

ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.: 030-15186

License No.: 40-02331-19

Report No.: 030-15186/97-01

Licensee: University of South Dakota
School of Medicine

Facility: University of South Dakota

Location: 414 East Clark Street
Vermillion, South Dakota

Dates: October 9 through November 7, 1997

Inspector: Richard A. Leonardi, Jr.
Radiation Specialist

Approved By: D. Blair Spitzberg, Ph.D., Chief,
Nuclear Materials Inspection and
Fuel Cycle/Decommissioning Branch

Attachment: Supplemental Inspection Information

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EXECUTIVE SUMMARY

University of South Dakota, School of Medicine, Vermillion, South Dakota
NRC Inspection Report 030-15186/97-01

This was a routine inspection conducted to review the radiation safety activities associated with a small, Academic Type B broadscope program primarily involving the University's medical school.

Purpose of Inspection and Licensee Program Overview

- The on-site portion of this inspection was conducted during the week of October 8-10, 1997. The licensee's use of licensed material is confined to some plant research in the biology department of Churchill-Haines Hall and the limited use of licensed material in the University's medical school in the Lee Medicine and Science Building (hereafter called Lee Medical Building)(Section 1).

Security of Licensed Material

- An apparent violation of 10 CFR 20.1801 and 20.1802 was identified involving the failure to properly secure from unauthorized access or removal licensed material located in controlled areas (Section 2).

Radiation Safety Program Management and Control

- An apparent violation of NRC requirements was identified involving the failure to conduct quarterly program reviews with the university president during the inspection. Because of the absence of management control over licensed activities, as evidenced by the numerous apparent violations identified during the inspection, an apparent violation of 10 CFR 33.14(b) was identified for failure of the licensee, through the radiation safety officer (RSO), to ensure that radiation safety activities were being performed as required (Section 3).

Management of Radioactive Waste

- An apparent violation of License Condition 19 was identified involving the failure to hold radioactive material for 10 half-lives prior to disposal in ordinary trash (Section 4).

Survey Instrument Calibration Program

- An apparent repeat violation was identified involving the licensee's failure to calibrate survey instruments on a 6-month frequency (Section 5).

Review of Other Program Areas

- Based on the inspector's review of other radiation program areas, the inspector identified five additional apparent violations. These apparent violations involved failures to:
(1) conduct a physical inventory of sealed sources at 6-month intervals; (2) ensure that licensed material was ordered by the RSO; (3) notify radiation workers of their annual dose; (4) provide training to housekeeping and security personnel; and (5) determine the dose to members of the public from exposure to airborne radioactive effluents (Section 6).

Report Details

1 Purpose of Inspection and Licensee Program Overview (87100)

The University of South Dakota (USD) is authorized under a Type B broadscope license to possess all byproduct material listed in Section 10 CFR 33.100, Schedule A, Column I, for research and training purposes. The licensee was issued a specific license for research in April 1979, which was converted to a Type B broadscope license in April 1985. Although the licensee possesses a plutonium-239 and cobalt-60 sealed source, neither source has been used in recent years. The licensee uses about 20-50 millicuries of licensed material annually in conjunction with research activities in the medical school. Some licensed material is used in the basic sciences program. Licensed material is not used for human use, and use in animals is limited to small animals (rats). The inspection involved personnel interviews, observations of activities in progress, and the review of licensee records.

2 Storage and Control of Licensed Material (87100)

2.1 Inspection Scope

This portion of the inspection included a review of the licensee's procedures for storage and use of licensed materials at the USD campus.

2.2 Observations and Findings

During a tour of the Lee Medical Building on October 9, 1997, the inspector observed that the door to a radioactive waste storage room (Room 61) in the basement floor containing millicurie quantities of radioactive waste was unlocked and unattended by licensee personnel. This was identified as a lack of adequate security. The room was actually a walk-in safe used for chemical as well as radioactive waste storage. The inspector also observed several research laboratories containing both microcurie and millicurie quantities of licensed material, with the doors propped open, without any licensee personnel in the labs or anyone in the immediate areas to challenge an unauthorized individual from gaining access to licensed material in the labs. The entrances to the Lee Medical Building were maintained unlocked during daytime hours, but the doors were locked after hours.

A review of the licensee's Radiation Safety Manual disclosed that it did not specifically address licensed material security, and interviews conducted with authorized users revealed that they were not aware of a specific policy or procedure relating to material security.

During discussions with the RSO and various researchers during the tour of the licensee's facilities and a review of limited material accountability records, the inspector

did not identify any evidence of misuse or unauthorized removal of licensed material from the storage or use laboratories; however, the potential did exist.

10 CFR 20.1801 requires that a licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that a licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside a restricted area but inside the site boundary, to which access can be limited by the licensee for any reason. An *unrestricted area* means an area in which access is neither limited nor controlled by the licensee.

The failure to secure the walk-in radioactive waste storage area and several research laboratories on October 9, 1997, was identified as an apparent violation of 10 CFR 20.1801 and 20.1802 (030-15186/97001-01).

2.3 Conclusions

An apparent violation of 10 CFR 20.1801 and 20.1802 was identified involving the failure to properly secure from unauthorized access or removal licensed material located in controlled areas.

3 **Radiation Safety Program Management and Control (83822, 87100)**

3.1 Inspection Scope

This portion of the inspection included interviews with licensee personnel, a review of licensee records and observations of licensee activities to determine the extent to which licensed activities had been managed and controlled effectively and in accordance with regulatory requirements.

3.2 Observations and Findings

A broadscope license is issued by the NRC to accommodate those institutions involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. The NRC grants significant latitude to licensee management to develop and implement an appropriate radiation safety program. Consequently, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. 10 CFR Part 33 requires that Type B broad scope licensees establish administrative controls and provisions, and ensure management oversight through the RSO, necessary to assure safe operations and compliance with NRC regulations.

License Condition 24 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in license

application dated March 30, 1990. The licensee's commitment to conduct activities in compliance with NRC requirements is specified in Item 7, *Management Control and Responsibilities*, of that application.

During an interview with the current RSO and previous RSO, the inspector determined that the RSO position turn-over conducted in July 1997 between the current and previous RSOs appeared inadequate, as evidenced by the fact that the current RSO at the time of the inspection was not familiar with certain required records, nor had he been briefed as to the location of all required records. The inspector noted that the current RSO had recently attended a 1-week RSO training course, and subsequent to the course, he had initiated a "To Do" list containing self-identified program concerns that he planned to address. It appeared that the current RSO had little guidance provided by either the previous RSO or University administration. In addition, through interviews with the current RSO, the inspector determined that the previous RSO did not appear to have sufficient time to focus necessary attention to the licensee's radiation safety program, nor had he been involved in daily activities associated with USD's radiation safety program. The RSO's limited knowledge of NRC regulations, USD's current Radiation Safety Manual (1990), and license conditions appeared, to some extent, to be the result of the an inadequate RSO turn-over between the previous and current RSO.

The inspector noted that the licensee's management control and oversight program required the RSO to meet quarterly with the university president to review audits of the procurement, use, disposal of licensed materials, the training programs for users, and the radiation safety program. However, the previous RSO acknowledged that these quarterly reviews with the university president had not been conducted since the license was renewed in July 19, 1994, nor had annual radiation safety program reviews been performed as of this inspection date. License Condition 24 requires, in part, that the licensee conduct its program in accordance with statements, representations, and procedures contained in the license application dated March 30, 1990, and letter dated June 1, 1993. The RSO's commitment to meet quarterly with the university president to review the audit of the procurement, use, and disposal of byproduct material, the training programs of users, and the radiation safety program was specified in Item 7, *Management Control and Responsibilities*, of letter dated June 1, 1993. The failure of the RSO to conduct quarterly radiation safety program reviews with the university president was identified as an apparent violation of License Condition No. 24 (030-15186/97001-02).

10 CFR 33.14(b) requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with Commission regulations, license conditions, and licensee's radiation safety procedures. This inspection identified numerous apparent violations of NRC requirements, including a repeat violation from the previous inspection of May 2-6, 1994 (see Section 6). The failure of the licensee, through the RSO, to ensure that radiation safety activities were being performed in accordance with Commission regulations, license conditions, and licensee's radiation

safety procedures was identified as an apparent violation of 10 CFR 33.14(b) (see Section 6) (030-15186-03).

3.3 Conclusions

An apparent violation of NRC requirements was identified involving the failure to conduct quarterly program reviews with the university president. Because of the absence of management control over licensed activities, as evidenced by the numerous apparent violations identified during this inspection, an apparent violation of 10 CFR 33.14(b) was identified for failure of the licensee, through the RSO, to ensure that radiation safety activities were being performed as required.

4 **Management of Radioactive Waste (87100)**

4.1 Inspection Scope

This portion of the inspection included interviews with licensee personnel, a review of licensee records, and observations of licensee activities to determine compliance with the license requirements and the regulations in 10 CFR 20.2001-20.2006 relating to the licensee's radioactive waste management program.

4.2 Observations and Findings

License Condition 19 specifies, in part, that the licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided: (1) radioactive waste to be disposed of in this manner is held for decay a minimum of 10 half-lives; and (2) before disposal as ordinary trash, byproduct material is surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that any radioactivity present cannot be distinguished from background.

During interviews of research laboratory personnel and review of laboratory use records, the inspector determined that some laboratories were routinely disposing of phosphorus-32 in ordinary trash after holding the radioactive waste for a minimum of 5-6 half-lives. The failure of the licensee to hold radioactive material for a minimum of 10 half-lives prior to disposal in ordinary trash was identified an apparent violation of License Condition 19 (050-15186/97001-04). However, the inspector determined that those same research personnel had routinely taken an aliquot of the liquid waste and determined its activity was indistinguishable from background prior to release to ordinary trash.

The inspector observed that some research laboratories had accumulated extensive low-activity-level liquid radioactive waste in numerous glass containers that had been placed on window sills, laboratory floors, and in locations that could pose a radiation contamination risk if the containers were damaged. Additionally, the inspection of

radioactive waste storage facilities in the Basic Science Building (Biology department) and in the Lee Medical Building (Biochemistry Department) revealed that the licensee had not maintained a current inventory of radioactive waste in each storage facility. The inspector discussed with licensee representatives his conclusion that they had not fully utilized all radioactive waste disposal options allowed under 10 CFR 20.2001, 20.2003, 20.2004, 20.2005, and 20.2006.

4.3 Conclusions

An apparent violation of License Condition 19 was identified involving the failure to hold radioactive material for 10 half-lives prior to disposal in ordinary trash.

5 **Survey Instrument Calibration Program (87100)**

5.1 Inspection Scope

This portion of the inspection included interviews with licensee personnel, a review of licensee records, and observations of licensee activities relating to compliance with the licensee's survey instrument calibration program.

5.2 Observations and Findings

License Condition 24 requires, in part, that licensed material be used in accordance with statements, representations, and procedures contained in the application dated March 30, 1990, and letter dated June 6, 1994. Item B of the letter states that authorized users will have available for use survey instruments calibrated within a 6-month period.

During a tour of research laboratories in the Lee Medicine Building on October 9, 1997, the inspector observed three survey instruments in three different laboratories which were being used to conduct daily radiation area surveys and personnel contamination checks. These survey meters had not been calibrated within the past 6 months. The inspector noted that the three survey meters had been calibrated on an interval between 12 and 18 months. The inspector determined that although the survey meters had not been calibrated at the required 6-month intervals, all three appeared to be operating properly. During discussions with the current RSO, he indicated that survey instrument calibration had not been given the priority and attention that was needed to maintain all instruments within the required 6-month calibration frequency. The RSO disclosed that he was considering calibrating survey instruments in-house, using a commercially available instrument calibration system, or purchasing a sealed source for use with a home-made calibration jig.

Based on the above information, the failure to calibrate the licensee's survey instruments at 6-month intervals was identified as an apparent repeat violation of License Condition 24 (030-15186/97001-05). A violation of the instrument calibration requirement was identified during the previous inspection conducted May 2-6, 1994.

5.3 Conclusions

An apparent repeat violation was identified involving the licensee's failure to calibrate survey instruments at 6-month intervals.

6 **Review of Other Program Areas (87100)**

6.1 Inspection Scope

This portion of the inspection involved the review of other radiation safety program areas including: the annual radiation exposure notification to radiation workers; required physical inventories, ordering of licensed material; the training of ancillary personnel; and the annual exposure evaluation to individual members of the public due to the release of radioactive air effluents to the environment.

6.2 Observations and Findings

License Condition 16 requires that the licensee conduct a physical inventory each 6 months to account for all sources and/or devices received and possessed under the license. Based on interviews with the current RSO and a review of licensee records, the inspector determined that the licensee had not been performing 6-month physical inventories of two sealed sources possessed by the licensee. The inspector determined that the licensee possessed a 900 microcurie cobalt-60 sealed source (Serial No. 1273), and two 16 gram plutonium-239 sealed sources (Serial Nos. 160A33 and 160A48) that had been in storage for several years. The licensee's current RSO indicated that the previous RSO believed that sealed sources that were in storage were exempt from inventory and leak testing requirements. The failure to perform 6-month physical inventories of sealed sources and/or devices was identified as an apparent violation of License Condition 16 (030-15186/97001-06).

License Condition 24 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 30, 1990. Item 10 of the application specifies that all orders for licensed material must be authorized by the RSO, and phone orders by authorized users without the RSO's authorization is prohibited.

During the review of the licensee's procedures for the purchase of licensed materials, the inspector noted that licensed material on occasion had been ordered by various authorized users by telephoning the radioactive material suppliers directly and ordering needed material by phone. The authorized user would then process a written requisition through the RSO's office for his signature. The inspector determined that the licensee's written procedures for ordering licensed material required that the RSO approve all requisitions for licensed material and that the RSO order all licensed material. The licensee's procedures explicitly prohibited phone orders made by authorized users prior to RSO authorization. The failure of the licensee to ensure that all orders of licensed

materials were authorized by the RSO prior to placing orders for material was identified as an apparent violation of License Condition 24 (030-15186/97001-07).

10 CFR 19.13(b) requires that each licensee advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to 20.2106 of Part 20. During the review of licensee personnel monitoring records, the inspector determined that the licensee had failed to notify all monitored personnel of their radiation dose for calendar years 1994-1996. The failure of the licensee to notify each worker annually of his/her occupational radiation dose was identified as an apparent violation of 10 CFR 19.13(b) (030-15186/97001-08).

Item 10, "Radiation Safety," Section 10.2.5 "Other Procedures," Subsection (a) Training and Supervision of Laboratory Personnel," of the license application dated March 30, 1990, specifies that all housekeeping and security personnel are to be informed of the hazards of handling radioisotopes, the areas in which isotopes are used to avoid cleaning specified areas such as bench tops, hoods, etc., in laboratories; and not to handle any waste disposal container labeled with an isotope warning sign. During a review of the licensee's training program, including records of ancillary personnel training, the inspector determined that housekeeping and security personnel had not been trained as specified above. The current RSO indicated that he had discussed this commitment with USD research staff, and they indicated that housekeeping did not perform any housekeeping functions in the research laboratories, nor did security personnel handle licensed materials. However, during further discussions with the current RSO, he stated that both the housekeeping and security personnel should have received general radiation safety awareness training as specified in the licensee's license application. Based on this information, the inspector identified the failure to train housekeeping and security personnel in radiation safety as an apparent violation of License Condition 24 which requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures in the license application (030-15186/97001-09).

10 CFR 20.1101(d) requires, in part, that each licensee establish a program to ensure that no member of the general public is likely to receive in excess of 10 millirem dose per year from the licensee's radioactive air effluents. The inspector determined that some licensee authorized users allowed radioactive liquids to evaporate under a source of heat in a vented hood as a means of reducing the liquid radioactive waste inventory. This practice would generate radioactive airborne releases to the environment. Based on interviews with the current RSO, he indicated that he was not aware of any evaluations that had been performed to evaluate USD's release of radioactive air effluents. Based on this information, the failure of the licensee to evaluate the potential radiation dose to a member of the general public from the licensee's release of radioactive air effluents was identified as an apparent violation of 10 CFR 20.1101(d) (030-15186/97001-10).

6.3 Conclusions

Based on the inspector's review of other radiation program areas, the inspector identified five additional apparent violations (Section 6). These apparent violations involved failures to: (1) conduct a physical inventory of sealed sources on a 6-month interval, (2) ensure that licensed material was ordered by the RSO, (3) notify radiation workers of their annual dose, (4) provide training to housekeeping and security personnel, and (5) determine the dose to members of the public from exposure to airborne radioactive effluents.

7 **Exit Meeting Summary**

The inspector presented the preliminary inspection findings to licensee administration on October 9, 1997. A telephonic exit briefing was conducted on November 7, 1997, with the university's RSO. Licensee representatives confirmed during the exit briefing that no proprietary information was reviewed by the inspector.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee

H. Coker, Ph.D., RSO
R. Engstrom, Ph.D., Director, Office of Research
R. Lynn, Ph.D.
R. Noiva, Ph.D., Department Head, Biochemistry & Molecular Biology
K. Johnston, Dosimetry Coordinator
J. Heisinger, Ph.D., Department Head, Biology
K. Weaver, Ph.D., Researcher
B. Goodman, Ph.D., Researcher

INSPECTION PROCEDURES USED

87100 Licensed Materials Programs
83822 Radiation Protection
87102 Effluents Program

LIST OF ACRONYMS USED

NRC	Nuclear Regulatory Commission
RSO	radiation safety officer
USD	University of South Dakota

ITEMS OPENED, CLOSED AND DISCUSSED

OPENED

030-15186/97-01	APV	Apparent violation of 10 CFR 20.1801 and 10 CFR 20.1802 involving a failure to secure licensed material from unauthorized removal or access that was stored in controlled areas and failure to control and maintain surveillance of licensed material that was in a controlled or unrestricted area and not in storage .
030-15186/97-02	APV	Apparent violation of License Condition 24 involving the failure of the RSO to have conducted quarterly radiation safety program reviews with the university president.
030-15186/97-03	APV	Apparent violation of License Condition 24 involving the failure of the licensee through the radiation safety officer to ensure management control and oversight of the radiation safety program.

030-15186/97-04	APV	Apparent violation of License Condition 19 involving the failure to hold radioactive material for a minimum of 10 half-lives prior to disposal as ordinary trash.
030-15186/97-05	APV	Apparent violation of License Condition 24 involving the failure to calibrate survey instruments at 6-month intervals.
030-15186/97-06	APV	Apparent violation of License Condition 16 involving the failure to perform 6-month physical inventories of sealed sources and /or devices.
030-15186/97-07	APV	Apparent violation of License Condition 24 involving the failure to ensure that all orders of licensed material were authorized by the RSO.
030-15186/97-08	APV	Apparent violation of 10 CFR 19.13(b) involving the failure to notify each radiation worker annually of his/her occupational radiation dose.
030-15186/97-09	APV	Apparent violation of License Condition 24 involving the failure to provide training for housekeeping and security personnel.
030-15186/97-10	APV	Apparent violation of 10 CFR 20.1101(d) involving the failure to evaluate the potential radiation dose to a member of the public from the licensee's release of radioactive air effluents.

CLOSED

None

DISCUSSED

None