

From: "Katzenson, Stephen" <Stephen.Katzenson@providence.org>
To: <jfk@nrc.gov>
Date: 08/22/2007 7:20:22 PM
Subject: MEMORANDUM

<<2nd Reply 082207 #4.doc>>

Janine,

Attached is PAMC's clarification response for the NRC survey on May 22-23.

Please let us know if you have any questions regarding our response.

You can contact me directly or via email.

Thanks. Stephen

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CC: "Cook MD, Rodney" <Rod.Cook@providence.org>, "Wallace, Steven A" <Steven.Wallace2@providence.org>, "Ning, Yongli" <Yongli.Ning@providence.org>, "Miller, Michelle" <Michelle.Miller@providence.org>

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Creation Date 08/22/2007 7:14:26 PM
From: "Katzenson, Stephen" <Stephen.Katzenson@providence.org>
Created By: Stephen.Katzenson@providence.org

Recipients

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RE: Reply to a Notice of Violation: Follow-Up Response

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

August 22, 2007

This letter is a follow-up response to the NRC inspection report 030-13426/07-001 and notice of violation done at Providence Alaska Medical Center on May 22-23 2007.

Violation A:

1. The reason for the violation:
Licensee personnel were not consistently monitoring their hands and clothing with a pancake probe after each procedure or when leaving the lab due to supervisors and staff incorrect interpretation and implementation of policy, spot checks of adherence to policy by Radiation Safety Officer or designee not being performed, and inaccessibility of the survey meter.
2. The corrective steps that have been taken and the results achieved.
 - a) Nuclear Medicine staff has been re-educated to PAMC's unaltered policy for personnel monitoring for contamination and documentation. The Nuclear Medicine Supervisor, in consultation with the Radiation Safety Officer and Radiation Safety Committee, conducted the review. A copy of the review has been placed in the staff's department personnel file. Previous supervisory staff had interpreted the policy as intending for daily wipes of staff's hands. This Quality Control, conducted at the end of the workday, was considered to be an adequate check for contamination. Staff is no longer performing these daily wipes of their hands. Effective date: May 25, 2007.
 - b) A second Geiger counter with pancake probe has been purchased for dedicated personnel monitoring. The probe has been in place since June 07.
 - c) A new Standard Operation Procedure (SOP) has been established for hand QC monitoring in Nuclear Medicine. After every procedure where radioactive material is handled, staff is monitoring their hands with a Geiger counter, utilizing a pancake probe. The pancake probe is located immediately outside the hot lab. If contamination above background is indicated via the Geiger counter, staff will then follow established and approved decontamination procedures.
 - d) Random spot checks are being performed on a weekly basis and documented to assure staff are following the policy correctly and to prevent any further incidents. Spot checks are to be done by the Nuclear Medicine Supervisor or a designee. Any infraction will be documented

and addressed presented to the Radiation Safety Officer or designee within 72 hours and at the next Radiation Safety Committee meeting.

3. The corrective steps that will be taken to avoid further violations.
Random spot checks will be done on a weekly basis and documented to assure staff are following the policy correctly and to prevent any further incidents. Spot checks are to be done by the Nuclear Medicine Supervisor or a designee. Any infraction will be documented and presented to the Radiation Safety Officer or designee within 72 hours and at the next Radiation Safety Committee meeting.

4. The date when full compliance will be achieved.
August 20, 2007.

Violation B:

1. The reason for the violation:
A vial containing licensed material, in the form of approximately 27 millicuries of yttrium-90, was not labeled with (1) the radiation symbol, (2) the words "Caution (or Danger) Radioactive Material," (3) the radionuclide, and (4) quantity, concentration and time of measurement. The dosage and isotope were correctly documented on the paperwork, but a label was not put directly on the syringe.

2. The corrective steps that have been taken and the results achieved.
Members from Nuclear Medicine, Radiation Therapy, and the Radiation Safety Committee met to discuss appropriate labeling of yttrium-90 isotopes. The intent was to attach a label to the isotope, which did not negatively impact the users ability to view the isotope at any time during preparation, transportation or administration. (Based on conversation with the NRC inspector during and post NRC inspection, it was agreed that the label could not be attached to the innermost vial containing the isotope. Attaching to the innermost vial would eliminate safe and adequate visibility of the vial throughout preparation and administration.) Discussions resulted in developing a SOP that meets both regulatory and clinical requirements as detailed in part 3 immediately below.

3. The corrective steps that will be taken to avoid further violations.
The vial, containing the yttrium-90 isotope, will be placed in a shielded container. Both the vial and the shielded container will be placed in a second shielded outer box. Staff will affix a label on the bottommost portion of the shielded container. (See accompanying photos.) The label will contain the following information: (1) the radiation symbol, (2) the words Caution Radioactive Material, (3) the radionuclide, and (4) quantity, concentration and time of measurement. The label will be visible when in both container and box.

The Radiation Safety Officer or a Radiation Safety Committee designee will spot-check every dose and document labeling for required information and location on the container. Any infraction will be documented and presented to the Radiation Safety Officer or designee within 72 hours and at the next Radiation Safety Committee meeting.

4. The date when full compliance will be achieved.
August 20, 2007.

Should you have any questions regarding any part of this response, please contact me at 907 261-3039.

Sincerely,
Stephen Katzenson,
Director of Radiology
Chairman of the Radiation Safety Committee
Providence Alaska Medical Center

