

November 16, 1990

Docket No. 030-29240
License No. 37-27830-01MD
EA 90-161

Roche Professional Service Centers, Inc.
Bldg. 86, 1st Floor
ATTN: John Kerins
Vice President Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,500
(NRC Inspection Report No. 89-001 and Investigation Report 1-89-019)

This letter refers to the NRC safety inspection conducted on October 23 and 31, 1989 at your facility in Philadelphia, Pennsylvania, of activities authorized by NRC License No. 37-27830-01MD. This letter also refers to the subsequent investigation conducted by the NRC Office of Investigations (OI). The report of the inspection and the synopsis of the OI report were forwarded to you on September 21, 1990. During the inspection and investigation, violations of NRC requirements were identified, including a willful violation involving the Facility Manager authorizing a technician to use licensed material when an authorized user was not present, as well as a subsequent failure by the individual to provide accurate information to an NRC inspector. These violations are described in Section I of the enclosed Notice. On October 2, 1990, an enforcement conference was held with you and members of your staff during which these violations, their causes, and your corrective actions were discussed.

With respect to the violations described in Section I of the enclosed Notice, on September 17, 1989, the then Facility Manager authorized a technician at the facility to use licensed material (by drawing doses) when an authorized user was not present. Although the safety significance of the violation was low because the Facility Manager knew that the technician was experienced and technically capable of drawing doses, the Facility Manager's actions constituted a willful violation of regulatory requirements since the Facility Manager knew that the conditions of your license prohibited the use of licensed material when an authorized user was not present. Furthermore, during the NRC inspection on October 23, 1989, the Facility Manager provided inaccurate information to the NRC inspector when she stated to the inspector that she was unaware of any occasions when licensed material was used without an authorized user present.

A license to use radioactive material is a privilege that confers upon the licensee, its officials and employees, the special trust and confidence of the

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public. When the NRC issues a license, it is expected and required that the licensee, as well as its employees and contractors, will strictly comply with all regulatory requirements, and will be completely candid and honest in all dealings with the NRC. Willfully violating regulatory requirements violates that trust and calls into question the licensee's ability to properly perform licensed activities. Such behavior cannot and will not be tolerated. Further, although the OI investigation concluded that there was insufficient evidence from which to conclude that the verbal false statement made by the Facility Manager to the NRC inspector was willful, it is incumbent upon you to ensure that all of your employees understand the need and importance of ensuring that all information provided to the NRC is complete and accurate in all material respects. Therefore, the violations in Section I of the Notice have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, (1989).

The NRC recognizes that you have taken disciplinary action against the former Facility Manager (including transferring the individual from the facility and issuing a formal written reprimand); however, to emphasize the importance of your responsibilities for ensuring that (1) licensed activities are conducted in accordance with regulatory requirements, and (2) all information communicated to the NRC (either orally or in writing) is both complete and accurate, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$7,500 for the violations set forth in Section I of the Notice.

The base civil penalty amount for a Severity Level III violation is \$5,000. The escalation and mitigation factors set forth in the enforcement policy were considered and the base civil penalty amount for the violations in Section I of the Notice has been increased by 50% because the violations were identified by the NRC. The remaining escalation and mitigation factors were considered and no further adjustment to the base civil penalty is warranted because: (1) your corrective actions, (which included the previously described disciplinary actions against the Facility Manager) while adequate, were narrowly focused on the individual and did not evidence a comprehensive programmatic effort to ensure that all of your employees understand the necessity of strict compliance with regulatory requirements and the need for ensuring that information provided to the NRC is accurate, and therefore, no adjustment in this factor is warranted; (2) while your performance at the time of the previous two inspections was good, it is not appropriate to allow mitigation for this factor in cases involving a willful violation. The other escalation and mitigation factors were considered and no further adjustment was considered appropriate.

In addition to the violations described in Section I of the Notice, other violations were also identified during the inspection and are set forth in Section II of the Notice. These violations involve (1) failure to provide training to licensee personnel in accordance with license conditions, (2) failure to perform required personnel monitoring before leaving the

restricted area, (3) failure to adjust or use a correction factor when dose calibrator constancy exceeded $\pm 5\%$ from the predicted activity, (4) failure to perform dose calibrator linearity tests at 3 month intervals, and (5) failure to restrict the exposure rate from decay wastes in a non-restricted area to background levels. These violations have been classified individually at Severity Level IV and are not the subject of a civil penalty.

While they are not the subject of a civil penalty, the violations described in Section II of the Notice are also of increased concern to the NRC because the number of violations, as well as the fact that several of the violations involved multiple examples, indicate the need for increased and improved management oversight of the licensed program. For example, you had prior notice that your training program was inadequate and that sufficient records to document the training given were not being kept. Specifically, on several occasions prior to this inspection, your consultant identified to you that the training program was not adequate.

In addition, management apparently is not fully cognizant of all applicable regulations and regulatory requirements. For example, although the provisions of 10 CFR Part 35 are not applicable to your activities, management apparently believed that 10 CFR 35.27 allowed work to be conducted under the supervision of an individual who was named as an authorized user on a different NRC license.

You are required to respond to the enclosed Notice and, in preparing your response, you should follow the instructions specified therein. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, your response to this letter should describe the changes that have been made and actions that have been or will be implemented to ensure that (1) licensed activities are conducted in accordance with the license, (2) records of licensed activities, as well as information submitted to the NRC, are complete and accurate, and (3) management is actively involved in, and committed to, compliance with NRC regulatory requirements. This response should also provide your basis for concluding that each person involved in licensed activities understands his or her responsibility and is committed to assure that NRC requirements will be followed and records or information submitted to the NRC will be complete and accurate. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rule of Practice," Part 2 title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Roche Professional Service
Centers, Inc.

4

The responses directed by this letter and the enclosure are not subject to the clearance procedure of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Original Signed By:
Thomas T. Martin

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encls:
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 OE on 11/15/90
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