



Roche Professional Service Centers

a subsidiary of Hoffmann-La Roche Inc.

Roche Professional Service Centers
27331 Roosevelt Avenue
PO Box 127
Kenilworth, NJ 07033

201-599-8926

March 7, 1990
PSC-K-153

William Adam, Ph.D.
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Roche Professional Service Centers Inc.
Radioactive Material License No. 34-25986-01

Dear Dr. Adam:

The following information is submitted in regard to the above referenced license for Roche Professional Service Centers Inc.'s (RPSC) nuclear pharmacy, located at 344 Gest Street, Cincinnati, Ohio.

On February 1, 1990, the undersigned was notified by a member of the Regulatory Affairs Department that on certain occasions during the period between approximately July 1989 and September 1989, radiopharmaceuticals were prepared by a registered pharmacist without the supervision of an authorized user. The investigation which we initiated regarding this matter revealed that these incidents occurred between July 13, 1989, and September 7, 1989, primarily during off hour, "on call" schedules when emergency STAT dose preparations were required. During the course of this investigation, all professional staff members of this pharmacy were individually interviewed. Further, various documentation pertaining to the above period was reviewed.

RPSC believes that the health and safety of the facility employees and the patients who were administered the above radiopharmaceuticals were not compromised by these inappropriate actions. No reports of misadministration have been received for this time period. Further, a review of routine radiation surveys, swipes, and personnel dosimetry during the course of our investigation did not reflect any abnormalities. Although we recognize that the pharmacist was not approved by NRC Region III as an authorized user at the Cincinnati pharmacy until September 26, 1989, we wish to point out that she had completed the requisite classroom and laboratory training on July 10, 1989. This training was certified on August 29, 1989, by Stanley Shaw, Ph.D., Professor of Nuclear Pharmacy, Purdue University.

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The following actions have been or will be taken by March 15, 1990, as a result of the above incidents:

1. The Pharmacy Manager of this facility will be issued a written warning, due to her lack of management control in allowing an unauthorized pharmacist to handle radioactive material without the supervision of an authorized user.
2. The individual pharmacist will be issued a written reprimand, due to her preparation of radiopharmaceuticals without the supervision of an authorized user.
3. A directive has been sent to all RPSC pharmacy managers and radiation safety officers regarding facility and personnel licensing requirements. Management's expectation that pharmacies be operated at all times in compliance with these licensing requirements was strongly emphasized.
4. All internal auditors responsible for RPSC radiation safety audits have been alerted of these incidents and have been requested to incorporate an evaluation of compliance with facility and personnel licensing requirements into their audit reports.

The senior management of RPSC is firmly committed to operating all of our nuclear pharmacies within regulatory compliance and regrets the occurrence of these incidents.

We hope this information is satisfactory. Please contact me if there are any questions.

Sincerely,

ROCHE PROFESSIONAL SERVICE CENTERS INC.

John Kerins
Vice President
Regulatory Affairs

JK:khk
J798D
cc: R. Fire
D. Gallaher
bcc: ~~John Kerins~~

**Roche Professional
Service Centers**



a subsidiary of Hoffmann-La Roche Inc.

Interoffice Memo

To: Distribution

From: John Kerins

Dept: DRA/CQC

Re: Facility and Personnel Licensing

Date: February 26, 1990
PSC-K-157

This memo is to serve as a directive to all pharmacy managers regarding facility and personnel licensing requirements.

The operation of a pharmacy requires the separate licensure of the facility and those professional staff members performing certain tasks in the pharmacy.

In regard to facility requirements, the following license requirements exist.

Home Health Care

- The Board of Pharmacy of the state in which the pharmacy is located.
- The Board of Pharmacy of any state which has issued an "out-of-state" license.
- Home Health Care license for those states which have such licensing requirements.

Nuclear Pharmacy

- The Board of Pharmacy of the State in which the pharmacy is located.
- The Board of Pharmacy of any state which has issued an "out-of-state" license.
- The Nuclear Regulatory Commission (NRC) and/or a State Radiological Health Department.
- Any local regulatory agencies associated with waste handling or storage of hazardous materials.

In addition to facility licenses, the following personnel licensing requirements exist:

Home Health Care

- Registered Nurses in the state where the facility is located.
- Potential nursing registration in a state which is different than where the facility is located, if nursing care is delivered.
- Registered pharmacists in the state where the facility is located.
- Potential pharmacist registration in a state where an "out-of-state" facility license is held.

Nuclear Pharmacy

- Registered pharmacists in the state where the facility is located.
- Potential pharmacist registration in a state where an "out-of-state" facility license is held.
- Authorized user status by the NRC or the State Radiological Health Department at the licensed facility.

We remind all managers that the pharmacy must conduct business at all times, including on-call, with the appropriately licensed personnel on site. Furthermore, we expect that all pharmacists, nurses, and authorized users of radioactive material will perform their duties in full compliance with the requirements and limitations of their respective facility and personal licenses.

The operation of a pharmacy at any time without appropriate licensed or authorized personnel on site is a serious violation of regulatory requirements which may result in disciplinary action against the managers and the individual depending on the circumstances. Such violations can also result in regulatory actions being taken against the company and the involved individual(s).

An inability to staff a pharmacy without appropriately licensed personnel on site, in the short or long term, should be immediately brought to the attention of Regional and Corporate Management.

Please discuss this directive with all professional staff and ensure that it is understood.

If there are any questions by you or any members of your staff, please contact me.

Distribution

John Bartlett
Kevin Boyd
Randy Brooks
Dan Brower
Jimmy Coker
Terry Colangelo
Tom DeFranco
Ken DeTurk
Rich DeVeau
Maureen Donnelly
Tony Edmond
John Ellis
Ron Fedeles
Rebecca Fire
Nori Morikawa
Felix Muniz
Karl Nigg
Jim Pancy
Rajiv Rao
Todd Schmidt
Richard Van Sant
Jim Velez
Randy White

cc: Dave Gallaher
~~James Reuther~~
Adrienne Shirk
Susanne Loarie

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Interoffice Memo

To: Safety Audit Team (SAT) Inspectors
From: John Kerins
Dept: DRA
Re: Facility and Personnel Licensing

Date: February 27, 1990
PSC-K-155

It has come to our attention that a few Roche Professional Service Centers Inc. (RPSC) facilities have operated on occasion without appropriate licensed personnel. Namely pharmacists have worked alone without being completely licensed in the state, or an authorized user was not present on site when radioactive materials were handled. These violations of regulatory requirements have occurred during routine shift operations and on "on call" periods.

When performing SAT inspections at RPSC facilities, please perform a specific review of the appropriateness of personnel licensing. The most opportune time for this problem to occur is during facility start up and hiring of new employees. However, an evaluation of routine shift should be conducted.

In the future, please provide specific commentary in your audit reports that you have performed an evaluation of personnel licensing. Please notify me immediately if any discrepancies are detected.

If there are any questions, please contact me.

SAT Inspectors

D. Behrendt
W. London
J. Reuther
D. Salmon

cc: T. Edmond
J. Ellis
D. Gallaher
A. Shirk
R. White