

Roche Professional Service Centers

ATTACHMENT I



a subsidiary of Hoffmann-La Roche Inc.

Roche Professional Service Centers Inc
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Direct Dial

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

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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

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Service Centers**

a subsidiary of Hoffmann-La Roche Inc.

Interoffice Memo

To: Distribution

Date: February 26, 1990
PSC-K-157From: John Kerins *Kerins*

Dept: DRA/CQC

Re: Facility and Personnel Licensing

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.

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cc: Dave Gallaher
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