

Cardinal Health
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CardinalHealth

cardinalhealth.com

July 3, 2007

Ken Lambert
United States Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Follow-up written report of a mislabeling incident on June 13, 2007, radioactive material license number 34-29200-01MD, Glastonbury, CT.

Dear Mr. Lambert:

This letter is a 30 day written report of a mislabeling incident. This occurred on June 25, 2007. This report is prepared as a courtesy follow up to a telephone report, and is not reportable under 10 CFR.

Description of Event

On June 13, 2007, a Cardinal Health Nuclear Pharmacy Services (hereafter Cardinal Health) customer telephoned the location at 628 Hebron Avenue, Building 4, Glastonbury, CT to report that a NaI¹³¹ capsule supplied by Cardinal Health assayed as 5.5 millicuries instead of the requested 4.0 millicuries that was ordered. The transport shield label was correctly identified for the requested prescription. However, the prescription label was for a different prescription and did not match the transport shield label. This prescription was not administered to a patient.

Subsequent investigation revealed that another NaI¹³¹ capsule supplied by Cardinal Health for a second prescription was also mislabeled. The transport shield label for this second prescription matched the prescription label for the first prescription, and the prescription label for this second prescription matched the transport shield label for the first prescription. This second prescription also was not administered to a patient.

When a prescription for a NaI¹³¹ capsule is filled, the individual that compounds the capsule labels the radiopharmaceutical container with the prescription label, compounds the capsule, assays the capsule in a dose calibrator, records the activity on the prescription, and places the transport shield on top of the prescription. The transport shield label is removed and placed on the transport shield, and the transport shield is wrapped prior to package preparation in accordance with DOT regulations.

The root cause of this event was the switching of the two transport shields with their respective labels by the individual who wrapped the shields prior to package preparation.

In order to prevent a recurrence of this type of event, the individual compounding the NaI¹³¹ capsule will apply the transport shield label and wrap the transport shield.

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If you have any questions regarding this report, please contact Dave Breuning at 614.757.3116.

Sincerely,

A handwritten signature in black ink, appearing to read 'Willie Regits', with a long horizontal flourish extending to the right.

Willie Regits, Ph.D.
Senior Manager, Health Physics
Nuclear Pharmacy Services

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