior to moving them to temporary storage.

Time in Temporary Storage

The inspectors noted that the licensee had approximately 20 SCOs marked as temporary storage within their inventory that were added between October 1, 2014 and February 18, 2015.

Condition 21. of Amendment No. 56 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated September 30, 2014, that includes a commitment to follow the licensee's Standard Operation Procedure-29 (SOP-29) titled "Storage of Surface Contaminated Objects."

Paragraph 1.1 of SOP-29 states, in part, that SCOs marked as temporary storage shall spend no longer than 12 months in the inventory. After 12 months, temporary storage items will have a 3-month grace period where it must either be disposed of as radioactive waste or decontaminated. The entry date in the inventory for all previously entered temporary storage items will be taken as October 1, 2014; therefore, the 12 and 3 month time frames shall take effect as of that date.

The aforementioned SCOs marked as temporary storage had been in the licensee's inventory for a period exceeding the 12 months plus the 3-month grace period referenced in SOP-29, resulting in a violation of Condition 21. of Amendment No. 56 of the license.

The root cause of this violation was a lack of dedicated resources available to decontaminate or dispose of SCOs in a timely manner. As corrective action, the licensee hired additional staff to assist with the decontamination and disposal of SCOs.

The inspectors noted that the number of SCOs in the dedicated storage location was greatly reduced since the last inspection.

5. PERSONNEL CONTACTED:

- # Beth Brockling, Accounting
- # Kamal Das, Vice President & Lab Manager
- # Surendra Gupta, Ph.D., President
- # Kristina Lafser, Administrative Assistant
- # Dustin McDermott, Assistant RSO
- # Janardhanam Selvasekaran, Vice President
- # Shin Yu, Authorized User
- #^ Jeffery Vollmer, RSO
- # Jason Yu, Authorized User

- # Attended preliminary exit meeting on October 12, 2017

- ^ Attended final exit meeting on October 26, 2017