U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-29240/89-001

Docket No. 030-29240

License No. 37-27830-01MD Priority I Category GI Program Code 02500

Licensee: Roche Professional Service Centers, Inc.
8312 State Road, Suite 3
Philadelphia, Pennsylvania 19136

Facility Name: Roche Professional Service Centers, Inc.

Inspection Conducted: October 23 and 31, 1989

Inspector: Judith A. Joustra
Judith A. Joustra, Health Physicist

9/2/90
date

Approved by: M. S. Shanbaky
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A

9/21/1990
date

Inspection Summary: Inspection Conducted on October 23 and 31, 1989 (Inspection No. 030-29240/89-001)

Areas Inspected: Organization and scope of licensed activities, training and audit program, radiation protection procedures, personnel protection-external, use of licensed radioactive materials, instrumentation, radioactive waste disposal and NRC Investigation.

Results: Seven apparent violations were identified: (1) failure to train a number of employees as required (Section 3); (2) failure to perform the required monitoring procedure before leaving the restricted area (Section 4); (3) failure to have an authorized user physically present when licensed material was being used (Section 6); (4) failure to adjust or use a correction factor when the dose calibrator constancy test exceeded ±5% (Section 7); (5) failure to perform dose calibrator linearity test at the required frequency (Section 7); (6) failure to restrict the exposure rate from decay wastes in "non-restricted area" to background levels (Section 8); (7) failure to provide complete and accurate information to an NRC inspector (Section 9).

DETAILS

1. Persons Contacted

*Becki Fire, RP.h., Facility Manager
A. Geiwitz, RP.h.
A. Shoen, Driver/Technician
H. Amoia, RP.h.
L. Culbert, Driver/Technician
D. Murray, Driver/Technician
J. Wooley, Driver
L. Joyce, Lab Dispatcher
M. Collman, Computer Operator
L. Sabo, Lab Dispatcher
*J. Reuther, Sr. Associate Regulatory Affairs

*Present at exit interview

2. Organization and Scope of Program

At the time of the inspection the nuclear pharmacy staff consisted of a pharmacy manager/proposed RSO, approximately 11 drivers, 1 computer operator, 6 pharmacists, and 2 lab dispatchers/prewrappers.

Roche Professional Service Centers, Inc. (Philadelphia Facility) receives 5 generators per week and services approximately 70 accounts.

3. Training and Audit Program

The inspector reviewed training records for those employees currently working at the Philadelphia facility at the time of the inspection. Based on the records reviewed and discussion between the inspector and a number of employees available during the inspection, the inspector concluded that the required training is not being provided to all personnel. Records provided to the inspector indicated that three drivers had not been given the required initial orientation, nine drivers had not been given training in the procedure for ammo box check out. ten drivers had not received training in the procedure for ammo box check in, and two drivers had not received training in the use of a survey meter.

Condition 23 of License No. 37-27830-01MD requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated April 30, 1986. Item 8 of this application requires that Appendix C of Regulatory Guide FC 410-4 be followed. Appendix C requires that training be provided before an employee assumes duties and annually thereafter, and that the training be sufficient to ensure that individuals are instructed in items specified in Section 12 of 10 CFR Part 19 as well as radiation hazards and appropriate precautions.

Failure to provide training as required by Appendix C of Regulatory Guide FC 410-4 is an apparent violation of Condition 23 of License No. 37-27830-01MD.

The inspector also reviewed records of audits performed by the licensee's Safety Team and licensee's consultant. The consultant performs audits three times per year and the licensee performs one audit per year. These audits have successfully identified areas of concern, some of which have been addressed by the licensee and corrected. However, the licensee's consultant did mention in audits that the training program was not adequate and that records were not complete. The licensee's consultant held a meeting with the licensee's management in order to discuss a letter she wrote to the license's Vice President of Regulatory Affairs. The letter was dated July 9, 1989. This meeting contained discussions concerning training.

Based on discussions with employees and a review of training records, it was apparent to the inspector that the licensee had not initiated adequate corrective actions in response to their consultant audit findings.

4. Radiation Protection Procedures

The inspector observed a number of instances in which drivers, who [redacted] red shipments of radiopharmaceuticals within the restricted area, leave the area without monitoring their hands and clothing for radioactive contamination.

License Condition 23 of License No. 37-27830-01MD requires that Appendix H, "General Rules for Safe Use of Radioactive Material", of Regulatory Guide FC 410-4 be followed. Item 3 of Appendix H requires that hands and clothing be monitored for contamination after each procedure or before leaving the area. During the inspection the inspector observed a sign-off sheet at each exit of the restricted area and survey instrument. The facility policy is for the worker to survey himself/herself including soles of shoes prior to leaving the area and to record the results on the sign-off sheet. Several drivers were observed during the inspection exiting the rear door of the facility, failing to survey themselves after completing their duties within the restricted area or prior to leaving the restricted area.

Failure of the drivers to monitor their hands and clothing prior to leaving the restricted area is an apparent violation of Condition 23 of License No. 37-27830-01MD.

5. Personnel Protection - External

The inspector observed licensee personnel in the restricted area wearing required personnel monitoring devices. The inspector also reviewed dosimetry records from the second calendar quarter of 1988 to the third calendar quarter of 1989. The inspector noted no exposure levels in excess of regulatory limits.

No violations were identified.

6. Use of Licensed Radioactive Materials

The inspector questioned a number of licensee staff members on October 23, 1989, concerning the use of licensed radioactive material without the presence of an authorized user. Of those staff employees asked, they all stated that they were not aware of licensed radioactive material being handled without an authorized user present. The inspector asked the facility manager if she was aware of any time in which licensed radioactive material was used without an authorized user being present. The facility manager stated no. At that time the inspector informed the facility manager that the inspector had observed licensed radioactive material being used during the inspection without an authorized user being present.

The facility manager then stated that Roche Professional Service Centers, Inc., gave approval for her to work without an authorized user present based on 10 CFR 35.27 which authorizes visiting authorized users. The inspector then informed the facility manager that Part 35 pertains to NRC licensed facilities which administer licensed material to patients and that NRC licensed nuclear pharmacies are not covered by Part 35 requirements.

The inspector discussed the fact that the NRC had in their possession an amendment request from the licensee to add a number of authorized users including the facility manager to their NRC license and that this request had not yet been acted upon by the NRC.

Condition 12 of License No. 37-27830-01MD requires that at least one individual named in Condition 11 be physically present at the authorized place of use whenever licensed material is being used.

Failure to have an authorized user physically present when licensed material is being used is an apparent violation of Condition 12 of License No. 37-27830-01MD.

7. Instrumentation

The inspector observed during the inspection that the licensee possessed a number of required operable and calibrated survey instruments.

The inspector also reviewed records of dose calibrator constancy checks and dose calibrator linearity checks performed by the licensee. The inspector noted that the dose calibrator constancy checks performed on the cobalt-57 setting on the CRC-12 dose calibrator varied greater than ±5% on nine occasions between April 5, 1989 and September 13, 1989. The licensee staff appeared to be unaware of the constancy test results or whether any action had been taken to correct the apparent problem. The test results exceeded the ±5% limit by a small margin. However, after September 13, 1989 the results were within the required ±5% limits.

The inspector also noted that the dose calibrator linearity had not been performed on the licensee's dose calibrators since June 10, 1989. The licensee acknowledged that the linearity test was late and had not been performed. However, the licensee committed to perform the test as soon as possible. On October 31, 1989 during the inspector's second site visit the licensee was in the process of performing the required linearity test.

License Condition 23 of License No. 37-27830-01MD requires that dose calibrators be calibrated in accordance with Appendix E of Regulatory Guide FC 410-4. Appendix E requires that if the measured activity of the constancy test varies greater than ±5% from the predicted activity, the dose calibrator is to either be adjusted or a arithmetic correction factor is to be used to correct dose assays.

Appendix E also requires that the linearity test be performed at installation and at 3-month intervals thereafter. The licensee's dose calibrators had not been tested for linearity since June 10, 1989 until at least October 31, 1989, an interval greater than 3 months.

Failure to calibrate the dose calibrators in accordance with Appendix E of Regulatory Guide FC 410-4 is an apparent violation of Condition 23 of License No. 37-27830-01MD.

8. Radioactive Waste Disposal

The inspector performed a survey of the licensee's waste storage area which was located in an area designated by the licensee in their application as a "non-restricted area." In order to gain access to this storage area, an individual must first enter the licensee's restricted area. The licensee has established this area to store decayed waste. License Condition 23 of License No. 37-27830-01MD requires that exposure rates of decayed waste stored in the non-restricted areas will not exceed background levels.

The inspector performed an area survey on October 31 1989, which was confirmed by a representative of the licensee who was present at the time. The inspector identified a box of waste in the non-restricted area which measured 3 mR/hr at the surface of the box. The box was sealed and dated August 22, 1989. Background for this area was approximately .03 mR/hr. The inspector questioned the facility manager and the licensee Senior Associate why the box was stored in the non-restricted area. The licensee representatives located files which indicated that the box contained thallium, gallium and iodine-131. The individual who originally surveyed the box recorded a reading of 5 mR/hr and placed the box in the non-restricted area. This individual is no longer employed by the licensee and therefore it was not possible to gain any additional information. The licensee was not aware that the box had been placed there or why the individual placed the box in the unrestricted area. The licensee removed the box and placed it in the restricted area

Failure to restrict the storage of decayed radioactive waste in the non-restricted area to material with exposure rates that do not exceed area background exposure rates is an apparent violation of Condition 23 of License No. 37-27830-01MD.

9. NRC Investigation

On October 18, 1989, NRC Region I received an anonymous telephone call alleging that licensed material was used at the licensee's facility without an authorized user being present. This prompted the inspection on October 23 and 31, 1989, and subsequent NRC investigation.

The NRC investigators interviewed a number of licensee representatives from December 12, 1989 to February 15, 1990. The investigation synopsis is enclosed.

Based on the NRC inspection and investigation findings, it is concluded that the Roche Philadelphia facility manager willfully caused a license condition to be violated by allowing a Roche employee to prepare radiopharmaceutical doses on September 17 and October 23, 1989, without a required authorized user being present. It is also concluded that that facility manager lied to the NRC inspector on or about October 23, 1989, when she answered, "No" in response to a question inquiring if doses had been prepared without an authorized user being present (see Section 6 of this inspection report).

10 CFR 30.9(a) requires that information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

Failure to provide complete and accurate information is an apparent violation of 10 CFR 30.9(a).

10. Exit Interview

The inspector met with the licensee representatives indicated in Section 1 of this report at the conclusion of the inspection on October 31, 1989. The inspector summarized the scope of the inspection and the apparent violations identified with the exception of the apparent violation described in Section 9 of this report. The licensee representatives stated that they would act or have already started to act on the items discussed.

SYNOPSIS

On October 18, 1989, Region I, Nuclear Regulatory Commission (NRC) received an anonymous telephone call, alleging that licensed material was used (radiopharmaceutical doses prepared) without an authorized user being present at Roche Professional Service Centers, Inc. (Roche), 8312 State Road, Philadelphia, Pennsylvania. The NRC license issued to Roche requires that at least one authorized user be physically present whenever radioactive material is handled (doses drawn) by qualified people.

On October 23 and 31, 1989, inspections of the Roche facility were performed by Region I personnel. During the October 23, 1989, inspection, the inspector asked Roche staff members (to include the facility manager) if nuclear material was ever handled (doses drawn) without an authorized user being present and all responded negatively.

During the October 31, 1989, inspection, three additional staff members were interviewed by the NRC inspector. One member denied drawing radiopharmaceutical doses and two were not questioned on the matter. On November 1 and 2, 1989, these staff members telephoned the Region I inspector and stated that they had been approached by the facility manager prior to the interview. They alleged that the facility manager told them, if they were asked whether they drew doses, they were to say no. Two of these staff members stated that they received telephone calls from the facility manager during the evening of October 31, 1989, following the inspection. They both alleged that the facility manager had apologized for asking them to lie to the NRC and asked one of them for suggestions on a way for her (the facility manager) to explain the situation to the NRC inspector without admitting that she had lied.

One of these staff members also informed the inspector that, with the approval of the facility manager, she had worked at the facility on September 17, 1989, and had drawn doses without an authorized user being present. The staff member stated that the facility manager was aware that an authorized user would not be present at the facility during this time. The staff member reported that the facility manager informed her that she would take full responsibility for this decision.

On November 24, 1989, the NRC Regional Administrator, Region I, requested that an investigation be initiated by the Office of Investigations (OI) to determine the veracity of allegations that radiopharmaceutical doses were drawn without an authorized user being present and that the NRC inspector was lied to by facility personnel when pursuing the allegations.

The facility manager was interviewed by the reporting investigator on February 15, 1990. The facility manager admitted to authorizing a staff member to cover the facility (draw doses) on September 17, 1989, without an authorized user present, knowing such action would be a violation of the facility's NRC license. The facility manager denied knowingly providing false information to the NRC inspector regarding unauthorized personnel drawing doses or that she had directed subordinates to lie to the NRC inspector about the matter.

Based on testimon and documentary evidence, it is concluded that the Roche Philadelphia fa lity manager willfully caused a license condition to be violated by allowing a Roche employee to draw radiopharmaceutical doses on September 17, 1989, without a required authorized user being present. It is also concluded that the facility manager lied to the NRC inspector on or about October 23, 1989, when she answered, "No" in response to a question inquiring if doses had been prepared without an authorized user being present. However, insufficient evidence exists to conclude that the verbal false statement was willful or that the facility manager directed subordinates to lie about the matter. Finally, it is concluded that the facility managers management was not aware of these activities until on or about November 3, 1989.