Cardiology Consultants of East Michigan

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July 30, 2012

Bill Lin
Materials Inspector
Region III – Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4352

RE: Reply to a Notice of Violation
Cardiology Consultants of East Michigan
1031 Suncrest Drive
Lapeer, MI 48446

Dear Mr Lin:

This letter is to inform you of the corrective actions that are being taken as a result of our recent violation. Section B2.1.1 (part of the Licensee's procedure for Safe Use of Unsealed Byproduct Material) "Patient Identification" states in part, before an injection of radioactivity is administered, the technologist asks the patient to state his/her name and Date of Birth (DOB).

Contrary to our protocol a patient was called by first name only. After which the patient was informed of the testing procedure and the following days testing instructions, the patient proceeded to be injected with a radioactive tracer for cardiac imaging. The patient that was incorrectly injected had been a previous patient at our facility for Cardiac Nuclear Medicine testing and was scheduled for a different procedure. The patient was familiar with our nuclear medicine testing procedure. It was assumed that the correct person was being tested. Immediately upon injection, a fellow technologist recognized the patient as being someone else other than the intended patient.

Upon identification of the incident, the Radiation Safety Officer and supervisor on staff were immediately notified. The patient was also privately informed of the incident. The patient's response was polite and understanding. An Accidental Radiopharmaceutical Incident Report was recorded. Our Radiation Physicist from Medical Physics Consultants was contacted to calculate the patient's organ and whole body dose equivalent.

ICANL Nuclear Cardiology Accredited Nuclear Cardiology Laboratory
ICAEL Accredited Echocardiography Laboratory
Accredited Vascular Laboratory

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Our corrective action process to ensure that no further violations occur was immediately addressed. A meeting with the RSO, office supervisor, and all nuclear medicine testing staff took place on May 10, 2012. At which time emphasis was put on identifying each and every patient irregardless of familiarity. As per our "Patient Identification Protocol" documented in our ICANL Certification documentation Part B2.1.1 states that "After check-in process is completed, patient is tagged in Medinformatix as ready for service. The nuclear technologist then knows that the patient has arrived and is ready. The nuclear technologist calls the patient by name from the waiting room when ready to begin the procedure. The technologist reviews the physician's orders and explains the procedure to the patient. Before an injection of radioactivity is administered, the technologist asks the patient to state his/her name and DOB. The information given by the patient is compared to the information in the patient's chart. The patient will not be injected if there are discrepancies in information or if the consent form is not signed."

In discussing this, we discovered the root cause of the violation was failure to follow the protocol that is currently in place. During our discussion emphasis was placed again on our protocol's step by step procedure for addressing each individual consistently and accurately according to the "Patient Identification Protocol" guidelines. Currently our department has an "Annual Review" of protocols that is implemented in the month of January each year. This includes all staff including doctors, management, office personnel, maintenance, and professional staff of each modality on the premises. To further increase the awareness and importance of our day to day activities it will become the technologists' responsibility to review our protocol manual more than on an annual basis.

Sincerely,

David A. Brill, MD
Radiation Safety Officer