APPENDIX D

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-02885/90-01 License: 35-03176-01

Docket: 30-02885

Licensee: The University of Oklahoma
Health Sciences Center
Oklahoma City, Oklahoma

Facility Name: The University of Oklahoma
Health Sciences Center

Inspection Conducted: July 30 through August 3, 1990

Inspector: Linda L. Kasner
Linda L. Kasner, Health Physicist, Nuclear Materials and Safeguards Inspection Section
October 19, 1990
Date

Approved: Charles L. Cain
Charles L. Cain, Chief Nuclear Materials and Safeguards Inspection Section
10/23/90
Date

Inspection Summary

Inspection Conducted July 30 through August 3, 1990 (Report 30-02885/90-01)

Areas Inspected: This was a routine, unannounced, radiation safety inspection of byproduct material program authorizing the use of licensed material in diagnostic or therapeutic medical procedures and medical research. This license also authorizes the possession of byproduct material in the University of Oklahoma Health Sciences Center (UOHSC) nuclear pharmacy; however, the preparation, dispensing, and distribution of such materials is authorized under NRC License No. 35-01376-04MD.

The inspection included a review of facilities and equipment; instrumentation and corresponding calibrations; byproduct material receipt, use, and waste disposal; radiation surveys and evaluations; and management organization. This inspection also included review of activities conducted by the radiation safety committee (RSC) and radiation safety officer (RSO) with specific attention to their review and authorization of proposed research projects and participation in an RSC meeting.

Results: While several violations of license conditions or NRC regulations were observed during this inspection, the findings of the inspection are generally consistent with the licensee's past performance, as evidenced by the absence of identification of any violation during two previous inspections. Although none of the violations observed indicate a significant safety risk, they do evidence a need for the licensee to continue to focus attention to the detail of internal safety audits, thereby enhancing this aspect of the program and their ability to self-identify safety issues and violations of license conditions or NRC requirements. Additionally, the licensee needs to establish a systematic review of problems or violations which are identified during routine audits to ensure that they are promptly corrected.

During this inspection the following violations were identified:

- Failure to adequately secure licensed materials. (Section 3)
- Failure to obtain procurement approval from the RSO prior to purchasing licensed materials. (Section 5.a)
- Consuming food and storing cosmetics in restricted areas where licensed materials were used and stored. (Section 5.b)
- Failure to maintain waste disposal records for all licensed material which had been disposed, and disposal of materials by methods other than those approved by the RSC. (Section 5.c)
- Failure to properly evaluate radiation or removable contamination surveys and to maintain all required information in records documenting these surveys. (Section 6.b)

One additional violation was identified but was not cited in accordance with Section V.A of the NRC's Enforcement Policy (10 CFR Part 2, Appendix C). This violation is described in Section 5.a.

DETAILS

1. Individuals Contacted

J. White, Assistant Provost
T. Godkins, Assistant Provost
V. Yanchik, Ph.D., Dean, College of Pharmacy
B. Ahluwalia, Ph.D., Director, Radiation Safety Officer
S. Mills, Ph.D., Director, Nuclear Pharmacy
E. Patterson, Ph.D., Assistant Professor of Pharmacology, Chairman of the Radiation Safety Committee
S. Danak, M.S., Assistant to the Radiation Safety Officer
G. Basmadjian, Ph.D., Professor and Director, Nuclear Pharmacy Programs
C. L. Marcham, M.S., CIH, Environmental Health and Safety Officer

All of the above attended the exit briefing.

2. Program Overview

This program includes a large number of researchers involved in activities conducted under this broad license as well as activities authorized under two other broad licenses associated with hospitals located at the UOHSC campus. Although the UOHSC does not provide medical care, some of the activities conducted under this license include the transfer of radiopharmaceuticals to the aforementioned broad licensed facilities for use in diagnostic or therapeutic applications in human subjects.

The majority of activities conducted under the UOHSC license involved the use of small quantities of carbon-14, hydrogen-3, and iodine-125 in applications strictly limited to in-vitro cell labeling or animal use. Two investigators associated with the UOHSC nuclear pharmacy have recently received approval to conduct projects involving diagnostic and therapeutic applications of radiolabeled monoclonal antibodies in human subjects.

A single radiation safety committee (RSC) reviews activities conducted under each of the three broad licenses as well as several other specific licenses authorizing activities at the medical facilities noted above and the UOHSC. The radiation safety officer (RSO) is responsible for the UOHSC broad license and several other specific licenses associated with facilities previously noted.

3. Facilities and Equipment

The majority of activities are conducted in a number of research labs located in the College of Medicine (Medical) and College of Pharmacy (Pharmacy) buildings. Activities conducted in the Medical building are primarily in-vitro labeling or radioimmunoassay (RIA) procedures using small quantities of licensed material. Those conducted in the Pharmacy

building include the use of millicurie quantities of licensed material in processing and dispensing radiopharmaceuticals for nonroutine (research) human and animal studies.

The possession of all materials processed and dispensed from the nuclear pharmacy is controlled under the broad license inventory. This involves curie quantities of byproduct material which is used and stored within the Pharmacy building.

The inspector observed that each of the research laboratories located in the Medical building were either secured by lock or under direct surveillance of licensee personnel. Several cold storage areas were available for storage of animal carcasses and cell samples, and these were secured as well.

The research laboratories located in the Pharmacy building were either adjacent or congruent to the nuclear pharmacy. Some of these areas were equipped with separate locked entry while others were not. This was particularly notable in a suite of rooms designated as 136, 138, and 140; which, although each has a separate hallway entry, also share interior doorways permitting passage between the adjacent rooms. The inspector observed that these doors were not routinely closed or locked, and although these rooms were removed from high traffic areas, nonetheless a variety of individuals routinely entered this area.

Room 140 is designated as a byproduct material receiving area for the nuclear pharmacy as well as the broad licensed program, and is frequented by individuals conducting activities under both licenses. These staff members include pharmacy couriers, graduate students involved in research projects, and students of the College of Pharmacy. The inspector observed that although each of these individuals were trained in their respective duties, they were not necessarily familiar with activities conducted by other investigators also working with licensed material in this area. This was discussed with two investigators who routinely work in this area, particularly with regard to the fact that several different radionuclides were stored in open refrigerators or fume hoods within these rooms, some of which involved millicurie quantities. The investigators explained that they relied on previous instruction given to the staff regarding restricted access to limited areas within these rooms and a nominal surveillance of the area by pharmacy personnel to constitute adequate security for licensed material stored in the area.

The inspector noted that the pharmacy staff could not always provide adequate surveillance of the area, due to their attendance to other duties, and that on one occasion during the inspection licensed material had been left unsecured on a workbench in Room 136. At the time, doors to this suite of rooms had been left open and the rooms were not under direct surveillance. The material consisted of a small lead pig holding a test tube containing an unknown source (neither was labeled at the time); miscellaneous gloves, needles, and used intravenous infusion sets; and an unlabeled syringe which had been placed in an open-top lead pig. The

inspector first identified this during the early morning, when surveys of the area revealed dose rates of 60-70 millirem per hour (mr/hr) directly over the pig containing the test tube and 5-6 mr/hr at an ~18-inch distance above the countertop. This was brought to the RSO's attention, who confirmed these readings.

One investigator who routinely works in this area was questioned regarding the content of the test tube and syringe, but was unable to identify the source since he had not been involved in this work. The inspector and RSO requested that the room be locked and restricted from access until the second investigator returned to identify the material and properly secure it. This was identified as a violation of 10 CFR 20.207 which requires that licensed material stored in an unrestricted area be secured from unauthorized removal or tended under the constant surveillance and immediate control of licensee personnel. The syringe and test tube were later confirmed as having contained millicurie quantities of an iodine-131 labeled monoclonal antibody which had been used the previous afternoon for animal research.

One violation was identified.

4. Instrumentation

The licensee possessed an adequate number and type of survey instruments and scintillation detection systems to conduct proper surveys and analysis for those radionuclides used. Survey instruments were located such that they were readily available for use in laboratories containing beta and gamma emitting radionuclides and those laboratories using only low energy beta emitters were equipped with liquid scintillation detection systems. A number of sodium iodine scintillation detection systems were available for counting bioassay samples or removable contamination survey samples.

During this inspection period, survey instruments had been calibrated at annual intervals as required by licensee procedure. Those scintillation systems used for analyzing removable contamination surveys for gamma emitters and bioassay samples had not been evaluated for instrument efficiency for some time, and the results of these evaluations had not always been properly documented. This was discussed with the RSO and pharmacy director who repeated the instrument evaluations prior to the conclusion of the inspection. These results were properly documented for future use in sample analysis.

No violations were identified.

5. Byproduct Material Receipt, Use, and Disposal Receipt and Inventory

a. Byproduct Material Receipt and Inventory

A general problem was identified with regard to the procurement, inventory, and disposal of licensed materials by individual investigators. Some products, particularly those received from and

returned to the nuclear pharmacy by independent investigators, had not always been procured under RSO approval as required by licensee procedures. Although distribution of some technetium-99m products had been documented and later submitted to the RSO, many had not. This was particularly notable with those investigators working with the nuclear pharmacy. Additionally, some iodine-131 products received at the nuclear pharmacy for use in research conducted under the broad license had not received prior receipt approval by the RSO, and had instead been documented for use under the pharmacy license. This was identified as a violation of License Condition 14, Item A.5, of the radiation safety manual submitted with the letter dated March 23, 1989, which requires that all orders for radioactive material be routed through the radiation safety office and that no purchase order be issued without concurrence of the RSO.

This problem evidences a failure of the RSC and RSO to implement the controls necessary to ensure that the products and purpose of use corresponded to research project protocols formerly approved by the RSC. Additionally, the RSO had permitted notification of the procurement and use of some technetium-99m products by means of monthly inventories which were submitted to the RSO after these products had been received and used. Although records later submitted to the RSO documenting these activities indicated that the use of these materials was in accordance with approved research protocols, this practice represents a failure to observe established procedures. Individual investigators should have obtained prior approval from the RSO, thereby permitting him opportunity to review and ensure that quantities of material received did not exceed the individual researcher's approved inventory limits and that materials were used only in locations which had been previously approved by the RSC. At the time of the inspection, the method of disposal for some of these products was not known (i.e., whether they had been returned to the pharmacy for disposal or disposed of through the radiation safety office as required), although it was determined that they had not been improperly released to unrestricted areas.

Inventory records for those research laboratories involved in active projects were reviewed and generally found to be adequate in documenting the use and disposal of licensed material with one exception. This involved an investigator who had used iodine-125 and technetium-99, and had failed to fully account for inventory on hand as well as that which had been disposed. In reviewing the records with the investigator, the inspector determined that the errors had occurred due to different accounting methods used by various staff members working under the investigator. The inspector noted that the discrepancies, most notable regarding the use of technetium-99, had not been identified during routine inventory audits conducted by the radiation safety office.

Following a detailed review of old inventory records known to be accurate, the investigator was able to reconcile the discrepancies noted in more recent records. The RSO confirmed the quantities on hand and the inspector concurred that the discrepancies had been adequately corrected. Inasmuch as this problem was determined to be limited to records only and was promptly corrected, this item is not being cited because the criteria of 10 CFR Part 2, Appendix C, Section V.A (NRC's Enforcement Policy) had been met.

b. Byproduct Material Use

As observed during this inspection, licensed material possessed under this license had been used in accordance with research protocols approved by the RSC. Established procedures governing the handling of radioactive material had been observed with one exception. During a tour of research laboratories conducted on the second day of the inspection, individuals working in the RIA laboratory were observed with food and beverage on countertops which, at the time, were in use for completing RIA procedures. This was immediately brought to the staff's attention as a violation of licensee procedures while the RSO was present. A tour of the same laboratory the following day revealed that these individuals had not terminated the consumption of food within this restricted area, and that cosmetics had routinely been stored on shelves where RIA materials were used or stored and contaminated pipette tips were collected for disposal. The RSO was present at the time and directed the staff to dispose of all cosmetics in this area and again reviewed safety procedures with the staff. This was identified as a violation of License Condition 14, Item 4, of section titled " Responsibilities" under "Radiation Worker," in the radiation safety manual submitted with the letter dated March 23, 1989.

c. Waste Disposal

Byproduct material disposal records for all active research laboratories were reviewed, revealing two examples of a violation of License Condition 14, Item 11, of the application dated January 27, 1988; and section titled "Minilicense Holder" of the radiation safety manual submitted with the letter dated March 23, 1989. These procedures require that each minilicense holder (investigator) maintain records of waste disposal and that radioactive waste be disposed of through the radiation safety office.

Two investigators were found to have improperly disposed of waste inasmuch as records of the disposals had not been maintained and the material was not routed through the radiation safety office but was instead returned to the nuclear pharmacy for disposal by

decay-in-storage. These disposals consisted of articles used to administer technetium-99m and iodine-131 products to animals for the purpose of research but did not include animal carcasses.

Two violations were identified.

6. Radiation Surveys and Evaluations

a. External Dosimetry

The inspector observed that radiation dosimetry records reflected a widespread problem in the return and subsequent processing of personal monitoring devices. Many individuals' badges were not returned for periods as long as 2-6 months after they had been issued throughout this inspection period. This had not been aggressively pursued by the RSO until the problem was brought to the attention of management during the course of an independent audit recently completed by an outside consultant. At the time of the inspection, corrective measures had not yet been implemented, although the RSO had drafted a policy statement which he plans to submit to the RSC for review. It should be noted that all badges were eventually processed and doses properly recorded.

Monthly whole body exposures for those individuals working with microcurie quantities of byproduct material were generally 10-40 millirem. These individuals were not required to wear extremity monitoring devices according to licensee procedure.

Those individuals participating in activities under both the UOHSC broad and pharmacy licenses wore whole body and extremity monitoring devices. Monthly whole body exposures for these individuals were generally 50-250 millirem, while extremity exposure ranged from 200 millirem to ~5 rem per month. These issues are discussed in NRC Inspection Report 30-12750/90-01, since the major portion of the occupational dose for these individuals is accrued while conducting activities specific to the nuclear pharmacy program.

b. Area Radiation and Removable Contamination Surveys

Licensee procedures require that all research labs be surveyed at weekly intervals and further specifies the type of survey to be conducted depending on the radionuclides used in each respective area. Records of surveys must include notations on sensitivity, location of the specific area surveyed, date the survey was conducted, personnel involved, and final results if decontamination was required. Specific requirements are described in License Condition 14, Item A.20, of the radiation safety manual submitted with the licensee's letter dated March 23, 1989.

The inspector observed that generally, surveys had been conducted at weekly intervals as required, but that evaluation of the surveys was inadequate and that records of such surveys did not contain all required information in every case. One investigator involved in conducting research within the nuclear pharmacy area had relied upon surveys conducted by pharmacy personnel (under the pharmacy license requirement) rather than conducting them himself. Records of these surveys had been maintained by the pharmacy although the investigator had not reviewed their results during this inspection period.

Other investigators had conducted the required radiation dose surveys or removable contamination surveys, but had failed to determine the efficiency of the counting and detection systems used to analyze samples to ensure that the methods employed provided the required sensitivity specified in action thresholds established in the licensee's procedures. In many cases, the instruments used to conduct the survey had not been annotated on the record nor were the locations where the samples had been taken identified on the record. (The licensee's procedures established action thresholds of either 200 disintegrations per minute [dpm] for scintillation detection systems or 50,000 counts per minute [cpm] for GM instruments.) These items were identified as a violation of License Condition 14, Item A.20, of the radiation safety manual.

The inspector noted that the licensee's routine internal audits had included review of surveys conducted in research laboratories, but had been primarily focused on the frequency of the survey and had not included detailed review of the results. The failure to ensure that survey methods met the required sensitivity limits had not been considered during these reviews.

7. Management Organization

As previously noted, the activities under this license are reviewed by an RSC responsible for managing several byproduct material licenses. This was identified by both the inspector and individuals involved with these programs as having created confusion regarding the principle responsible facility for certain activities. Specifically, individuals involved with both research and routine radiopharmaceutical dispensing in the nuclear pharmacy were not certain of which license, the pharmacy or broad, authorized specific activities, while other investigators were involved in projects simultaneously authorized under more than one license. Some of these projects involved activities conducted in facilities other than the one associated with the license under which the project was authorized. This had in part, contributed to some of the violations related to inventory control and waste disposal observed during this inspection. These issues were noted as worthy of further review to clarify organizational structure within these programs.

The inspector observed that the RSC membership consisted of an adequate sample of representative personnel involved in licensed activities and that meetings had been conducted at proper intervals throughout this inspection period. As observed during an RSC meeting held during this inspection, the committee conducted a thorough review of research proposals and properly tabled those which did not provide adequate information for future review pending submission of supplemental information by the investigator.

The inspector observed that internal audits of licensed activities had routinely been conducted according to licensee procedure; however, these audits had not been detailed enough to identify violations of license conditions or NRC requirements in every case. For those items which had been identified, resolution of the problem was not always aggressively pursued. This was evidenced by the fact that some audit records indicated the same problem during consecutive reviews. This was reviewed with the RSO who indicated that he had recognized these issues and was attempting to improve internal communications in order to bring these items to the investigators' attention.

The inspector also reviewed concerns that some of the audits had been scheduled according to information provided by the investigators (i.e., whether material had been used during the previous audit period) rather than having been scheduled and conducted independently by the audit staff. This was most notable with one investigator associated with the nuclear pharmacy who had informed the radiation safety office that he had not used material during a 6-8-month period, and therefore was not audited during this period. He had, however, used material in association with another investigator's project during this period. This had gone unnoticed by the radiation safety office because the material had been procured without prior approval of the RSO. Had the required audits been conducted, some of the violations associated with receipt and inventory may have been identified, although the inspector also noted that they had gone unnoticed during previous audits.

The inspector noted that the radiation safety office staff needed to improve attention to detail during program audits rather than conducting cursory reviews focused on the performance of certain tasks while omitting review and evaluation of test results, and that the audits should be prompted by observations of activities during a walkthrough of each laboratory rather than by information supplied by the individual investigator.

No violations or deviations were identified.

8. Exit Summary

The inspector met with licensee representatives, as previously noted in Section 1, to review the inspection findings as documented in this report. This discussion included the specific violations identified during the inspection, as well as discussion of program management led by the licensee's representatives.