



St. Joseph Health Center
St. Joseph Hospital West

SSM St. Joseph Health Center
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September 14, 2006

Steven A. Reynolds, Director
Division of Nuclear materials Safety
Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

SUBJECT: Response to apparent violations in inspection report No. 030-08664/2006003; EA – 06-188

Apparent violation #1:

Failure to obtain a written directive prior to the administration of an iodine – 131 dosage in a quantity greater than 30 microcuries to a patient. 10CFR 35.40a

RESPONSE:

The Nuclear Medicine technologist failed to follow the department's I-131 Protocol paragraph IV which states: "If the patient is having an I-131 whole body scan or is receiving more than 30 microcuries I-131, additional paperwork for the NRC has to be filled out before administering the dose." This paperwork will include a permit form, a written directive, a patient identification form, a dose identification form and a form for the technologist to fill out stating that all of the above was performed and that the patient was given written information about patient safety.

The department's I-131 protocol has been revised effective July 11, 2006 to have a second technologist check the dose and all appropriate paperwork. The revised protocol has insured that no additional medical events have occurred or will occur.

The revised I-131 protocol is reviewed during new employee orientation and annual competency assessment. This review is documented and maintained in the employee's file. Full compliance with department protocol has been achieved immediately upon initiation on July 11, 2006.

Apparent violation #2:

Failure to follow radiation protection procedures established by the institution.
10CFR 35. 27a(2)

RESPONSE:

The Nuclear medicine technologist failed to follow the department “out patient protocol” paragraphs #4 and 5 which states: “with the physician’s orders in hand, go to the Hot Lab and prepare the dose and enter it into the Pinestar dose computer. Make sure you have the correct patient and dose by using two patient identifiers and that the drawn dose is within acceptable limits and that it is the proper radionuclide for the patient’s exam.”

All new department employees review the Out Patient Protocol during orientation and documentation of orientation is maintained in the employee file. When a new employee performs a procedure for the first time, they will be observed by another employee to monitor compliance with the appropriate protocol.

Annual employee competency assessment includes technologist’s radiation safety responsibilities and dose tracking protocols.

Full compliance with department protocol has been achieved immediately upon initiation on July 11, 2006.

Apparent violation #3:

Failure to report a medical event to the NRC by the next calendar day after discovery. 10CFR35.3045c

RESPONSE:

The patient’s referring physician was immediately notified that the patient received a therapeutic dose versus a diagnostic dose of I-131. The patient’s physician confirmed that the patient had hyperthyroidism and he would subsequently order a therapeutic dose. This was explained to the patient and she was satisfied with the outcome. She understands that no medical harm was done and that she received an I-131 dose that may have well treated her hyperthyroidism. The department misunderstood the reporting procedure. We thought that an official written report had to be submitted in 14 days. After consulting with the physicist it was determined that while the NRC must be notified in writing within 14 days, verbal notification of a misadministration must be given within 24 hours. In the future medical events will be verbally reported by the next calendar day.

Each Nuclear medicine technologist has reviewed the department Quality Management policy and will be required to review the Quality Management policy in part of their annual competency assessment.



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St. Joseph Health Center administration, the radiation safety officer and Radiology leadership fully comprehend the severity of the apparent violations that took place on June 28, 2006. We are confident that we have taken the necessary corrective actions to avoid further violations and comply with NRC regulations.

A handwritten signature in black ink, appearing to read 'Sidney Machefsky'. The signature is fluid and cursive, with a large, sweeping flourish at the end.

Sidney Machefsky, M.D.
RSO

A handwritten signature in black ink, appearing to read 'L. Halverson, M.D.'. The signature is cursive and includes a small flourish at the end.

Lewis Halverson, M.D.
Medical Director