U.S. NUCLEAR REGULATORY COMMISSION

REGION I

Enforcement Conference Report No. 88-001

Docket Nos. 030-08748
030-13045

License Nos. 20-15215-01
20-15214-02MD Priority II Category G1

Licensee: Gamma Diagnostic Laboratories
P.O. Box 1349
Attleboro Falls, Massachusetts 02763

Facility name: Gamma Diagnostic Laboratories

Enforcement Conference at: Region I, King of Prussia, Pennsylvania

Enforcement Conference Conducted: January 5, 1988

Inspector: C. Thor Oberg, Health Physicist — date: March 31, 1988

Approved by: John R. White, Chief, Nuclear Materials Safety Section C — date: 4/6/88

Summary: The findings documented in Inspection Report Nos. 030-08478/87-002 and 030-13045/87-001 were discussed. The licensee described corrective actions taken and planned. The NRC's enforcement policy was explained.

DETAILS

1 0 Persons Attending

Gamma Diagnostic Laboratories

Robert Ferris, President
Vincent DiSpigno, Pharm.D., Health Physicist and Radiation Safety Officer

Nuclear Regulatory Commission

James M. Allan, Deputy Regional Administrator
Frank J. Congel, Acting Director, Division of Radiation Safety and Safeguards
James H. Joyner, Chief, Nuclear Materials Safety and Safeguards Branch
John R. White, Chief, Nuclear Materials Safety Section C
Daniel J. Holody, Enforcement Specialist
Jay M. Gutierrez, Regional Attorney
C. Thor Oberg, Health Physicist

2.0 Conference Summary

2.1 Introductions were made and the representatives of the Gamma Diagnostic Laboratories were welcomed to Region I by James M. Allan, Deputy Regional Administrator.

2.2 Mr. Thomas T. Martin, Director, Division of Radiation Safety and Safeguards, explained the purpose and format of the Enforcement Conference. He stated that enforcement conferences provide NRC management an opportunity to evaluate the facts of the inspection, including licensee input and corrective actions taken prior to the conference.

2.3 Mr. John R. White, Chief, Nuclear Materials Safety Section C, reviewed the inspection findings and the information supplied by the licensee's letter dated November 9, 1987, in which an extremity exposure in excess of regulatory requirements was reported, i.e., hand exposure of 20.29 Rem.

He commented that the licensee had identified an individual who had the potential to receive an exposure in excess of regulatory requirements during production operations, but failed to intervene in a timely and aggressive manner to prevent such exposure. The licensee was asked to provide explanations.

2.4 Mr. Robert C. Ferris, President of Gamma Diagnostic Laboratories (GDL) presented the licensee's evaluation of the exposure and circumstances for consideration by the NRC. He explained that recent licensee problems with the Federal Drug Administration (FDA) leading to voluntary shutdown of the technetium-99m (Tc-99m) production operation was a factor for consideration.

Mr. Ferris indicated that based on their calculations performed prior to resumption of activities, the full time Production Manager Production Manager would receive an excessive exposure only if he performed all of the production operations himself. It was believed that with the aid of part time technicians and a new hire, exposures would have been within acceptable limits. Mr. Ferris was unable to explain why the actual exposure did not follow the model predicted by the licensee's calculations.

Vincent DiSpigno, Pharm. D., Health Physicist and the GDL Radiation Safety Officer (RSO) presented and reviewed a time line summary of significant events for the period between July and November 1987.

Mr. Ferris indicated that the exposure individual, as Production Manager, was informed to minimize exposure. However, no instructions were provided by the the RSO or other management as to specific dose reduction actions to be taken.

It was indicated that at the beginning of the third quarter, the Production Manager was possibly performing three times his previous work load. It was expected that dose reduction efforts initiated by the Production Manager would be sufficient to assure that quarterly personnel exposures would be acceptable.

Further discussions established that each step in the SOP is signed off by the performing individual. In a letter dated January 21, 1988, the licensee presented an analysis of the SOP operation.

2.5 The possibility of contamination on the individual's badge was discussed. The licensee does not survey each badge holder prior to shipment for processing, but does survey the final package of badges before shipment. No significant contamination had been identified. The licensee stated that they had questioned the processor regarding possible contamination on the badge but were not able to obtain any information.

2.6 To prevent further excessive exposures, the licensee stated that a method of equitable dose distribution had been established. Consequently, extremity exposure levels were lower. For the fourth quarter of 1987, the highest extremity exposure level was in the order of 7 Rem. It was indicated that the work schedule has been modified with the RSO and the part time technicians performing some of the production operations to aide in reducing specific personnel exposure. Two new technicians have been hired and were in training.

Redundant personnel extremity monitoring is now provided for the Production Manager by the Harvard University, University Health Services group. It was indicated that results are now available within two or three days after receipt of the badge by the University, to permit better cognizance of personnel exposure. The licensee stated they are also considering engineering changes or modifications to affect exposure reduction.

3.0 Closing

Mr. Martin thanked Mr. Ferris and Dr. Spigno for their attendance and presentation. He concluded by stating that the information presented at this meeting would be considered in deciding the enforcement action to be taken.