APPENDIX C

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-12750/90-01 License: 35-03176-04MD

Docket: 30-12750

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

Inspection At: The University of Oklahoma
Health Sciences Center

Inspection Conducted: July 30 through August 3, 1990

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

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

Inspection Summary

Inspection Conducted July 30 through August 3, 1990 (Report 30-12750/90-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a byproduct material program authorizing the preparation, dispensing, and distribution of radiopharmaceuticals to medical licensees. The inspection included the review of facilities and equipment; instrumentation and corresponding calibrations; byproduct material receipt, use, and waste disposal; radiation surveys and evaluations; transportation of licensed materials; and management organization. This inspection also included review of activities conducted by the radiation safety committee (RSC) and radiation safety officer (RSO), as well as participation in a RSC meeting.

Results: The licensee had improved management controls over licensed activities during this inspection period and had implemented corrective actions for the eleven violations observed during previous inspections conducted on March 8 and May 3, 1989. Although the radiation safety program had been the subject of closer review by both management and the RSO during internal program audits, the results of this inspection indicate a need to focus greater

attention to the details of methods used to perform certain tests and evaluations rather than limiting these audits to a cursory review of test results.

Within the areas inspected, the following violations were identified:

(1) Failure to monitor or evaluate filter systems located in exhaust pathways of fume hoods used to store and dispense volatile radioactive material. (Section 4.a)

(2) Failure to repair or adjust a dose calibrator when linearity test results varied more than +/- 5 percent from predicted values and to include a graph of assay results on linearity test records. (Section 5.a)

(3) Distributing radiopharmaceutical reagent kits without the required manufacturer's package insert and in packages other that the manufacturer's original packing. (Section 6.b)

(4) Failure to ensure that the method used to conduct removable contamination surveys was capable of detecting 220 dpm per 100 square cm. and to record survey results in units of dpm or microcuries as required. (Section 7.a)

Four additional violations were identified but were not cited in accordance with Sections V.A or V.G.1 of the NRC's Enforcement Policy (10 CFR Part 2, Appendix C). These violations are described in Sections 5.a, 7.a, and 8.

DETAILS

1. Individuals Contacted

J. White, Assistant Provost
*T. Godkins, Assistant Provost
*V. Yanchik, Ph.D., Dean, College of Pharmacy
*B. Ahluwalia, Ph.D., 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
A. Maleck, R.Ph., Nuclear Pharmacist
P. Tyler, R.Ph., Nuclear Pharmacist
C. Sanders, Site Support
S. Sifers, Driver, Nuclear Pharmacy

*Denotes those individuals present at the exit briefing.

2. Followup on Previous Violations

(Closed) (30-12750/89-01) Violation of License Condition 18 (Item 15 of the application dated April 20, 1982) - Failure to issue (use) "whole body" film badges or finger thermoluminescent dosimeter (TLD) ring badges for couriers. The inspector observed that all couriers had been issued personal monitoring devices and that they were used when participating in licensed activities.

(Closed) (30-12750/89-01) Violation of License Condition 18 (Item IV of the letter dated June 20, 1983) - Failure to use the required U.S. Department of Transportation (DOT) Type A packaging when transporting radiopharmaceutical doses. The inspector observed that all radiopharmaceutical doses were packaged in DOT Type A containers prior to transporting them to and from client medical facilities.

(Closed) (30-12750/89-01) Violation of 10 CFR 20.201(b) - Failure to perform an evaluation necessary to determine the occupational exposure of individuals whose personal monitoring devices had been lost or damaged and could not be processed. The inspector verified that all required evaluations necessary to determine the occupational exposure of individuals participating in licensed activities had been completed during this inspection period.

(Closed) (30-12750/89-01) Violation of 10 CFR 71.5(a) (49 CFR 172.200) - Failure to prepare and use shipping papers when transporting licensed material. The inspector observed that shipping papers had been properly prepared and used when transporting licensed material during this inspection period.

(Closed) (30-12750/89-01) Violation of 10 CFR 71.5(a) (49 CFR 172.502[a]) - Improper placarding of vehicles used to transport packages labeled as RADIOACTIVE WHITE I or RADIOACTIVE YELLOW II. Vehicles used to transport packages other than those labeled RADIOACTIVE YELLOW III were appropriately not placarded as RADIOACTIVE.

(Closed) (30-12750/89-01) Violation of 10 CFR 71.5(a) (49 CFR 172.403) - Failure to perform the surveys necessary to properly catagorize packages used to transport licensed material. The inspector observed licensee personnel conduct the required surveys necessary to catagorize packages used to transport radiopharmaceutical doses.

(Closed) (30-12750/89-01) Violation of 10 CFR 71.5(a) (49 CFR 172.301[a] and 172.310[a][2]) - Failure to mark DOT Type A packages with the proper identification number or the words "TYPE A." All packages used to transport licensed materials were marked with the proper identification number and the words "TYPE A."

(Closed) (30-12750/89-01) Violation of 10 CFR 71.5(a) (49 CFR 177.842[d]) - Failure to block or brace packages containing licensed material during transportation. The inspector observed that packages were properly blocked or braced to prevent movement during routine transportat on.

(Closed) (30-12750 89-02) Violation of License Conditions 7.B and C and 9.B and C - Processing liquid iodine-131 labeled "Not to be Used as a Drug" to make iodine-131 capsules for distribution to medical facilities for human use. The inspector verified that the licensee had discontinued processing the subject iodine-131 and had distributed only prepared iodine-131 capsules as authorized.

(Closed) (30-12750/89-02) Violation of License Condition 13.A - Distribution of iodine-131 capsules for human use that were not the subject of a notice of claimed investigational exemption for a new drug (IND) or new drug application (NDA). The inspector verified that all iodine-131 capsules distributed for human use during this inspection period were appropriately approved under an IND or NDA.

(Closed) (30-12750/89-02) Violation of License Condition 18 (letter dated June 20, 1983) - Failure to: (1) maintain required air flow face velocity in three fume hoods, (2) provide a label on one hood indicating the proper sash height during use, and (3) install charcoal filters in exhaust paths for three fume hoods. The inspector verified that the required face velocity had been maintained in three hoods located in the nuclear pharmacy, that all hood sashes were properly labeled, and that charcoal filters had been installed in hood exhaust pathways.

3. Program Overview

This byproduct material program includes the preparation, dispensing, and distribution of radiopharmaceuticals, reagent kits, and sealed sources to local hospitals and clinics in the Oklahoma City, Oklahoma, area as well as to other researchers and clinics which are considered a part of the University of Oklahoma Health Sciences Center (UOHSC). The Nuclear Pharmacy (licensee) is authorized to prepare, dispense, and distribute radiopharmaceuticals and other licensed material under NRC Byproduct Material License 35-03176-04MD; however, possession of these materials is authorized under the UOHSC broad license, NRC License No. 35-03176-01. Activities conducted under the broad license are documented in NRC Inspection Report 30-02885/90-01. Additionally, the licensee is authorized to receive and dispose of, by decay-in-storage, radioactive waste generated from byproduct materials distributed to, and subsequently collected from, customers of the licensee.

4. Facilities

a. Ventilation and Exhaust Pathway Evaluation

Four fume hoods located in rooms 139, 139C, and 139D had been designated for storage and use of xenon-133 and volatile iodine-131 or iodine-125. The hood located in Room 139 had primarily been used for xenon-133 storage and dispensing, while the other three hoods had been used to store, label, and dispense iodine-131 or iodine-125 products. Room 139 had a dedicated exhaust path while Rooms 139C and D shared a common exhaust path. In response to violations identified during a previous inspection conducted in May 1989, the licensee had installed charcoal filters in each of the two air exhaust pathways from the nuclear pharmacy, and had implemented a routine evaluation of the ventilation provided by each of these hoods.

A review of these evaluations revealed that the hoods had been checked for average face velocity and total exhaust volume at the required 6-month intervals during this inspection period. Results of these evaluations demonstrated that each hood was operating within the required specifications and that the required room air exhaust had been maintained. The licensee had also clearly labeled each hood for proper sash height when in use.

Although the licensee had placed charcoal filters in the exhaust system as required, the filters had not been monitored or evaluated for saturation or to determine that the specified 99 percent efficiency had been maintained during this inspection period. Further, the pharmacy director stated that the licensee had not yet developed a procedure to routinely evaluate these filters. This was reviewed with the RSO who indicated that he had not been aware that the filters had not been checked for saturation until the matter was recently brought to his attention by the assistant RSO (Asst. RSO).

However, at the time of the inspection, no monitoring or evaluation had been done. The failure to monitor or evaluate the pharmacy air exhaust filters was identified as a violation of License Condition 24 which references a letter dated November 20, 1989. Item 7 of the letter references the duties of the RSO as described in the radiation safety manual. These duties include, but are not limited to, the monitoring/maintaining of any special filter systems associated with the use, storage, or disposal of radioactive material.

As a result of their review of the system, the Asst. RSO and pharmacy director proposed installation of an air effluent monitoring system, using Eberline Model RAS-1 devices, to enable a simple evaluation of filter saturation on a routine basis. Their proposed procedure, which included evaluating the smaller charcoal "traps" for residual contamination using a sodium iodide detector, was being prepared for review by the RSC at the time of the inspection. The inspector observed that the devices had been installed at the conclusion of the inspection.

b. Spilled Gas Clearance Evaluation

The Asst. RSO had recently noted that the licensee had never posted the emergency procedures to be observed following a "spill" of a radioactive gas, such as xenon-133, nor had the room air clearance times been posted in the pharmacy should such circumstances occur. Although spilled gas clearance times had been calculated and the corresponding emergency procedures had been posted in July 1990, the inspector noted that the calculations had been based on an assumption that the maximum quantity of xenon-133 received or handled would be a single vial, or 10-16 millicuries. The inspector reviewed this with the Asst. RSO, indicating that the pharmacy routinely received containers holding 4 vials (10-16 millicuries each) as well as single vials, and that in the worst case, a total of 40-60 millicuries should be evaluated in the event of a spill. The Asst. RSO agreed, indicating that he was only recently employed at the UOHSC and had not yet observed the receipt of these containers and further, had been mistakenly informed that only single vials were handled. He stated that he would reevaluate the spilled gas clearance times and repost the appropriate emergency procedures.

One violation was identified.

5. Instrumentation and Calibrations

a. Dose Calibrators

The pharmacy has two Capintec Model CRC 10 (Serial Nos. 11056 and 10468) dose calibrators available for use. As specified in Item 10.4 of the licensee's letter dated November 20, 1989, the licensee had adopted the model procedure described in Regulatory Guide 10.8 (RG 10.8), Revision 2, Appendix C, for daily constancy,

quarterly linearity, annual accuracy, and geometry independence testing of these instruments.

Daily constancy checks had been conducted using cesium-137 and cobalt-57 reference sources. Although the licensee's procedures require that only the Tc-99m and I-131 settings be checked daily, in April 1990, the licensee revised this procedure to include the corresponding setting for each isotope that is routinely dispensed. A review of records documenting the results of these checks revealed that both instruments had routinely met the test acceptability limits of +/- 5 percent of the predicted value for each reference source.

The licensee had noted, and subsequently corrected, one violation of procedures referenced in Item 3.e, Appendix C, RG 10.8, regarding the record content for daily constancy checks. This violation involved the failure to document (for user comparison when conducting the test) the limits of acceptability on each monthly record. The inspector noted that the licensee's corrective action had been sufficient to prevent recurrence of this violation. Therefore, 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. (The inpsector confirmed that the acceptable tolerance limits had not been exceeded during the periods when these limits had not been annotated on the record for user reference.)

Dose calibrator linearity tests had been conducted using a "Calicheck" system throughout this inspection period. A review of the test results revealed a failure to conduct the tests in accordance with the licensee's approved procedures. Two items were identified as a violation of Item 5, Appendix C, RG 10.8. These included the following.

(1) Records of linearity tests conducted on Dose Calibrator A (Serial No. 11056) during the first and third quarter of 1989, showed test results which varied from - 15 percent to + 10 percent of the predicted assay value at certain activities. The licensee's procedures require that either a repair or adjustment of the calibrator be done or, alternatively, that a mathematical correction table be used when test results exceed +/- 5 percent of the predicted assay value. During the first quarter of 1989, the licensee had failed to adjust the calibrator or implement use of a correction table, but had instead concluded and noted on the record, that since the average variance was only 3 percent (over a range of 430-1.0 millicuries) the instrument was considered satisfactory. The second quarter 1989 test results were not annotated regarding any evaluation of the instrument's performance. The inspector noted that subsequent test results were within the required +/- 5 percent tolerance limits.

(2) Records documenting linearity tests conducted during the period from January 1989 through August 1990, did not include a graph of the assay results as required by procedure.

Two additional items, also violations of the licensee's linearity test procedures, had been previously identified and corrected by the licensee. These involved: (1) the failure to have conducted a linearity test on either instrument during the second quarter of 1989 and (2) the failure to test calibrator linearity over an activity range as low as 10 microcuries. The licensee identified the first problem in August 1989, when it was noted that the tests had last been conducted in January 1989, and promptly tested both instruments. The second problem was identified later during a review of the third quarter linearity test results, and was corrected at the time that the fourth quarter tests were conducted in October 1989. The licensee had also implemented measures to prevent these problems from recurring, some of which were documented in a letter dated September 7, 1989, from the pharmacy director to the RSC chairman. The inspector noted that the licensee's corrective action had been sufficient to prevent further recurrence of these problems during the remainder of this inspection period. Therefore, no citation is being issued for these items because the criteria of 10 CFR Part 2, Appendix C, Section V.G.1 (NRC's Enforcement Policy) had been met.

b. Survey Instruments

The licensee had several instruments available for use in conducting routine radiation and removable contamination surveys. These included a Ludlum Model 177, Serial No. 37869; a Ludlum Model 14C survey meter, Serial No. 58788; and two Eberline Model MS-2 Miniscalers, Serial Nos. 689 and 674, one of which had been used with a 1-inch sodium iodide detector, and the other with a Picker Well Counter, Serial No. 1642. Each of these instruments had last been calibrated during the fourth quarter of 1989, within the required annual interval.

One violation was identified.

6. Byproduct Material Receipt, Use, and Waste Disposal

a. Byproduct Material Receipt

During this inspection period, the licensee had received, prepared, and dispensed radiopharmaceuticals or reagent kits which had been approved by the Food and Drug Administration (FDA) as the subject of a NDA or an IND. These products had been distributed to medical licensees appropriately authorized under 10 CFR Part 35.

The licensee had received byproduct materials and reagent kits from properly authorized manufacturers in accordance with the procedures referenced in the license and further described in the UOHSC Broad license. Inventories of licensed material had been maintained for the RSO's review and had been updated daily on the licensee's computerized inventory control system. All required records of byproduct material receipt had been maintained.

b. Use, Dispensing, and Distribution of Byproduct Material

The licensee had properly tested each technetium-99m eluate for molybdenum-99 content prior to distribution for human use. Although the licensee had only recorded the total molybdenum-99 content for each elution throughout the greater part of this inspection period, this evaluation had recently been changed to document the molybdenum-99 content per millicurie of technetium-99m prior to using such material to prepare radiopharmaceuticals for distribution. This change was made to facilitate earlier detection of molybdenum-99 concentrations which may have exceeded the permissible levels under 10 CFR Part 35.

The inspector reviewed the licensee's radiopharmaceutical quality control testing program with the pharmacy director, noting that only one test had been routinely performed on technetium-99m products. The pharmacy director explained that further testing would be performed if a customer indicated that there had been a problem with a radiopharmaceutical and that records of such tests would be maintained and reported to the RSC as required by licensee procedure. Two individuals, including a member of the administrative staff and the RSO, indicated during later interviews that a customer had complained of poor radiopharmaceutical quality, although no report of such complaints had been presented to the RSC. This was later discussed with the pharmacy director who indicated that he had not been notified of such complaints, and therefore, would not have reported any such incident to the RSC. Although this was not identified as a violation in the absence of evidence of such complaints, the inspector cautioned the pharmacy director to ensure that all pharmacy personnel understood the necessity to notify him of such circumstances so that the required evaluations and notifications could be completed.

One violation was identified regarding the distribution of pharmaceutical reagent kits to medical licensees. During the period from February 1990, when the license was renewed (as Amendment 04) until August 1990, the licensee had distributed these kits as single vials, without the manufacturers' original packing, and without a copy of the manufacturers' package insert or instructions for the preparation and use of the material. This is a violation of License Condition 24 which references a letter dated November 20, 1989. Item 6.a of the letter specifies that reagent kits will be

distributed as received from the manufacturer and that the manufacturer-supplied package insert or other document describing the procedures to be followed will be with the reagent kit.

The pharmacy had also participated in two monoclonal antibody research projects during this inspection period. Both projects are the subject of FDA approved INDs in which the UOHSC is named as a participant and the pharmacy director is either named as a principal or co-investigator. The projects had been properly authorized under the UOHSC Broad license, and the labeling and preparation of the antibodies had been conducted under this license as well.

Although the monoclonal antibody products had been prepared and transferred under the authority of the UOHSC broad license, individual patient doses had been recorded in the pharmacy's computerized inventory system for the purpose of generating a prescription to document the patient dose for the user physician. While this activity was not identified as a violation under the pharmacy license, being limited to the generation of a dosage record, the RSO and pharmacy director were cautioned to ensure that adequate controls were maintained in strictly limiting the use and transfer of these products to the broad license. The licensee was advised that distribution of this product under the pharmacy license would require license amendment inasmuch as the license currently limits the distribution of NDA or IND products to those prepared from reagent kits or repackaged, prepared radiopharmaceuticals.

c. Waste Disposal

The licensee had disposed of byproduct material waste generated from the pharmacy by decay-in-storage. This waste material included byproduct materials received by the pharmacy and miscellaneous materials used in dispensing, as well as materials distributed from the pharmacy and later retrieved unused, from customers. This activity had included implementation and use of the required transfer and shipping documents as described in the license.

The inspector observed that generally, the licensee's system for segregation, labeling, and conducting the required radiation surveys prior to release of such material (as "normal" waste) was well organized. Records of release surveys had been maintained as required.

However, the inspector noted that the licensee's documentation was not detailed enough in that records did not indicate that all contaminated items had been held for 10 half-lives of the specific isotope(s) involved in every case. This was particularly noted with regard to packages containing longer lived isotopes, or non-technetium products. Records of the content, length of time in storage, and subsequent disposal date for these packages appeared to

indicate that in some cases, the package may not have been held for 10 half-lives for isotopes such as iodine-125 or iodine-131 (as well as other isotopes not regulated by NRC), although all survey results indicated that radiation levels measured at the package surface were equivalent to background rates.

This discrepency was due to the fact that the licensee had packaged waste materials weekly, using a weekly "material use" record (from the inventory system) to document package content and had not corrected the record to delete those items which had not been returned for disposal, nor had they annotated the record to include other items which had been returned for disposal but may not have appeared on the weekly use record. This was discussed with the pharmacists responsible for packaging and disposing of these materials, who made several suggestions to improve record accountability of the materials involved to ensure that a proper length of time had elapsed prior to disposal. These items are to be reviewed with the RSO and pharmacy director for future revision.

One violation was identified.

7. Radiation Surveys and Evaluations

a. Area Surveys

As specified in License Condition 24, which references a letter dated November 20, 1989, the licensee had adopted the procedures described in the Guide for the Preparation of Applications for Nuclear Pharmacy Licenses (Draft dated August 1985), Appendix J, for conducting area surveys. In accordance with these procedures, daily surveys had been conducted in Room 139, an area where radiopharmaceuticals were routinely prepared and dispensed, while Rooms 139C and D had been surveyed weekly using a Ludlum Model 14C survey instrument throughout this inspection period. Removable contamination surveys had also been conducted weekly using an Eberline Model MS-2 Miniscaler and sodium iodide detector to analyze the wipe samples. Records of these surveys had been maintained and were reviewed during the inspection. Several violations regarding the licensee's survey procedures and the documentation and evaluation of survey results were identified, some of which had recently been detected and corrected by the licensee.

Item 5, Appendix J, requires that records of area radiation and removable contamination surveys include a plan of the area surveyed with measured exposure rates and detected contamination levels keyed to locations on the drawing. The Asst. RSO had reviewed this requirement during a routine audit in July 1990, and determined that the procedures which had been observed in documenting survey results were in violation of this requirement. This was subsequently corrected, and the inspector noted that records of surveys conducted after July 23, 1990, included the required diagram. Additionally, the Asst. RSO had revised procedures to include a greater number of

locations within the pharmacy to be sampled for removable contamination and had implemented requirements to fully document the instruments used to conduct these surveys. In accordance with NRC's Enforcement Policy, 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.

During the previously noted July 1990 audit, the Asst. RSO identified and discussed with the pharmacy director, the fact that certain evaluations associated with removable contamination surveys had not been conducted. However, this problem had not been corrected at the time of the inspection. This problem included the failure to: (1) evaluate the method used to obtain and analyze wipe samples for removable contamination surveys to ensure that the procedure was capable of detecting 220 disintegrations per minute (dpm) per 100 square centimeters, and (2) to record wipe sample results in units of dpm or microcuries as required. This was identified as a violation of License Condition 24, and the procedures described in Items 4 and 5, Appendix J, Guide for the Preparation of Applications for Nuclear Pharmacy Licenses.

The inspector noted that the instrument used to analyze these samples had not recently been evaluated to determine the counting efficiency. After discussing this with the pharmacy director, the required evaluation was conducted, although the sample analysis procedure had not yet been corrected at the conclusion of the inspection.

b. External Dosimetry

All couriers and pharmacists had been issued both whole body and ring badges for personal radiation monitoring. As observed during this inspection, these individuals used the monitoring devices as required. Reports of occupational exposures received by these individuals were reviewed monthly by the RSO. The licensee had recently changed dosimetry vendors in January 1990, and had experienced a 1-2 month delay in receiving dosimetry reports from the vendor. Due to the nature of activities conducted within the pharmacy, and the fact that these individuals handled curie quantities of radiopharmaceuticals daily, the RSO was cautioned to ensure that this reporting delay was corrected.

A review of dosimetry records revealed that whole body doses had been within the limits specified in the licensee's ALARA program, and had averaged 50-150 millirem per month throughout this inspection period. Although whole body doses received by these individuals had remained within institutional guidelines, several individuals had exceeded the licensee's extremity dose limits during the period January through May 1990. During this period, extremity doses received by these individuals ranged from 900 millirem to 4.8 rem per month. The

inspector noted that although the extremity doses received by these individuals had not exceeded the limits specified in 10 CFR Part 20, they were higher than those observed in other programs conducting similar activities.

The licensee's ALARA program establishes two investigational levels and doses in excess of either level requires review by the RSC and RSO. Doses exceeding Level II, or greater than 5.025 rem per quarter for extremities, require timely investigation by the RSO and corrective action if warranted. Reports of the exposure and the reason for the exposure, as determined during the RSO's investigation, are required to be presented to the RSC for review at the first meeting following completion of the investigation. The RSO had implemented review procedures which included a letter requesting a written response describing work activities, directed to any individual whose monthly whole body or extremity dose exceeded 104 or 1560 millirem, respectively.

The inspector observed that one individual of the group noted above, had received extremity exposures of 9.73 rem during the first quarter of 1990, and 7.6 rem during April through May 1990. This was discussed with the RSO, who stated that he had sent several letters to this individual regarding extremity exposures received during the fourth quarter of 1989, as well as during the first two quarters of 1990. He recalled having received only one letter in response at the time of this discussion, although two additional letters were subsequently received at the radiation safety office during the latter part of the inspection.

The RSO's first letter, dated March 28, 1990, referenced exposures received during the fourth quarter of 1989. The second and third letters, dated June 20, 1990, referenced exposures received during February and March 1990. The responses to the second and third letters were dated July 31, 1990, the day that the subject individual had been interviewed regarding these exposures. When questioned why the subsequent evaluation and reporting had been delayed, the RSO attributed the delay to the failure of the pharmacy director to return the responses to him, although he admitted that he had not contacted the pharmacy director regarding the delay. The RSO further noted that he intended to review these reports at the RSC meeting scheduled the following day.

The inspector expressed her concern that these reviews had not been conducted in a timely fashion and that the RSO had not yet determined the reason for these exposures. Based on interviews of one of these individuals, she noted that the failure to aggresively investigate these exposures may have contributed to the continuation of practices resulting in unnecessary extremity exposures. Specifically, one individual had attributed his exposure during these periods to the failure to routinely use syringe shields when dispensing doses of 10 millicuries or less, although he stated that he later identified

this as a problem and had discontinued this practice. (This individual was observed using syringe shields during several unannounced visits to the pharmacy during this inspection.)

One violation was identified.

8. Transportation

The inspector noted that requirements for properly labeling and catagorizing packages containing radioactive materials had been observed, and that shipping papers were prepared for each package transported by the licensee. Removable contamination surveys were conducted for both the outer package surface as well as the containers used to shield and transport unit dose syringes. The licensee had maintained records, also used as shipping papers, which identified the package content, catagorization, and survey results for both removable contamination and external radiation level of the package. A review of these records disclosed that packages had been properly catagorized and that survey results were within acceptable limits.

The licensee had evaluated one transportation incident, involving shipments to two medical facilities, which occurred on June 13, 1990. The RSO had previously reviewed this incident with regional staff during a telephone conversation in June 1990, indicating that he would provide a record of his investigation at a later date. This investigation was completed on July 12, 1990, and a report of such was provided to the inspector during the inspection.

The incident involved the delivery of two packages containing unit dose technetium-99 radiopharmaceuticals with internal removable contamination. This problem was brought to the licensee's attention by the customers, who had determined radiation levels of 2 millirem per hour at the surface of one package, and removable contamination survey results of 1000 counts per minute for a wipe sample taken from the unit dose syringe holders inside the package. (Both packages were properly retrieved from the two hospitals immediately after the pharmacy was notified of the problem.) The RSO's evaluation determined that removable contamination surveys had not been conducted properly at the pharmacy prior to shipment, and that the levels of contamination had not resulted in any hazard to individuals who handled the packages. The pharmacy director agreed, and further noted that although the surveys had been performed, the unit doses had subsequently been transferred to another container prior to shipment. He believed that the outer surface of the unit dose containers had become contaminated during this transfer. He also stated that the individual which he believed responsible for the incident was no longer participating in licensed activities, and that the remainder of the staff had been reinstructed in packaging and transportation survey requirements. The inspector noted that the licensee had implemented and properly documented

corrective actions, and that measures had been taken to prevent recurrence of similar incidents. Therefore, this item is not being cited because the criteria of 10 CFR Part 2, Appendix C, Section V.G.1 (NRC's Enforcement Policy) had been met.

No violations were identified.

9. Management Organization

The inspector observed that licensee management, as well as the RSC, had implemented a more thorough review of program activities since the previous inspection in May 1989. As described by the pharmacy manager, this involved an increased number of written responses required of him, documenting resolution of items of noncompliance identified by the RSO through the licensee's internal audit program.

Although the inspector noted that this effort had improved documentation of the resolution of some problems, she observed that many of the items noted during this inspection had not been identified by the licensee's internal audits and that the focus of the audit program had remained unchanged throughout the majority of this inspection period. The inspector observed that this had recently improved with the addition of an Asst. RSO who had worked closely with the pharmacy manager to improve survey procedures, instrument calibrations, and to address some items of concern identified by the pharmacy manager.

This inspection also included observation of an RSC meeting conducted on August 3, 1990. The inspector observed that the RSC membership represented a selection of individuals participating in licensed activities conducted under three broad licenses, as well as the nuclear pharmacy and the University's waste management license. She noted that the individuals participating in this committee represented an appropriate sampling of departments participating in licensed activities under these licenses.

The activities conducted during this meeting were largely devoted to review of several requests for authorization to conduct research projects under each of the broad licenses. The inspector noted that although each RSO provided a report of activities conducted under the respective licenses, these reviews were cursory in nature. This was particularly notable with regard to the report provided by the RSO regarding the extremity exposures received by individuals working in the pharmacy. This issue was not resolved during this meeting, but was instead tabled until the next RSC meeting in September pending further recommendations by the RSO.

During interviews conducted with the RSC Chairman and management representatives, the inspector expressed her concern that although review of research proposals for activities conducted under the broad licenses served by this committee had been very thorough, review of other

activities had not. The management representative concurred with the inspector's observation, stating that this issue is currently under review, although not yet resolved.

No violations were identified.

10. 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 improvements and resolution of previous violations. The inspector also reviewed concerns that although improvement in management controls had been observed during this inspection, the RSO and RSC had not yet conducted program reviews of sufficient detail to identify violations of program requirements and to ensure that these items are promptly resolved. The inspector also noted the role that the RSC serves in managing program activities worthy of further review.