APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-00871/93-01

License: 25-00326-06

Licensee: Montana State University
Bozeman, Montana 59717

Facility Name: Montana State University

Inspection At: Bozeman, Montana

Inspection Conducted: November 3-4, 1993

Inspector: Mark R. Shaffer, Radiation Specialist
Nuclear Materials Inspection Section

Approved: Linda Kasner 12/29/93
Linda L. Kasner, Acting Chief, Nuclear Materials Inspection Section — Date

Inspection Summary

Areas Inspected: Routine, unannounced radiation safety inspection of licensed activities including the use of byproduct material for research and development activities conducted under authorization of the licensee's Radiation Safety Committee.

Results:

- Within the scope of the inspection 12 violations were identified. Two of these violations were identified as repeat violations. Collectively, the number and nature of the violations indicate weaknesses in management oversight of the radiation safety program and a lack of attention to detail with program implementation.

- The inspection disclosed that the licensee had maintained adequate records of its byproduct material inventory to insure that the total quantity of byproduct material on hand was within allowable license limits for each radioisotope. Additionally, it was noted that procedures for package receipt and monitoring had been implemented as stated in the license.

Summary of Inspection Findings:

- Failure of the Radiation Sources Committee (RSC) to perform audits of the amounts of radioisotopes purchased and disposed of under various proposals, and failure of the RSC to examine exposure records from film badge usage (Section 1).

- Failure of the RSC to audit individual research projects to ensure that appropriate training was provided to personnel (Section 1).

- Failure to return film badges for processing at the required monthly intervals (Section 2).

- Failure to perform surveys or evaluations of the occupational radiation dose received by individuals who had not returned film badges at the required frequencies (Section 2).

- Failure to check survey instruments with a radiation source (calibration) at the required frequency (Section 3).

- Failure to equip fume hoods used to perform iodinations with an air sampling device as specified in the license (Section 6).

- Failure to perform visits, inspections, and/or surveys of research laboratories at the required frequencies (Section 6).

- Failure to perform audits of vehicles transporting radioactive material off campus to temporary jobsites (Section 6).

- Failure to maintain records of information important to the safe and effective decommissioning of the facility in an identified location (Section 7).

- Failure to prepare shipping papers in accordance with 49 CFR 172.200-203 (Section 7).

- Failure to maintain documentation on file, including records of tests and engineering evaluations showing that the construction methods, packaging design, and materials of construction complied with the specification as described in 49 CFR 178.350, for DOT Specification 7A Type A packages used to transport radioactive material (Section 7).

- Failure to maintain documentation on file, including a complete safety analysis demonstrating that special form material met the requirements of 49 CFR 173.469, for special form material transported by the licensee (Section 7).

Attachment:

- Attachment - Person Contacted and Exit Meeting

DETAILS

1 PROGRAM OVERVIEW

This broad scope program includes the use of byproduct material for research and development activities as authorized by the licensee's Radiation Sources Committee (RSC). Approximately 35 individuals have been approved by the RSC to conduct research activities. The majority of the research projects conducted during this inspection interval involved labeling cells or protein with microcurie quantities of hydrogen-3, carbon-14, phosphorus-32, sulfur-35, and iodine-125. In addition, the licensee possessed numerous sealed sources including; several americium-241 and cesium-137 sources contained in portable moisture/density gauges for use at temporary job sites, nickel-63 sources contained in gas chromatography devices, and a cesium-137 source used for instrument calibrations. However, the majority of the licensee's sealed sources were not in use and were being held in storage.

1.1 Organization and Management Controls

The organizational structure was found to be as required, and key personnel were as identified in the attachment to this report. The Radiation Safety Officer (RSO), research personnel, and the majority of authorized users had been at the facility in their current positions during previous inspections.

A review of the RSC minutes maintained for meetings conducted during this inspection interval revealed that a meeting had been conducted during each calendar quarter as required. The RSC membership included adequate representation from each program area.

However, the inspector noted that the discussions held during these meetings had not included an appropriate range of topics consistent with the size and scope of the licensee's radiation safety program. Specifically, Item 1B of the licensee's procedures, as outlined in the licensee's letter to NRC dated October 14, 1983, requires that the committee review work in progress and exposure records in order to implement the licensee's ALARA program. Further, in accordance with Item 1B of the aforementioned letter, the reviews were to include, in part, (1) an examination of the exposure records from film badge use each year and (2) an audit of the amounts of radionuclides purchased and disposed of under various research projects each year. From these reviews, one or two projects were to be selected for a more detailed review involving input from the associated authorized user so that the RSC could establish whether the quantities of material used appeared appropriate given the scope of the research project. Through discussions with members of the RSC and by review of committee minutes, the inspector noted that the RSC had not examined exposure records from film badge usage each year, nor had an audit been performed of the amounts of radioisotopes purchased and disposed under various projects each year. This was identified as a violation of Item 1B of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

1.2 Personnel Training

Item 14 of the licensee's procedures, as outlined in the licensee's letter to NRC dated October 14, 1983, specifies that basic "instructions to workers" are intended as a first step in training persons working under a particular research proposal. Item 14 also specifies that authorized users will provide further training to these individuals either by the authorized user or working through the RSO and that the RSC would be responsible for checking individual projects selected for audit each year to ensure that further training was proceeding. As noted in Section 1.1 of this report, the licensee's RSC had not performed an audit on selected research proposals and as a result, reviews of training for individuals working in these areas had also not been performed. This was identified as a violation of Item 14 of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

2 PERSONNEL MONITORING (83822 and 87100)

Personal dosimetry devices for whole body and extremity monitoring had been provided to various individuals in accordance with guidance developed by the RSC in order to demonstrate compliance with 10 CFR Part 20. Item 16G of the licensee's procedures, as outlined in the licensee's letter to NRC dated October 14, 1983, specifies that film badges would be distributed and that old badges were to be returned once each month. Through review of the licensee's personnel dosimetry reports, the inspector observed that on several occasions film badges had not been returned for processing each month. Specifically, although new badges had been distributed to each individual requiring the devices, some of these individuals had not returned their film badges at the required frequency. Specifically, individuals assigned badge numbers 87, 88, 234, 304, 332, 337,338, and 339 had not sent their film badges in for processing for periods of up to 5 months after the date of issuance. This was identified as a violation of Item 16G of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

In addition to failure to ensure that film badges were returned for processing at monthly intervals, the inspector identified a second violation associated with the licensee's personnel monitoring program as described below.

10 CFR 20.201(b) requires that each licensee make surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), a "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. The inspector noted that the licensee had not made such surveys for individuals who had not returned their film badges in a timely manner. Specifically, on several occasions, film badges worn by various individuals had not been returned for processing and the licensee had not performed an evaluation of the individuals' occupational radiation dose to

assure compliance with 10 CFR 20.101. This was identified as a violation of 10 CFR 20.201(b).

3 INSTRUMENTATION AND CALIBRATIONS (83822)

The licensee has maintained several radiation detection survey instruments which were utilized for package surveys and area monitoring. The licensee was authorized to perform instrument calibrations in accordance with procedures outlined in the licensee's letter to NRC dated October 14, 1983. Item 2 of the licensee's procedures, described in the aforementioned letter, specifies that G-M type survey meters which are used most frequently for checking incoming packages and for area surveys would be checked at intervals of approximately 6 months by taking a series of readings at various distances from a cesium-137 source.

During his walkthrough of several research laboratories, the inspector observed that some of the licensee's G-M type survey instruments used for package surveys and area monitoring within these labs had not been calibrated, or checked by taking a series of readings from a cesium-137 source, at the required frequency. Specifically, some of the meters had not been calibrated for periods of greater than 12 months. This item was also identified during the previous NRC inspection. This was identified as a repeat violation of Item 2 of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

4 MATERIALS RECEIPT, PREPARATION AND UTILIZATION (87100 and 83822)

As noted in Section 1 of this report, the licensee had received several different radioisotopes for use in laboratory research. The licensee had implemented and complied with the package receipt procedures outlined in the license application. Discussions with licensee personnel indicated that personnel involved with the receipt, preparation and utilization of byproduct material had received the appropriate training and had complied with applicable licensee procedures.

The inspector observed that byproduct material use and storage areas were properly posted with appropriate signs and that adequate measures were in place to prevent an unauthorized individual from entering restricted areas.

The licensee's package receipt records indicated that all incoming packages containing radioactive material were properly surveyed, and proper shielding was in place to reduce exposure rates during use, storage, and disposal of the licensed material.

5 LEAK TESTS AND INVENTORY CONTROL (83822)

As noted in Section 1 of this report, the licensee possessed several sealed sources. A review of records associated with the sources indicated that a physical inventory had been conducted every six months, and the sources were

tested for leakage at 6-month intervals as required. Inventory and leak test records contained the model number of each source, the serial number if one had been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the RSO

6 RADIATION SURVEYS, RECORDS, AND INDEPENDENT MEASUREMENTS (87100 and 83822)

Item 16D(5) of the licensee's procedures, as outlined in the licensee's letter to NRC dated October 14, 1983, specifies that research laboratories involved with the use of radioactive material in quantities in excess of 10 times the applicable limit specified in Appendix C of 10 CFR Part 20 would receive visits, inspections, and/or surveys approximately four times a year, at intervals of 6 months or less. Although the RSO had conducted surveys of the majority of research laboratories requiring these visits, the inspector noted that some labs had not been audited at the required frequency. For example, the laboratories located in Johnson Hall Rooms 725 and 815, and Linfield Hall Room 123A had not received an inspection at the specified frequency. This was identified as a violation of Item 16D(5) of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

The license also specifies additional audits which are to be performed by the licensee, including random surveys of vehicles transporting radioactive material off campus. Specifically, Item 16I of the licensee's procedures, as outlined in the aforementioned letter, specifies that for transportation of portable moisture/density gauges to temporary jobsites, approximately 10 percent of the vehicles will be examined and surveyed by the RSO or his designate. The inspector's review of records pertaining to these audits revealed that of approximately 60 shipments of gauges during calender year 1993, no such surveys had been conducted. This was identified as a violation of Item 16I of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

Also reviewed were the licensee's procedures for monitoring air concentrations during iodination procedures involving millicurie quantities of iodine-125. Item No. 3 of the licensee's procedures, as outlined in the licensee's letter to NRC dated October 14, 1983, requires that experiments using iodine-125 for iodinations of proteins or cells be performed in a specially designed hood equipped with a Bendix 4-19102 air sampler. This air sampler was to be used to draw measured air samples through charcoal filters which would then be counted to evaluate compliance with 10 CFR Part 20 with respect to facility effluents.

Through a review of licensee records and discussions with laboratory personnel, the inspector noted that not all iodination procedures involving millicurie quantities of iodine-125 had been conducted in a hood equipped with the specified air sampler. Specifically, some iodination procedures were performed in a dedicated fume hood located in Linfield Hall, Room 123A, without an air sampler in place during the procedures. During the previous

NRC inspection, this item was also noted a violation of the licensee's procedures. This was identified as a repeat violation of Item 3 of the licensee's procedures outlined in a letter dated October 14, 1983, which is incorporated in the license by reference in License Condition 24.

During this inspection, independent measurements of radiation levels in several areas were performed by the inspector and compared to measurements performed by the licensee. The inspector's survey results proved consistent with those documented by the licensee.

7 WASTE MANAGEMENT, TRANSPORTATION, AND DECOMMISSIONING (87100, 86740 AND 83822)

7.1 Waste Management

The licensee had used several methods for disposal of radioactive waste material. These included decay-in-storage for solid wastes, disposal via sanitary sewerage system for certain liquid wastes, and shipment of some waste generated by research activities to an authorized disposal site. Records associated with disposal through the sanitary sewerage system and decay-in-storage were adequate and contained all required information.

7.2 Transportation

10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or place of use, or who delivers licensed material to a carrier for transport, must comply with the applicable requirements of the regulation appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200-203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material. The inspector observed that records associated with waste shipments properly described the material in a manner specified in Subpart C of 49 CFR Part 172. However, a review of records associated with transportation of the licensee's portable moisture/density gauges containing byproduct material revealed that shipping papers prepared for these shipments did not contain all required information. Specifically, the shipping papers did not contain the proper hazardous materials description, shipping name, nor identification number. This was identified as a violation of 49 CFR 177.817(a).

In addition to the requirement for proper shipping papers, the licensee is also required to maintain certain documentation of tests and engineering evaluations for its DOT Specification 7A Type A packages and for its special form sources. Specifically, for shipment of the licensee's portable moisture/density gauges containing licensed material in special form, which were transported in a DOT Specification 7A Type A package, the following apply: (1) 49 CFR 173.415(a) requires that each shipper of a DOT

Specification 7A Type A package must maintain on file for at least 1-year after the latest shipment a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, package design, and materials of construction comply with the specification as described in 49 CFR 178.350; and (2) 49 CFR 173.476(a) requires, in part, that each shipper of special form radioactive materials maintain on file, for at least 1-year after the latest shipment, a complete safety analysis that demonstrates that the special form material meets the requirements of 49 CFR 173.469.

The inspector's review of records associated with transportation of the gauges revealed that the licensee had not maintained documentation of either of the above mentioned tests and engineering evaluations. These issues were identified as violations of 49 CFR 173.415(a) and 49 CFR 173.476(a), respectively.

7.3 Financial Assurance and Record Keeping for Decommissioning

During this inspection, the licensee discussed with the inspector its decommissioning funding plan and options for reducing the financial assurance required to comply with 10 CFR 30.35. Specifically, licensee representatives discussed their intent to reduce quantities of radioactive material presently authorized for possession and use under the license. The possession limits currently authorized on the license are considerably higher than those required to maintain the program. Therefore, the licensee was considering reducing these limits which would, in turn, reduce the financial assurance required to comply with 10 CFR 30.35.

With regard to the licensee's current decommissioning plan, the inspector attempted to review records maintained by the licensee to demonstrate compliance with 10 CFR 30.35(g). However, the inspector was unable to review the licensee's decommissioning records as described below.

10 CFR 35.35(g) requires, in part, that the licensee keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. Information the Commission considers important to decommissioning consists, in part, of: (1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, (2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and (3) records of cost estimates performed for the decommissioning funding plan or the amount certified for decommissioning, and the method used for assuring funds if either a funding plan or certification is used. Contrary to the above, the licensee's RSO informed the inspector that the above mentioned records were not kept in an identifiable location as required. As a result, the inspector was unable to review the licensee's decommissioning records. This was identified as a violation of 10 CFR 30.35(g).

8 FOLLOWUP ON CORRECTIVE ACTIONS FOR VIOLATIONS (92702)

8.1 (Open) Violation 030-00871/9101-A2: Failure to calibrate survey meters at intervals of approximately six months as outlined in the licensee's procedures

This inspection identified that the licensee's corrective actions for the violation, as stated in the licensee's letter dated December 13, 1991, were not effective in that this item was identified as a repeat violation.

8.2 (Open) Violation 030-00871/9101-A3: Failure to provide appropriate air sampling equipment during iodination procedures as outlined in the licensee's procedures.

This inspection identified that the licensee's corrective actions for the violation, as stated in the licensee's letter dated December 13, 1991, were not effective in that this item was identified as a repeat violation.

8.3 (Open) Violation 030-00871/9101-B1: Failure to make surveys ensure compliance with the requirements of 10 CFR Part 20. Specifically, the licensee had not made an evaluation of yearly air concentrations of radioactive material in air discharged to unrestricted areas.

During this inspection interval, the licensee had made an evaluation of discharged air concentrations which proved them to be within acceptable limits as defined in 10 CFR Part 20. However, this inspection identified another failure of the licensee to make surveys, as defined in 10 CFR 20.201(a), to ensure that occupational radiation doses were within regulatory limits as specified in 10 CFR 20.101.

ATTACHMENT

1 PERSONS CONTACTED

1.1 Licensee Personnel

R. Adair, Research Assistant
J. Berardinelli, Authorized User
N. Black, Research Assistant
+C. Bond, Authorized User, Chairman, RSC
W. Cranston, Research Assistant
J. Darland, Research Assistant
W. Dyer, Authorized User
H. Gaber, Research Assistant
*T. Gibson, Treasurer
B. Granger, Authorized User
*P. Griffin, Industrial Hygiene
*+R. Howald, Radiation Safety Officer
W. Inskeep, Authorized User
A. Jesaitis, Authorized User
S. Pickett, Research Assistant
*J. Schada, Director of Safety
D. Siemsen, Research Assistant
J. Starkey, Authorized User
*R. Swenson, Vice President, Research
L. Talbert, Authorized User
D. Ward, Authorized User

1.2 NRC Personnel

*Charles L. Cain, Acting Deputy Director, DRSS
*Vivian H. Campbell, Health Physicist, NMLS
*Linda L. Kasner, Acting Chief, NMIS
*+Mark R. Shaffer, Radiation Specialist, NMIS

+Denotes individuals present during the exit briefing conducted on November 4, 1993

*Denotes individuals present during telephonic exit briefing conducted on November 12, 1993.

2 EXIT MEETINGS

A site exit briefing was conducted on November 4, 1993, with the licensee's RSO and the Chairman of the RSC. Additionally, on November 12, 1993, an exit briefing was conducted telephonically with those individuals identified in Section 1. The inspection findings were reviewed as noted in the report. In addition, concerns regarding management oversight of the licensee's radiation safety program were discussed.