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**To:** United States Nuclear Regulatory Commission  
Attention: Kenneth J. Lambert

**From:** Dawn M. Kirchner, RDCS, RVT  
Director, Cardiovascular Testing Dept.

Dr. Gregory Sutliff, FACC  
Radiation Safety Officer

**Subject:** Reply to a Notice of Violation

**Date:** September 8, 2008

On Thursday, September 4, 2008 the Cardiovascular Testing Department's Nuclear Cardiology Division at IMA, Inc. received a Notice of Violation after a routine inspection on July 23, 2008. Listed below is our reply to the notice of violation.

**I. Review of Circumstances:**

- A. After meeting with Kenneth J. Lambert at the conclusion of his inspection of our facility on July 23, 2008, I spoke with our RSO via telephone and met with one of our Licensed Nuclear Medicine Technologists regarding the violations that were discovered. Our RSO was very concerned. I assured him that we would get these issues resolved to the satisfaction of the NRC. Our Nuclear Tech who was present during the inspection, was quite upset and embarrassed as this clearly was a consistent oversight which should have never occurred. She was most embarrassed that she herself has failed in her role as a nuclear technologist. After speaking with Mr. Lambert, it became more than apparent that these violations were the result of poor management rather than poor clinical skills.
- B. On July 24, 2008, I met with our Technical Director of the Nuclear Lab to discuss the violations. Like our other Nuclear Technologist, she was quite upset. While she maintains that the weekly surveys had been overlooked since she changed her schedule, the daily constancy checks of the dose

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calibrator and daily radiation dose surveys were being performed but that they were not always being entered into the computer. She recognized that since they were not logged into the computer this equated to "not performed". I addressed my biggest concern with her which was the fact that these violations were consistently documented in our quarterly consultant reports with little regard for correcting. She could offer me no acceptable explanation for why things were not corrected or why our Consultant reports were not taken seriously. I informed the Technical Director that effective immediately, I would be reviewing the quarterly reports and would be contacting our consultant. I also explained that the manner in which the RSO received the quarterly reports from her (simply tagged where his signature was needed) was inadequate. The Technical Director and I determined that we would immediately institute a daily log to verify that these things were completed and who did them. This in turn would be verified with the computer report.

- C. On Tuesday, July 29, 2008 I met with the RSO, the Technical Director, and our other nuclear technologist to further discuss the violations. Our RSO was pleased with the log which was immediately implemented and voiced his concern that we have to assure that this never happens again. He confirmed that his role as RSO will be a more active one. After his departure I continued the meeting with the nuclear staff and myself. I stressed that we would take this as an opportunity for improvement. More importantly, no matter how busy we get and no matter how quickly medicine changes we simply can not let requirements of the job and requirements to stay in operation go unattended for one day. I explained that I was going to review and meet with our consultant every quarter after her survey to also assure that potential problems are addressed immediately.
- D. During the week of July 28-August 1, 2008, I called and spoke with our consultant about our violations. She claimed that there was an obvious lack of communication between staff as well as concern that our Technical Director worked only 3 days per week. I mentioned that the Inspector also raised the issue of the Technical Director working 3 days per week. We discussed what the level IV violations meant. While the violations were ultimately our fault, I explained that I was disappointed that neither I nor our RSO was not notified when she consistently found the same violations in her quarterly surveys for well over a year. I told our consultant that effective immediately, quarterly surveys will be scheduled through the Director of Cardiovascular Testing. I asked that the reports be sent directly to me and that she is to meet with me at the end of her survey each quarter. I assured her that the information in her quarterly reports will be looked at closely in the future. I also apologized for not being involved sooner.

## **II. Root Cause of the violations:**

- A. Since our last inspection, the nuclear cardiology department has grown from 1 nuclear technologist to 2 and the addition of a nuclear tech. aide. This growth happened without clearly defining who was responsible to do what and when.
- B. The cause of the violations was due to insufficient oversight of who performed what and who was responsible for certain duties each day.
- C. MPC Consultant Reports were never formally addressed with the RSO or the Director of Cardiovascular Testing.

## **III. Plan of Correction:**

- A. Implementation of a daily log which includes the duty performed with the staff initials of who performed it.
- B. Daily log will be cross referenced monthly with the computer report which will be given to the Director of Cardiovascular Testing.
- C. Any discrepancies with the written log and the computer log will result in formal performance warnings in accordance with the policy of IMA, Inc.
- D. MPC. Inc. quarterly surveys will be scheduled with the Director of Cardiovascular Testing.
- E. MPC Inc. quarterly reports will be sent to the Director of Cardiovascular Testing. The Director of Cardiovascular Testing will be responsible for discussing the results with the RSO and the Technical Director.
- F. Licensed Nuclear Medicine Technologists are ultimately responsible and accountable for assuring daily compliance with NRC and ICANL standards.
- G. Formal orientation for any new nuclear staff to the nuclear department will now include a formal check-list which will be signed off by the Technical Director and will be kept on file.
- H. The Technical Director will revise current check list.
- I. The Technical Director will work 4 day per week.