Roche Professional Service Centers
a subsidiary of Hoffmann-La Roche Inc.

Roche Professional Service Centers Inc.
340 Kingsland Street
Nutley, New Jersey 07110

Direct Dial (201) 235-8749

December 21, 1990

Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20055

RE: Reply to a Notice of Violation
License No. 3727830-01MD
Docket No. 030-29240
EA 90-161

Dear Sir,

This Reply is provided to the Notice of Violation, dated November 16, 1990, regarding the Roche Professional Service Centers Inc. (RPSC) facility located at 8312 State Road, Suite 3, Philadelphia, Pennsylvania.

Mr. Robert Ross, counsel for RPSC, spoke to Mr. E. Baker, Assistant Director, NRC Office of Enforcement and Dr. R. Bellamy, Chief, Nuclear Materials Safety Branch A, Region I on December 12, 1990. During these conversations, Mr. Ross requested and received approval for an extension to file this Reply from December 16,1990 until December 26,1990.

During these discussions, Mr. Baker and Dr. Bellamy both agreed that due to the divestiture of the radiopharmacy portion of RPSC's business, effective June 13, 1989, RPSC's Reply will be limited to a discussion of admission or denial of the violations, reasons for the alleged violations and corrective steps that have been taken and results achieved. MPI Pharmacy Services Inc., an Amersham company, will be responsible for preparing and submitting under separate cover, further information regarding any additional corrective actions with respect to the alleged violations set forth in the above Notice of Violation, dated November 16, 1990.

During an NRC inspection conducted on October 23 and 31, 1989, at the licensee's facility in Philadelphia, Pennsylvania, and a subsequent investigation by the NRC Office of Investigations, alleged violations of NRC requirements were identified as set forth in the above Notice of Violation.

For ease of review, these alleged violations are repeated and our responses are provided below.

Violation I.A.

Contrary to license conditions, on September 17, 1989, a technician used licensed material (by drawing doses) when an authorized user listed in Condition 11A of the license was not physically present at the authorized place of use. Additionally, on October 23, 1989, technicians also utilized licensed material when an authorized user listed in Condition 11A of the license was not present at the authorized place of use.

Response: RPSC admits that on September 17, 1989, radioactive materials were handled without an authorized user present. This incident occurred when the newly hired Facility Manager (still residing out-of-state) authorized a nuclear medicine technician to prepare radiopharmaceutical doses. This authorization was granted by the Facility Manager when the staff pharmacist left the facility without a licensed pharmacist and authorized user on duty. The staff pharmacist departed the facility despite the Manager's request for him to remain on duty in the facility. The Facility Manager arrived at the site approximately four hours later after flying in from out of state.

The decision by the Manager was made without the knowledge of RPSC's corporate or regional management. It was RPSC's policy that in the absence of appropriately licensed personnel, customer orders were to be referred to another pharmacy. RPSC has closed pharmacies when an authorized user was not physically present. It is our understanding that the Facility Manager's decision to authorize the handling of radioactive material without an authorized user being present was based on her knowledge that the nuclear medicine technician was qualified to perform this function and that the delays resulting from waiting for a pharmacist/authorized user to arrive at the site could negatively affect patient welfare.

RPSC admits that on October 23, 1989, technicians utilized licensed materials when an authorized user listed in the license was not present at the authorized place of use. However, RPSC

corporate management had interpreted 10 CFR 35.27 as allowing work to be conducted under the supervision of the then Facility Manager who was named as an authorized user on a NRC license for a different RPSC pharmacy. Since this interpretation was not accepted by the NRC, RPSC immediately discontinued any reliance on its interpretation of this regulation.

In regard to RPSC's corrective action, we would like to reference the November 21, 1989 meeting among NRC and RPSC representatives. This meeting was requested by RPSC once we became aware of technical and management issues at the Philadelphia pharmacy of which we wished to advise the NRC, Region I. At this meeting, RPSC presented the specific details of the above referenced September 17,1989 incident. Furthermore, an action plan (Attachment I) was presented, components of which included commitments by RPSC to improve corporate oversight of the radiation safety program and to improve training of personnel. All items noted in the action plan were completed in a timely fashion,including the additional training of Ms. Fiore by a Radiation Safety Officer (RSO) at another NRC licensed pharmacy during the week of February 4,1990.

Furthermore, as a result of another incident brought to management's attention, a directive was sent to all pharmacy managers regarding facility and personnel licensing requirements (Attachment II). This directive emphasized that the pharmacy must conduct business at all times, including periods of on-call, with appropriately licensed personnel present. The directive also stated that the inability to staff a pharmacy without appropriately licensed personnel was to be immediately brought to the attention of regional and corporate management. In addition, an interoffice memo was sent to all in-house radiation safety auditors requiring them to pay particular attention to facility and personnel licensing during their inspections.

VIOLATION I.B.

Contrary to 10 CFR 30.9, information provided by the licensee's then Facility Manager during an interview with an NRC inspector on October 23, 1989 was inaccurate in that the Facility Manager answered "No" in response to a question from the inspector regarding whether licensed material was ever used or handled without an authorized user being present. This statement was not accurate in all material respects in that the Facility Manager subsequently admitted to an NRC investigator on February 15, 1990, that she had authorized a technician to draw doses on September 17,

1989 without an authorized user being present in the facility. This statement was material because had NRC been aware that the technician had drawn doses on September 17, 1989 without an authorized user being present at the facility, NRC would have taken further regulatory action at that time.

RESPONSE: While RPSC admits that the then Facility Manager answered "No" to the inspector's question as described above, we wish to reiterate that RPSC management advised the NRC of the September 17,1989 incident during the November 21, 1989 Management Meeting with the NRC, which was held at RPSC's request (see NRC's Managements Meeting report, MN No. 89-206, of the November 21, 1989 Management Meeting.)

On November 3, 1989 Mr. J. Kerins, RPSC, Vice President - Regulatory Affairs initiated an investigation into various technical and management issues at the Philadelphia pharmacy. Furthermore, on November 6 and 7, 1989, when Mr. Kerins visited the Philadelphia pharmacy, he emphasized the necessity to respond truthfully to any regulatory inspector. In addition, upper management's expectation of candid responses to inquiries during regulatory inspections was further discussed during a training session conducted by a member of the corporate regulatory department, during the week of November 27, 1989.

VIOLATION II.A.1.
Contrary to Appendix C of Regulatory Guide FC 410-4, as of October 23, 1989, licensee employees who worked in or frequented restricted areas or worked in the immediate vicinity of radioactive materials had not received all the required training to ensure that they were adequately instructed in the items specified in Section 19.12 of 10 CFR, as well as radiation hazards and appropriate precautions.

RESPONSE: RPSC admits that the training of employees was deficient in certain aspects. As a result of this and other potential violations identified by the inspector during the inspection, a training session was conducted by the now Corporate Radiation Safety Officer during the week of November 17,1989. Furthermore, the now Corporate RSO provided direct oversight of the radiation safety program for a minimum of five days per month for three consecutive months.Subsequently, training sessions have been conducted by the facility RSO, including such topics as personnel monitoring, survey meter use, room survey and wipe procedures. In

addition, the annual retraining of certain personnel was conducted during the first week in January 1990. The Corporate RSO has subsequently prepared a training syllabus for use at all facilities to assist in training.

VIOLATION II.A.2(a)
Contrary to Item 10.4 of the license application, on nine occasions between April 5, 1989 and September 13, 1989 the measured activity of the constancy test, performed on the cobalt-57 setting for the CRC-12 dose calibrator, varied greater than +/- 5% from the predicted activity, and the dose calibrator was neither adjusted nor was an arithmetic correction factor used to correct the dosage assays.

RESPONSE: RPSC admits that on nine occasions between April 5, 1989 and September 13, 1989 the constancy test varied greater than +/- 5% from the predicted activity, and the dose calibrator was neither adjusted nor was an arithmetic correction factor used to correct the dosage assays. The need for investigation of all variant constancy check readings was reinforced to the Philadelphia employees by Mr. Kerins during his November 6 and 7,1989 visit. To enhance assurance that these procedures would be followed, a weekly report from the facility RSO to the Corporate RSO was instituted for a limited period of time. Furthermore, as previously mentioned in our response to Violation II.A.1., specific corporate oversight was given by a member of the corporate regulatory department for a minimum of 5 days per month for three months.

VIOLATION II.A.2(b)
Contrary to Item 10.4 of the license application, as of October 31, 1989, the licensee's dose calibrators had not been tested for linearity since June 10,1989, an interval greater than 3 months.

RESPONSE: The quarterly linearity test required to be performed by September 10, 1989, was not performed. The scheduling of the linearity test is provided in the pharmacy computer. The delay in performing the linearity test was due in part to the resignation of the Facility Manager/RSO and absence of the arrival of a full time replacement. The linearity test was initiated by the new manager during the week of October 23, 1989. The importance of performing in compliance with license conditions was emphasized during the corporate oversight periods mentioned above.

VIOLATION II.A.3.
Contrary to Item 9.1 of the license application, on October 31, 1989, a box of decayed waste located in the non-restricted storage area above the first floor measured 3 mR/hr at the surface, which exceeded the background level of 0.03 mR/hr for this area.

RESPONSE: RPSC admits that a box of radioactive waste was located in a non-restricted storage area. The importance of surveying all material prior to storage was reinforced to the Philadelphia facility staff on November 6 and 7, 1989 by corporate representatives. An additional survey of all boxes in the non-restricted storage area was performed by corporate representatives on November 6, 1989. The performance of periodic surveys of this non-restricted area is the responsibility of the RSO.

VIOLATION II.A.4.
Contrary to license condition, on October 23, 1989, several licensee employees who prepared shipments of radiopharmaceuticals within the restricted area did not monitor their hands and clothing prior to leaving the area where radioactive materials were used.

RESPONSE: RPSC admits that on October 23, 1989, several drivers at the Philadelphia facility did not monitor their hands and clothing prior to leaving the area where radioactive materials were used. This violation appears to be a result of inadequate training and management oversight at the facility. During the above referenced corporate on-site oversight period, reminder notices were posted to help improve employee compliance with monitoring requirements.

* * *

RPSC conducted an investigation into the concerns raised during the October 1989 NRC inspection. As information became available, RPSC has proactively brought this information to the attention of the NRC and other appropriate regulatory agencies. In addition, Mr. Kerins made a special trip to the Philadelphia pharmacy in January 1990 to bring these issues to the new Facility Manager's attention and to help assure that these matters would be continued to be addressed in the future. Furthermore, RPSC has responded to the issues it discovered as well as those revealed during the inspection with various actions directed not only toward specific involved individuals but also on a corporate-wide basis.

RPSC disagrees in part with the reason given for the increase in the civil penalty. The reason for the increase in the civil penalty in part was noted as being the identification of the incidents by the NRC. Although we are unaware of exactly what the NRC knew or when it knew, we would like to remind the agency that we requested and participated in a meeting with the agency to notify the NRC of the specific events that transpired on September 17,1989 with regard to the presence of an authorized user on duty.

As discussed with Mr. E. Baker, Hoffmann-La Roche Inc. and several of its subsidiaries, other than RPSC, hold current NRC licenses, including broadscope and materials licenses. Since Hoffmann-La Roche Inc. and these other subsidiaries are managed separately and independently from RPSC, we do not believe that the violations noted above will have any negative affect on the operations conducted by these other companies pursuant to their respective NRC licenses.

We trust this information is satisfactory.

John J. Kerins
Vice President
Regulatory Affairs

STATE OF NEW JERSEY)
: ss.:
COUNTY OF ESSEX)

I, John J. Kerins, Vice President - Regulatory Affairs, Roche Professional Service Centers Inc., being duly sworn, state that I have read the foregoing "Reply to a Notice of Violation" dated December 21, 1990 and that the foregoing is true and correct to the best of my knowledge and belief.

John J. Kerins

Sworn to before me this 21st Day of December 1990

Notary Public

RITA L. PERELES
Notary Public of New Jersey
My Commission Expires May 9, 1994

Attachments

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406