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December 14, 1989

Docket No. 030-03521
License No. 52-10270-01
EA 89-186

Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: REPLY TO A NOTICE OF VIOLATION

Gentlemen:

The following refers to the NRC inspection conducted on August 30 and 31, 1989, of activities authorized by NRC license number 52-10270-01. Several violations were identified during this inspection which were notified to us on communication of December 1, 1989. In the remainder of this communication, these violations will be identified and a specific reply as to the admission or denial, the reason for violations, if any, and the corrective actions that have been taken will be described.

1. **Failure to provide monthly personnel monitoring devices between December 1st. 1988 and May 31, 1989.**

REPLY: The violation is admitted. The reason for this was a discontinuation of services by our previous provider of personnel monitoring devices due to lack of payment. This was brought to the attention of the Administration on multiple occasions. The situation was resolved in May, 1989. The radiation safety officer and this administration are working very closely on this matter. We believe to be in full compliance at present.

2. **Failure to review, investigate, and report to the radiation safety committee, personnel exposures exceeding ALARA investigational Levels I and II.**

REPLY: Violation is admitted. After the internal investigation by the Department of Nuclear Medicine, it was found that a sonographist, which belongs to the same department, was leaving her film badge next to a Cobalt 57 source used as an external marker on clinical studies. That this was not accepted by both by the radiation safety officer and the president of the committee. They both accepted using as a parameter the maximum permissible dose, which is higher. A reorganization of the radiation safety

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committee has been made and the ALARA program has been reviewed. In the last meeting of the radiation safety committee exposures for the last three quarters were discussed. No exposures exceeding investigational level I was found. We believe to be in full compliance of this regulations.

3. **Failure of personnel to observe prohibitions against eating, drinking and smoking in the hot laboratory.**

REPLY: Violation admitted. All personnel has been instructed as to this matter. We have been assured that the only reason water was kept in the refrigerator, were no radiactive material is stored, was for patients given lodine capsules for uptake tests. We have been assured this will not happen in the future as drinking water will be stored somewhere else in the department. We feel to be in full compliance with this regulation.

4. **Release of patients administered lodine 1131 doses greater than 30 milicuries from hospitalization with dose rates greater than 5 mR/hr at one meter.**

REPLY: Violation admitted. The reason for this violation was the physician's belief that extrapolation could be made from the initial dose and exposures rate to actual activity in the patients. This has been discussed with both the radiation safety officer and the physician in charge of the Nuclear Medicine Department. Several patients have been admitted since the inspection and all of them have been discharged after the exposure rate is less than 5 mR/hr. We believe to be in full compliance of this regulation.

5. **Failure to perform contaminations surveys of rooms of patients who had been administered doses of lodine 131 greater than 30 milicuries prior to assigning another patient to the room.**

REPLY: Violation admitted with a qualification. Contamination surveys were performed with survey meters in all rooms of patient treated with doses of lodine 131 greater than 30 milicuries prior to assigning another patient to the room. However, wipe tests were not being performed. The physician in charge and technologist admit not being aware at that time of the new regulations. This has been discussed with the radiation safety officer, the physician in charge and the technologist. Wipe tests have been performed in all room of patients treated with doses of lodine 131 greater than 30 milicuries since the inspection. We believe to be in full compliance of this regulation.

6. **Failure to evaluate doses received by individuals when monthly personnel monitoring devices were not provided.**

REPLY: Violation admitted. A retrospective evaluation of these doses was performed by the radiation safety committee and the personnel involved. At the recent RSC meeting, the exposure dose for the last two quarters were discussed. We believe to be in full compliance with this regulation.

7. **Failure to check survey instruments from proper response with a dedicated check source each day of use.**

REPLY: Violation admitted. Personnel unaware of new regulations. It has since been enforced. We are now using a Cesium-137 source for all survey instruments.

We believe to be in compliance with this regulation.

8. Failure to conduct quarterly physical inventories of calibration sources.

REPLY: We denied this violation. This was pointed to Mr. Philip Stohr, Mr. C. M. Hosey and Ms. Sandra L. Waldron. Inventory of calibration sources is a part of the software program we have been utilizing since February 1989 (Dupont Nuclear Medicine Manager). This was raised by Lillian Rodríguez, CNMT, but aparently it was misunderstood. We believe to be in full compliance of this regulation.

In summary, this administration has reviewed all your communications and the violations identified in your recent inspection. These have been discussed with the Radiation Safety Committee and the Radiation Safety Officer. We sincerely believe to have taken the corrective actions to avoid further violations and that we are in full compliance with all the regulatios where violations were identified.

Sincerely,

José R. Madera
President & CEO
Damas Foundation, Inc.

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