

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 89-002

Docket No. 030-29240

License No. 37-27831-01MD Priority 1 Category G1 Program Code 02500

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

Management Meeting At: Region I, King of Prussia, Pennsylvania

Management Meeting Conducted: November 21, 1989

Prepared by:

Judith A. Joustra
Judith A. Joustra
Health Physicist

1/4/90
date

Approved by:

M. Shanbaky
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A

1/4/90
date

Summary: The licensee described additional information of which they became aware after completion of the NRC inspection on October 31, 1989 and described their ongoing investigation of both technical and management issues at the Philadelphia facility.

DETAILS

1. Persons Attending

Roche Professional Service Centers, Inc.

David J. Gallaher, Vice President of Operations
Adrienne E. Shirk, Legal Counsel for Hoffman LaRoche
Robert Ross, Legal Counsel for Roche Professional Service Centers, Inc.
John J. Kerins, Vice President, Regulatory Affairs
Janet Reuther, R.Ph., Senior Associate, Regulatory Affairs

Nuclear Regulatory Commission

Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards
Lee H. Bettenhausen, Chief, Nuclear Materials Safety Branch
Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A
Judith A. Joustra, Health Physicist
Richard Matakas, Office of Investigations
Karla Smith, Regional Counsel (by phone)

2. Conference Summary

- a. Introductions were made and the representatives of Roche Professional Service Centers, Inc. (RPSC) were welcomed to Region I by Dr Lee H. Bettenhausen, Chief, Nuclear Materials Safety Branch.
- b. Mr. Robert Ross, Legal Counsel for RPSC, introduced the RPSC staff. Mr. Ross explained the purpose of the meeting and identified a number of issues which have raised concerns among the members of management within RPSC. Mr. Ross described additional information of which RPSC became aware after completion of the NRC inspection on October 31, 1989. The following additional information was provided by the licensee: On September 17, 1989, for approximately 4.5 hours radioactive material (radiopharmaceuticals) was handled at the Philadelphia facility without an authorized user being present; and that Ms. Rebecca Fire is not a licensed pharmacist in the Commonwealth of Pennsylvania.

Mr. Ross also addressed the apparent conflicting information which was obtained by the inspector during the inspection and subsequent telephone conversations. Mr. Ross indicated and Mr. Kerins, Vice President, Regulatory Affairs, concurred that when Ms. Fire approached the RPSC staff on October 31, 1989, she posed a question to the staff in order to determine whether certain members of the staff had ever drawn doses and that she did not intend to direct the staff, in any way, to tell the NRC inspector that they did not draw doses.

- c. Mr. Kerins presented the NRC staff with a letter addressed to Mr. Joyner, dated November 21, 1989, (attached) which identifies their plan of action. The plan includes a number of commitments by RPSC to improve corporate oversight of the radiation safety program and improve training. In addition, the plan addressed certain personnel actions.

3. Closing

- a. Dr. Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards addressed the RPSC staff and their legal counsel at the conclusion of the meeting. Dr. Knapp informed the RPSC staff that he had read their letter dated November 21, 1989, and he had two questions: (1) What new information did they present to the NRC staff? (2) What would they like or expect from the NRC at this time?
- b. Mr. Ross and Mr. Kerins restated the information they provided during the meeting and concluded by stating that RPSC does not expect a response from the NRC at this time, only that the NRC monitor their proposed actions.
- c. Dr. Knapp thanked the RPSC representatives for the information they provided. Dr. Knapp also encouraged the continued flow of communication between RPSC and the NRC.

**Roche Professional
Service Centers**

ROCHE

a subsidiary of Hoffmann-La Roche Inc.

Knapp
Greeves
Joyner
Shambaky
Jowtha
Battenhanson
orig to desk file

Roche Professional Service Centers Inc.
140 East Ridgewood Avenue
PO Box 289
Paramus, New Jersey 07653-0289

Direct Dial (201) 593-8926

November 21, 1989
PSC-K-106

Mr. James Joyner
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA. 19406

Re: Radioactive Material License
No. 37-27831-01MD
Philadelphia Nuclear Pharmacy

Dear Mr. Joyner:

The senior management of Roche Professional Service Centers Inc., (RPSC) would like to reiterate our commitment to operate the Philadelphia nuclear pharmacy and all nuclear pharmacies according to regulatory requirements and promoting effective management of each pharmacy. As a result of the incidents discussed with the Nuclear Regulatory Commission (NRC) and our ongoing investigation of technical and management issues at the referenced license, the following action plan is provided:

1. To assure Corporate oversight of the radiation safety program, RPSC will request that Ms. Janet Reuther, R.Ph., be named a Corporate Radiation Safety Officer. RPSC commits to having Ms. Reuther at the Philadelphia site for at least five (5) days per month. This commitment will be for a minimum of three (3) months.
2. Ms. Maureen Donnelly, R.Ph. (RSO) will perform a weekly audit of the radiation safety program at the Philadelphia facility. The results of this audit will be sent to Ms. Reuther for review. The transmittal of these audit results to Ms. Reuther will be performed for a minimum of three (3) months.
3. Ms. Rebecca Fire will be sent to a RPSC or Medi-Physics, Inc. facility licensed by the NRC for further training. Ms. Fire's training will be directly under the supervision of an RSO. Topics for training will include at a minimum: Adherence to



license conditions and compliance with appropriate NRC regulations, practical administration of a radiation safety program, and management and execution of pharmacy on-call procedures.

4. During the week of December 4, 1989, a training meeting will be conducted by a corporate representative at the Philadelphia facility. The topics will include:
 - Facility and corporate organizational structure and lines of and methods of communication regarding radiation safety and managerial issues.
 - Upper management's expectation of candid responses to inquiries during regulatory inspections.
 - Dealing with regulatory inspections.
 - Upper management's commitment to resolve outstanding issues.
 - Clarification of who are NRC authorized users, PA. authorized users, and PA. licensed pharmacists.
 - Policies and procedures for employees who are not authorized users, regarding the "drawing of doses."
5. Quarterly audits of the Philadelphia facility will be conducted by Ms. Mary Moore or any other suitably qualified individual. This suitably qualified individual will be defined as Ms. Reuther or any other individual named as a RSO on a RPSC or Medi-Physics, Inc. radioactive materials license.
6. Based on our investigational findings, Ms. Rebecca Fire will be issued a written warning according to the company's disciplinary policy. This warning is a result of Ms. Fire's operation of the Philadelphia facility on select occasions without appropriately licensed personnel on site.

We hope this information demonstrates our commitment to radiation safety and the NRC's regulations and license commitments.

Please contact me if there are any questions.

Sincerely,

Roche Professional Service Centers Inc.

John J. Kerins
Vice President
Regulatory Affairs