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Roche Professional Service Centers

a subsidiary of Hoffmann-La Roche Inc.

June 6, 1990

Roche Professional Service Centers Inc.
140 East Ridgewood Avenue
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Direct Dial (201) 599-8917
PSC-R-191

License File
34-25986-01

Mr. Bruce Mallett
Chief, Nuclear Materials Safety Branch
US Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Roche Professional Service Centers Inc.
Letter and Notice of Violation
License No. 34-25986-01
Docket No. 030-30854

Dear Mr. Mallett,

This is in response to your letter and enclosed Notice of Violation, dated May 8, 1990, regarding the routine safety inspection which was conducted by Mr. W.P. Reichhold on April 3 and 4, 1990, of Roche Professional Service Center Inc.'s (RPSC) nuclear pharmacy in Cincinnati.

During this inspection, five violations were identified. In addition, your letter notes an incident involving a therapy dose sent by our facility, which was over 10% of the amount requested by the customer. Your letter also reflects what "...appears to be a breakdown of management's control over the radiation safety program during the radiation safety officer's absence." Set forth below are responses to these violations and issues, each of which is preceded by a summary thereof, for your ease in review.

Violation No. 1:

"The alternate Radiation Safety Officer (RSO) received neither the 40 hour on-the-job training course nor an outside training course on the duties and responsibilities of an RSO. The alternate RSO assumed the RSO's duties from October 1, 1989 until January 2, 1990."

Response: While we acknowledge that the alternate RSO did not receive the requisite training, during a substantial portion of the above period of time, we had been actively recruiting a new nuclear pharmacist who would have assumed the role of pharmacy manager and alternate RSO. In late November, at about the same time this potential employee changed her mind and decided to not work for RPSC, we learned that Ms. R. Fire would be returning to the Cincinnati facility.

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In the future, before any designated alternate RSO assumes the duties of an RSO, his or her experience will be reviewed and evaluated by the corporate Regulatory Affairs Department to determine whether or not said individual requires a 40 hour on-the-job training course or an outside training course on the duties and responsibilities of an RSO. In the event such training is required, said individual will not assume the duties of an RSO until the completion thereof. In those instances where an individual has had prior experience as an RSO, or has functioned as a senior level radiopharmacist, he or she will not be required to complete either of the above training courses. However, a review of the facility's NRC and State radioactive materials license will be performed by any such individual. In addition, future audits of this facility will include an evaluation of any alternate RSO's experience and/or training.

Violation No. 2:

"The RSO did not investigate the cause of an exposure over the investigational level. For example, the extremity exposures for an individual were 1,960 millirem and 3,970 millirem for the third quarter of 1989, but the exposures were not investigated."

Response: It has always been a practice in this facility that each individual review his or her exposure reports and subsequentially initial them, as part of documentation of that review. Further, discussions have occurred in the past regarding exposures that are over investigational levels; however, it was not common practice to document these discussions. As of April 5, 1990, weekly and monthly exposure reports are being reviewed by the RSO, who monitors for quarterly limits. Further, the cause(s) of exposures exceeding ALARA limits are being investigated and documented by the RSO as of April 5, 1990. Future audits of this facility will also include a review of documentation of investigation of exposures exceeding ALARA limits.

Violation No. 3:

"The Safety Audit Team did not audit the pharmacy quarterly for at least the first year of operation. For example, audits were not done in the first quarter and last quarter within the first year of operation."

Response: The facility was licensed in March 1989. Safety Audit Team inspections have been conducted at this facility on the following dates: August 22, 1989, December 20, 1989 and April 20, 1990. To enhance compliance with license conditions and regulations, two audits (rather than one audit, as required by license condition) will be conducted at this facility prior to April 1991 These visits will also include a training session by the auditor in those areas that he/she views as appropriate.

Violation No. 4:

"An individual named in Condition 11 was not physically present at the authorized place of use when licensed material was used. For example, an individual not named in Condition 11 used licensed material at the place of use eight times from July 13, 1989 to September 7, 1989."

Response: In a letter addressed to William Adam, Ph.D., dated March 7, 1990, this licensee-identified violation was reported to your office. A copy of that letter is attached. All corrective actions outlined in this letter have been taken. Among these corrective actions were memos issued regarding compliance with license requirements. One memo was sent to all pharmacy managers dated February 26, 1990 and another memo, dated February 27, 1990 was sent to the safety audit team inspectors, copies of which are also attached. In accordance with our conversation with you, Mr. Reichhold, and Mr. McCann on May 16, 1990, we respectfully request that this violation be documented as a non-cited violation, since we self-identified this violation and completed all corrective action prior to its being noted during Mr. Reichhold's inspection of our facility.

Violation No 5:

"The weekly area surveys were not performed on the neighbors' side of the wall since the license was issued."

Response: In the past, neighbors' walls have been monitored by means of personnel dosimetry placed on the pharmacy's side of adjoining walls in areas where radioactive materials have been used and/or stored. Reports of exposure for these badges have never exceeded Part 20 limits for exposures to unrestricted areas. Although we believe that this method satisfactorily performs radiation detection on the neighbors' walls, we will evaluate the appropriateness of the locations of film badges for estimating exposure to neighbors' premises, and make changes deemed necessary by June 15, 1990. Nonetheless, we acknowledge that the above method of survey differs from the method specifically described in license condition 24. Beginning the week of May 4, 1990, weekly surveys commenced at Roche Home Healthcare inside of their cleanroom, which has an adjoining wall with our restricted area. Weekly surveys of our neighbor's side of the remaining adjoining wall began on May 23, 1990. Furthermore, to minimize the potential for excessive radiation fields to one of our neighbors' premises, additional lead shielding has been placed around the Sulfur Colloid work station. This action was taken, since this particular work station was the highest dose area that could potentially have provided a vector of radiation to one of our neighbors.

As reflected in your letter dated May 8, 1990, it was noted during the inspection that on September 5, 1989, an iodine-131 therapy dose which exceeded 10% of the amount requested was sent to a customer. The following actions are being taken to enhance assurance that therapy doses are within ± 10% of the requested dose:

Using NRC Draft Regulatory Guide, entitled "Basic Quality Assurance Program For Medical Use" (Task DG-8001) as a guideline, procedures for dispensing therapeutic dosages of iodine have been drafted, which include the requirement that all radioiodine dosages be within ± 10% of the requested dose. These procedures are currently undergoing internal review, and will be issued in final form to all of our nuclear pharmacies by no later than June 30, 1990. Management's expectation that all pharmacies comply with these procedures will be emphasized.

Your letter also reflects what "...appears to be a breakdown in management's control during the radiation safety officer's absence." You also note that two apparent violations occurred during the RSO's absence from the facility.

We disagree in part that these two apparent violations are indicative of a "breakdown in management's control." Once alerted to one of these apparent violations, we took action which we believe was both expeditious and appropriate. With regard to the other apparent violation, certain actions of control were taken, but unfortunately were not documented. As reflective of management's concern for radiation safety, we wish to point out that Mr. K. Boyd, the Cincinnati facility's recently appointed RSO, was provided with on-the-job training relating to the duties and responsibilities of an RSO. This training was provided during the week of February 26, 1990 (i.e., prior to Mr. Reichhold's inspection), by the undersigned, a licensed radiopharmacist with 5 years experience as an RSO.

In conclusion, we wish to emphasize that RPSC is firmly committed to the operation of all nuclear pharmacies with properly trained radiopharmacists and in compliance with regulatory and license requirements.

Sincerely,

Janet Reuther

Janet Reuther
Senior Associate
Regulatory Affairs

cc: Mr. K. Boyd
Mr. A. Edmond
Ms. R. Fire
Mr. J. Kerins
Ms. A. Shirk