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Director, Office of Enforcement
US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

REFERENCE: NRC Inspection Report # 030-09946/9201
Docket # 030-9946
Licence # 20-01412-05
EA 92-114

DATE: September 14, 1992

ANSWER TO NOTICE OF VIOLATION

1. The violation cited in Item A is incorrect. Our QM program as submitted (a copy enclosed) does contain the requirement of the written directive to be signed by authorized user for administration of I-131 for activities of 30 uCi to 250 mCi. The only clear violation that occurred is technologist not obtaining the authorized user's signature before administration of 4.1 mCi of I-131.

   During the investigative phase one of the violations discussed was lack of in-service related to QM Rule. The recommended corrective actions in the form of several in-service classes for different groups were conducted by R.S.O. Refer to copies of enclosed documents.

2. The reason for this violation is a mis-step created by the Nuclear Medicine technologist's failure to obtain the authorized user's signature and requiring written order signed by physician.

   The violations were identified within 24 hours and corrective steps put in place within 72 hours before NRC decided to conduct the inspection. During last three months several of these meetings and conferences have not changed the initial self-identified errors in our own new QM Rule program. The immediate corrective actions were put in place during the NRC inspection on May 27, 28, 1992.

3. The corrective actions have been implemented as per our letters dated June 2, 1992 and July 13, 1992 (copies enclosed).

4. The effectiveness of corrective actions will be monitored periodically (e.g. monthly). A Q.M. Rule inservice will be conducted in Nuclear Medicine at 6 month intervals.

5. Full compliance has been achieved as of July 13, 1992.

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6. Our NRC license (#20-01412-05) renewal application dated August 14, 1990 is under review by NRC. We were sent a letter of continuation (dated October 15, 1990) of our licensed activities pending action by the NRC. Our license which expired on Oct. 31, 1990 was based on old part 10 CFR Part 35. We have also paid $51,850.00 in annual fees for last two years for operations of our license which is basically still under renewal by NRC.

7. REASONS FOR REQUESTING FULL MITIGATION OF PROPOSED CIVIL PENALTY

* The new QM rule went into effect as of January 27, 1992. BMC made every effort to implement an effective program to maintain full NRC compliance.

* BMC was one of the voluntary participants in development of QM rule by NRC. In fact BMC was one of the sites chosen by NRC officials to visit and learn about the clinical/practical aspects of QM program.

* BMC has an excellent record of 24 years of full compliance with NRC regulations.

* BMC's original procedures (Management Audit and In-Service Program) have been a part of NRC's Regulatory Guide NUREG 0267 on ALARA.

* BMC has voluntarily participated and actively contributed to the development of NRC new regulations.

* When violations occur BMC has self-identified them and reported them to NRC without hesitation or delay. The corrective actions have been put in place immediately without waiting for NRC inspection recommendations.

* This is the first time NRC has proposed a civil penalty on a self-identified, self-corrected incident at BMC.

* Further, the overexposure has been identified as 250 times the intended dose. In arriving at this conclusion all the information given regarding the clinical outcome to the patient has been completely ignored. As was stated 72 hours after the incident and even now, the patient's diagnosis of Graves' disease will require additional treatment of this patient with additional dose of I-131. Recent evaluation of this patient (as of August 19, 1992) reconfirms this course of action.

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* The issue of overexposure is overstated and is done without any consideration why the patient came to Nuclear Medicine study. This incident has not overexposed the patient, staff or a member of public to any unnecessary radiation.

* Therefore, when you put the entire incident in proper perspective the classification as aggregate violation related to safety is improper.

We would like you to reconsider the proposed civil penalty in light of all the information submitted here as well as our past contributions to NRC regulatory process. We urge you to mitigate fully the proposed civil penalty and help us maintain our excellent track record of full NRC compliance.

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9.14.92

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