UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OCT 03 1991

Docket No. 030-13204
License No. 21-00864-02
EAs 91-017 and 91-130

Lafayette Clinic
ATTN: Gerald Sarwer-Foner, M.D.
Director
951 East Lafayette
Detroit, Michigan 48207

Dear Dr. Sarwer-Foner:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $11,500 AND ORDER MODIFYING LICENSE (IMMEDIATELY EFFECTIVE) (NRC INSPECTION REPORT NO. 030-13204/88001(DRSS) AND INVESTIGATION REPORT NO. 3-89-002)

This refers to the inspection conducted on October 3 through 24, 1988, and the subsequent investigation conducted by the NRC Office of Investigations (OI) of the events surrounding the unauthorized use of licensed material in June 1988, employment discrimination, and other technical issues at Lafayette Clinic, Detroit, Michigan. On March 9, 1989, a management meeting was conducted in the Region III office to discuss the technical issues and your proposed corrective actions. The report documenting the inspection was sent to you by letter dated March 15, 1989. The synopsis of the OI investigation was sent to you by letter dated April 30, 1991. During the inspection and investigation, violations of NRC requirements were identified. On May 22, 1991, an enforcement conference was conducted in the Region III office to discuss the violations, their causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated June 11, 1991.

On May 31, 1988, Dr. Natraj Sitaram, an individual researcher, circumvented the clinic's procedures for "Ordering and Use" of radioactive materials and ordered 500 microcuries of phosphorus-32. This material was used in Room 256R during the period June 4 through 7, 1988. On June 7, 1988, Dr. Sitaram was informed by the Radiation Safety Officer (RSO) that his unauthorized procurement and use of these materials was a violation of the clinic's license conditions, and he was informed of the proper procedures for ordering licensed materials through Mr. Warner. Subsequently, Dr. Sitaram violated procedures and used phosphorus-32 again during the weekend of June 18 through 19, 1988. OI conducted an investigation into this matter and determined that Dr. Sitaram deliberately violated the clinic's license conditions when he used licensed

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material the second time. At the enforcement conference, you claimed that Dr. Sitaram's second use was authorized rather than a deliberate violation. In support of your claim, you referenced a memorandum to the Acting Clinic Director from the RSO dated June 23, 1988, which documented the RSO's June 15, 1988 statement that since Dr. Sitaram was provided with a personnel monitoring badge and a ring monitor, there was no objection to his working with phosphorus-32. However, we believe that the RSO's statement meant that it was acceptable for Dr. Sitaram to work with phosphorus-32 from a radiation monitoring standpoint only, provided that the other required procedures were followed. In the same memorandum, the RSO further stated that Dr. Sitaram was asked to familiarize himself with the clinic's procedures prior to doing any further phosphorus-32 work, and, to his knowledge, Dr. Sitaram had not communicated with Mr. Warner as requested by the RSO's June 7, 1988 memorandum to Dr. Sitaram. We also note that in your July 18, 1988 Radiation Safety Committee (RSC) minutes, it was stated that no requests to order radioisotopes for the Affective Disorders Unit would be accepted by the clinic until there was complete resolution of what happened in Room 256R. It should also be noted, in a letter to the NRC dated June 2, 1989, the RSO (no longer RSO at that time), in response to our questions regarding interpretation of his June 23, 1988 memorandum, reiterated that at no time did he give Dr. Sitaram permission to use any radioisotopes. Therefore, we conclude that Dr. Sitaram's second use was not authorized and was a deliberate violation.

On June 6, 1988, the research assistant working in Room 256R, for Dr. Sitaram, became concerned about her exposure to radiation and requested a radiation monitoring badge. This request for a monitoring badge led to the discovery by the RSO of violations of the clinic's license conditions by Dr. Sitaram. On June 20, 1988, the research assistant received a letter of termination from Dr. Sitaram, her supervisor. This termination appeared to be directly linked to her involvement in identifying the unauthorized use of radioactive materials. This incident of alleged discrimination was investigated by the Michigan Department of Labor (MDL) and a finding was made in favor of the research assistant. At the enforcement conference, you denied that discrimination against the research assistant occurred. We acknowledge that Wayne State University's entering into a settlement agreement with the research assistant was not an admission of liability. However, you did not provide any evidence to dispute the Michigan Department of Labor finding. In particular, you were unable to provide any evidence of poor performance by the research assistant.

During June and July 1988, the clinic's RSO investigated several matters dealing with regulatory compliance related to the events discussed above, and reported his findings, including unauthorized use of material and potential discrimination against the research assistant, to the upper management of both Lafayette Clinic and Wayne State University. This individual had been appointed to the

position of RSO in March 1988, and had never been informed of any prior dissatisfaction with his job performance. However, on August 26, 1988, shortly following the RSO's identification of the compliance issues to Dr. Thomas M. Sullivan, his supervisor, and the Acting Clinic Director, Dr. Sullivan issued a memorandum advising him of his removal from the RSC and his position as RSO effective September 1, 1988. The NRC finds this removal action to have been discriminatory. At the time the RSO was removed from the RSC, Dr. Sitaram was placed on the RSC by Dr. Sullivan. Dr. Sitaram is the same individual the RSO had previously reported to Dr. Sullivan for violating the clinic's procedures and discriminating against his research assistant.

At the enforcement conference, you denied that discrimination against the RSO occurred. However, you did not provide any evidence to dispute our finding. You claimed that the RSO was replaced because of his poor performance and to have a more qualified RSO prior to the proposed reorganization when Wayne State University would take over the clinic's function. However, there is no documentation of the RSO's poor performance or evidence of counselling. In addition, in Dr. Sullivan's memorandum removing the RSO, Dr. Sullivan commended the RSO for his hard work and stated he was surprised that the removal was occurring at that time. Several times during the conference you admitted that the clinic's licensed program was deficient in the 1988 time frame, and indicated that the previous RSO was accountable for the deficient program. It appears that the RSO inherited the deficient program in March 1988, was not given sufficient time to make improvements, and was removed from his position subsequent to his identification of unauthorized use of licensed material. Additionally, Wayne State University's RSO was to take over the clinic's RSO function after the reorganization; therefore, it appears unnecessary to have replaced the RSO for this short period of time unless discrimination was the motivating factor.

The NRC considers deliberate violations of NRC requirements and discrimination against employees who raise safety concerns very serious matters. The NRC relies on the integrity of licensees and their employees to perform licensed activities in accordance with NRC requirements. Violation I involves two instances of unauthorized use of licensed material and would normally be categorized at Severity Level IV. However, due to the deliberate nature of the second instance, it is considered to be very significant. These unauthorized uses reflect on the effectiveness of management control of licensed activities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1988), Violation I has been categorized at Severity Level II.

Violations II.A and II.B concern discrimination against two employees. In both cases, the adversarial and confrontational

attitude of management and Dr. Sitaram had the potential to adversely impact the clinic's radiation safety program. Violation II.A is considered to be very significant because it involved discrimination against an employee by the senior manager of the clinic. Violation II.B is considered to be significant because it involved discrimination by a first line supervisor. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1988), Violations II.A and II.B have been categorized at Severity Level I and III, respectively.

To emphasize the need for continued and effective management control over activities authorized by your license, the need to adhere to regulatory requirements, and to prevent future discriminatory activities, I have been authorized, after consultation with the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $11,500 for the violations described in the enclosed notice. The base civil penalties for Severity I, II, and III violations are $5,000, $4,000, and $2,500, respectively. The escalation and mitigation factors in the Enforcement Policy were considered for each violation.

With respect to Violation I, the more significant issue is I.B due to the associated deliberateness, and therefore the civil penalty has been assessed on that example only. The base civil penalty for Violation I.B was not mitigated for identification and reporting. Although the RSO identified this violation, he was subsequently removed from the Radiation Safety Committee and his position as RSO for pursuing this matter. Although you conducted an investigation and implemented prompt corrective action to prevent Dr. Sitaram from circumventing procedures when ordering licensed materials, we would have expected additional corrective actions, including for example, a memorandum from Lafayette Clinic's management suspending Dr. Sitaram's use of licensed materials and training of other researchers on the lessons learned from this event. Therefore mitigation is not warranted for corrective action. The other adjustment factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, no adjustment to the base civil penalty for Violation I.B has been deemed appropriate.

The base civil penalty for Violation II.A was not mitigated for identification and reporting since you did not identify the violation. Additionally, the base civil penalty for Violation II.B was not mitigated for identification and reporting. Although the RSO warned upper management that the termination of the research assistant might be considered discrimination, the research assistant was terminated anyway. Mitigation is not warranted for corrective action for violations II.A and II.B because your actions were not prompt and extensive in assuring that all employees understood their rights to raise safety issues without fear of

discrimination. Therefore, based on the above, and consideration of the other factors in the Enforcement Policy, no adjustments to the base civil penalties for Violations II.A and II.B have been deemed appropriate.

We are also concerned about a letter to the NRC dated October 20, 1988, requesting a license amendment in response to our Confirmatory Action Letter (CAL) dated October 14, 1988. In the letter, Dr. Sullivan stated that he was not informed by the RSO that he was terminating his services as RSO as of September 6, 1988. Obviously, Dr. Sullivan knew that the RSO had been replaced on the RSC and a new chairman appointed who would also serve as the "radioactivity officer," since it was Dr. Sullivan's August 26, 1988 memorandum which made these changes effective. It appears that Dr. Sullivan was not informed that the RSO had notified the NRC on September 6, 1988 that he was no longer the RSO and that his name should be removed from the license. This letter is misleading. In your response please describe what action will be taken to ensure that all future correspondence with the Commission will be clear and accurate.

Another area of concern is that during a meeting with the research staff on June 7, 1989, the Clinic Director stated that he was the clinic's spokesman in dealings with outside agencies. Several individuals in attendance at that meeting believed that the Clinic Director implied that actions would be taken against any employee who contacted an outside agency about problems in the clinic and they believed that also meant the NRC. In your response please address what actions have been taken to ensure that clinic employees fully understand that they can contact the NRC without threat of retribution.

Section III of the attached Notice sets forth a series of violations regarding the radiation safety program. While these items are of lesser significance than the violations for which civil penalties are proposed and have been categorized as Severity Level IV and V violations, they demonstrate a need for a more constant vigilance over the use of radioactive materials at Lafayette Clinic. The staff recognizes that during our April 1989 and February 1990 inspections, corrective actions were taken regarding these violations. However, you are required to respond and document the action taken for each violation as described in the attached Notice.

In addition to the enclosed Notice, an Order Modifying License (IMMEDIATELY EFFECTIVE) is enclosed. The Order prohibits the reinvolvement of Dr. Sitaram or Dr. Sullivan in licensed activities for a period of three years. Questions concerning this Order should be addressed to James Lieberman, Director, Office of Enforcement, who can be reached at (301) 492-0741.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this letter and Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalties
2. Order Modifying License

cc w/enclosures:
State of Michigan

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