APPPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-29613/91-01 License: 30-26860-01

Docket: 30-29613

Licensee: New Mexico State University
Primate Research Institute
Holloman AFB

Inspection At: Primate Research Institute
Holloman AFB
Alamogordo, New Mexico

Inspection Conducted: February 14, 1991

Inspector: Linda Kasner 3/21/91
Linda L. Kasner, Senior Radiation Specialist Date
Nuclear Materials and Safeguards Inspection
Section

Approved: Charles L. Cain 3/21/91
Charles L. Cain, Chief, Nuclear Materials and Date
Safeguards Inspection Section

Inspection Summary

Inspection Conducted February 14, 1991 (Report 30-29613/91-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a byproduct material program authorizing the use of licensed material in laboratory research and as tracers in nonhuman biologic systems. The inspection included a review of facilities and equipment; byproduct material receipt, use, and waste disposal; radiation surveys and evaluations; and management organization.

Results: During this inspection period, the licensee had instituted a number of changes, including the designation of a new director, and had recently requested amendment of the license to designate another individual as the radiation safety officer (RSO). The number of research projects designated as "active" had diminished during this inspection period, due to personnel changes and other matters not associated with licensed activities.

Although several concerns had been identified during NRC's previous inspections conducted in January 1988 and March 1990, New Mexico State University (NMSU)

had taken the necessary actions to correct the violations identified during these inspections. NMSU's corrective actions had, with one exception, been successful in preventing recurrence of the violations. Notwithstanding this observation, the findings of this inspection revea' a need to focus further attention to radiation survey procedures and inventory accountability.

The individuals recently appointed to manage licensed activities had taken several steps towards improving NMSU's inventory controls, including the disposal of all contaminated wastes previously on site, through a commercial waste broker. This project, which was in its initial phase at the time of this inspection, should significantly improve NMSU's inventory accounting and ability to assure that its possession limits are not exceeded. Although several improvements to procedures had been proposed by the individual chosen to serve as RSO, these changes had not yet been implemented at the time of this inspection.

Within the areas inspected, the following violations were identified:

- The use and storage of licensed materials in areas other than those designated in the license. (Section 4)

- The failure to maintain records of sealed source leak test results in the proper units, as required by license condition. (Section 5)

- The failure to conduct radiation surveys after each use of licensed materials, as required by licensee procedures. This is a repeat violation. (Section 6)

The following concern was also identified:

- The failure to promptly return and process personal exposure monitoring devices.

DETAILS

1. Individuals Contacted

*Preston A. Marx, Ph.D., Director
*Agegnehu Gettie, (proposed) Radiation Safety Officer
*Carolyn Dittmer, Research Assistant

*Indicates those individuals present during the exit briefing.

2. Followup on Previous Violations

(Closed) (30-29613/90-01): Violation of License Condition 18 - An individual other than the one designated in the license had been appointed to serve as the RSO. The licensee had requested an amendment of the license to designate as RSO the individual serving in this position, and had received approval for this action from NRC.

(Closed) (30-29613/90-01): Violation of License Condition 18 - Failure of the RSO to maintain an inventory listing of all radioactive materials in the licensee's possession. The licensee had established an inventory system which included documentation of all byproduct material in its possession.

(Closed) (30-29613/90-01): Violation of 10 CFR 20.205(d) - Failure to establish procedures for safely opening packages in which licensed materials were received. The licensee had established procedures for opening packages containing licensed materials and had observed the procedures during this inspection period.

3. Program Overview and Inspection History

This facility is authorized under a broad license for the use of byproduct material for laboratory research and as tracers in nonhuman biologic systems. These activities primarily involve the use of microcurie or millicurie quantities of iodine-125, phosphorus-32, hydrogen-3, carbon-14, chromium-51, and selenium-75. Although the license authorizes tracer studies in primate subjects, due to a number of organizational changes during the previous year, this specific activity had notably diminished. The licensee had continued the use of iodine-125 in radioimmunoassay procedures, and intends to discontinue its use of millicurie quantities of carbon-14, replacing current test procedures with alternative techniques. A limited number of researchers are involved in licensed activities, and only one research project request had been received and approved during this inspection period.

During NRC's previous two inspections, violations involving the inventory and disposal of licensed material were observed. These findings were notable for the fact that in January 1988, NRC determined that the licensee had exceeded the permissible release limits for iodine-125 to the

sanitary sewerage system. This finding served as the basis for NRC's request to conduct a telephonic enforcement conference in February 1988. NRC's inspection in March 1990 confirmed that although NMSU had corrected the three violations identified during the January 1988 inspection, a violation involving the failure to fully inventory licensed materials had occurred. The findings of the March 1990 inspection also included two additional violations, and observations which raised a concern regarding the RSO's failure to investigate repeated episodes of surface contamination within certain laboratory areas.

4. Facilities and Equipment (87100)

Facilities

NMSU had designated 13 rooms of Building 1264, at Holloman AFB, for the use and storage of licensed materials. This facility, located in a remote area within the base complex, was observed to have adequate security and safety equipment and had been installed as described in the license.

The licensee had also used a building designated as "P-3," located in the "Animal Isolation Area" approximately 2 miles from Building 1264, for the use and storage of licensed materials. The current RSO was not aware of how long this area had been in use; however, a radiation safety committee (RSC) meeting record noted its use as early as December 1989. This building housed the virology and immunology laboratories, which were involved with the use and storage of chromium-51, hydrogen-3, and phosphorus-32. Although the building was remote from the primary research center, adequate security had been provided. The inspector noted that the RSC had discussed the need to amend the license to include this area in those designated in the license during a meeting conducted in December 1989, but had later failed to do so. This issue was identified as a violation of License Condition 18, which references the license application dated November 7, 1986. Item 9 of the application, "Facilities and Equipment," describes the areas designated for the receipt, use, and storage of byproduct material.

Equipment and Instrumentation

The licensee possessed an adequate number and type of radiation detection and counting systems for the materials currently in use. Survey instruments had been calibrated by an authorized vendor, and the licensee had maintained the appropriate reference sources necessary to determine the counting efficiency for those systems which had been used to analyze removable contamination survey samples.

One violation was identified.

5. Byproduct Material Receipt, Use, and Waste Disposal (87100)

a. Byproduct Material Receipt

During this inspection period, all materials had been received at Building 1264, as specified in the license application. Subsequent to NRC's findings during the previous inspection, NMSU had implemented a procedure for package receipt, requiring that the RSO conduct external radiation surveys and obtain a wipe sample of the package surface to determine the presence of removable contamination. Therefore, this item is considered closed.

The majority of materials received during this inspection period involved radioimmunoassay test kits containing iodine-125, microcurie quantities of hydrogen-3, and the occasional receipt of millicurie quantities of phosphorus-32. Each shipment had been ordered per licensee procedure and had been promptly delivered to the respective authorized users. With the exception of the use of Building P-3, licensed material had normally been stored under refrigeration within the respective laboratories designated in the license.

b. Byproduct Material Use

NMSU had taken corrective action for a violation involving the failure to have maintained a comprehensive inventory, which was identified during NRC's March 1990 inspection. This issue primarily involved the failure of the RSO to maintain a record of all materials possessed by NMSU, rather than the failure of the individual researchers to document the receipt and disposal of licensed materials. This was notable in that although receipt and disposal records had been maintained, the RSO had failed to account for material which had been placed in storage, or to fully ensure that the possession limits identified in the license had not been exceeded.

The licensee's corrective actions included the requirement for each researcher to submit a monthly report identifying the types and quantities of materials received, as well as those disposed of during the specific interval. Although the majority of the staff had complied with this directive, during the latter part of 1990, the RSO noted that several researchers were delinquent in submitting the reports. In conjunction with a comprehensive effort to reduce the total inventory (by transferring all stored waste materials to a commercial broker), the RSO initiated a systematic review of inventory reports and had provided written notices to the authorized users who failed to submit a monthly report. This effort had effected an improvement in the timely submission of inventory reports.

The inspector observed that NMSU had met the requirement to maintain an inventory of all materials in its possession, and had implemented

the corrective actions described in NMSU's letter dated May 15, 1990. However, the quantity of material possessed by independent users had not been documented consistently, and various units of measure had been recorded. Furthermore, inventory records of sealed sources did not uniquely identify the source or the quantity of material which it contained in every case. These items were noted as worthy of further attention in order to improve the uniformity of inventory records and to make them consistent with the possession limits identified in the license.

NMSU possessed several sealed sources, many of which were small reference standards and were exempt from leak testing in accordance with the conditions of the license. The licensee had conducted leak tests for the remaining sources, which were primarily nickel-63 sources contained in gas chromatographs. However, test results for the most recent leak test samples had been maintained in units of counts per minute (cpm), rather than the units specified in the license. This was identified as a violation of License Condition 12.D, which requires, in part, that records of leak test results be kept in units of microcuries. This issue was identified as a violation during NRC's January 1988 inspection as well. Although the licensee had implemented corrective actions and leak test records were annotated with the appropriate units and necessary conversion equation, the individuals conducting the tests had failed to convert the measured cpm value to a microcurie unit.

c. Waste Disposal

NMSU had continued the disposal of certain radionuclides to the sanitary sewerage system throughout this inspection period. The majority of this waste consisted of small quantities of iodine-125, generated in the radioimmunoassay laboratory. The licensee's corrective actions for a previous violation, involving the disposal of quantities of iodine-125 in excess of the limits specified in the license, had remained effective in preventing a recurrence of this violation.

The licensee had stored a large volume of miscellaneous wastes, accumulated from activities conducted during the previous years. This material had recently been inventoried and segregated for transfer to a commercial waste broker. The RSO was reminded of the necessary transfer requirements in accordance with 10 CFR Parts 20 and 30. This project is expected to be completed within 1 month from the date of this inspection.

One violation was identified.

6. Radiation Surveys and Evaluations (87100, 83822)

a. Area Surveys

NMSU had implemented procedures for radiation surveys to be conducted following each use of material. These surveys consisted of the measurement of either the radiation levels in the area of use, or collection of removable contamination samples, depending on the radionuclide in use. Surveys were also conducted by the RSO biweekly, to determine the presence of removable contamination within laboratory hoods, storage refrigerators, or on countertops.

A review of survey records revealed that certain laboratory areas demonstrated repeated contamination of work surfaces, at levels ranging from 1000 disintegrations per minute (dpm) per 100 square centimeters (cm) to 15,000 dpm/100 cm^2. This issue had also been identified during NRC's previous inspection, and was discussed in NRC's letter dated March 14, 1990. During discussions with the RSO and members of the research staff, the inspector determined that although the RSO had taken steps to promptly identify the areas of contamination to the researchers, his efforts had not addressed the reason for the repeated contamination of certain areas.

This problem occurred most frequently in Rooms 201, 210, 109, 305, 523B, 525, and 530. The RSO had recently initiated the practice of issuing a memo to those users whose laboratory areas evidenced removable contamination, specifying that areas were either to be decontaminated or that the privilege of participating in licensed activities would be suspended. While this had improved the timely decontamination of certain areas, during interviews with certain staff members the inspector was informed that the areas were not resurveyed in each case. The staff had instead relied upon the RSO's next survey to verify that the area had been properly decontaminated. Furthermore, one staff member admitted that surveys had not been routinely conducted after each procedure. This admission was noteworthy because the individual worked within a laboratory noted for repeated contamination. The failure to conduct routine surveys was identified as a repeat violation of License Condition 19, which references the licensee's letter dated January 9, 1987. Item 10.2.C of the letter describes radiation survey procedures, and specifies that surveys for radioactive contamination will be made before and after each radioisotope manipulation.

b. Personnel Monitoring

NMSU had provided and required the use of film badges for whole body monitoring, as well as extremity thermoluminescent dosimeters (ring badges) for individuals using millicurie quantities of phosphorous-32 and those using radioiodine. The latter had been provided in response to concerns identified by the United States Air Force

inspection staff during a routine base inspection conducted in September 1987.

Whole body exposures had averaged 40-90 millirem per quarter, and extremity exposures averaged 90-120 millirem per quarter for those individuals who had routinely prepared and handled radioactive material during this inspection period. The highest whole body exposure observed during this period was 90 millirem for a single month.

While the licensee had clearly maintained personnel exposures within reasonable limits, and the individual staff members had generally accrued exposures that were below 25 percent of the permissible occupational limits, one concern regarding the personnel monitoring program was identified. This issue involved the failure to promptly return film badges and to ensure that they were processed in a timely fashion. The inspector noted that on several occasions, film badges had not been returned for processing for as long as 3-5 months after they had been exchanged for new badges. This problem did not include the NMSU staff as a whole, but was limited to a few individual researchers. This issue had not been addressed by either the former RSO or RSC. The inspector reviewed the problem with the individual currently serving as RSO, noting that although delinquent badge returns had occurred less frequently during the latter part of 1990, the issue warranted continued attention in order to correct a recurrent problem.

One violation was identified.

7. Management Organization (81700)

Licensed activities at this facility had been overseen by both the RSC and an individual designated as the RSO. Decisions regarding general policy or specific procedures had been properly addressed by the committee, while the RSO was responsible for management of the day-to-day operations. As previously noted, certain individuals responsible for managing this program had only recently been appointed to their respective positions at the time of this inspection. These included the director of the facility and the RSO, who had not yet been authorized by NRC.

The inspector noted that the RSC had met at quarterly intervals, and that minutes of these meetings revealed that program activities had been reviewed although on some occasions, the reviews appeared cursory in nature. However, she also noted that the detail of program reviews had improved during the latter part of 1990, and that the committee had initiated followup discussions to ensure that issues were resolved. Furthermore, the inspector observed that the RSC and RSO had implemented systematic followup and reporting in several program areas, most notably with regard to inventory and contamination issues.

No violations were observed.

8. Exit Briefing (30703)

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 the corrective actions taken in response to previous violations. The licensee's representatives were encouraged to continue the recent efforts taken to improve management controls.