Patient Safety Alert

Veterans Health Administration Warning System
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AL13-08 **June 7, 2013**

Item: **GE dual-head gamma cameras: Unintended movement of gamma camera head can cause serious injury or death. Please note, this Patient Safety Alert affects a more comprehensive list of dual-headed gamma cameras than included in previous communications.**

Specific Incident: The gantry support of a detector on a GE Infinia Hawkeye 4 single photon emission computed tomography and computed tomography (SPECT/CT) system experienced a catastrophic failure which led to a patient death.

General Information: This is a preliminary Patient Safety Alert intended to provide initial information and actions. An investigation is in progress. As we come to know more information this Patient Safety Alert will be updated. The affected equipment has the equipment category of VA MDNS, SCANNING SYSTEMS: GAMMA CAMERA, U$18448.

Actions:

1. By Close of Business (COB) **June 7, 2013**, the **Medical Center Director (or designee)** shall ensure that the Chief of Nuclear Medicine and Chief of Biomedical Engineering are made aware of this Patient Safety Alert.

2. By COB **June 7, 2013**, the following actions must be completed

    1. The **Chief of Nuclear Medicine and Chief of Biomedical Engineering (or designee)** shall review this Patient Safety Alert and determine if your facility has the following systems with dual-head gamma camera configurations.
        a. GE Infinia Hawkeye 4 systems, all configurations
        b. GE Hawkeye, all configurations
        c. GE Infinia Dual Detector Gamma Camera, all configurations

    If so, proceed to 2b. If not, proceed to Action 3.

    2. The **Chief of Nuclear Medicine (or designee)** shall take the systems defined in action 2a out of service immediately. This

is a precautionary measure until more information regarding the root cause(s) of the above cited failure is known.

3. By COB **June 14, 2013**, the **Patient Safety Manager** must document on the VHA Hazard Alerts and Recalls Web site that medical center leadership has reviewed and implemented these actions or that individual actions are not applicable to your facility.

   When closing out this Patient Safety Alert on the VHA Hazard Alerts and Recalls Web site, the "Estimated Number of patients affected per month" should be the estimated average number of patients that would be imaged on this system per month over a 12 month period.

Source: A Department of Veterans Affairs medical center

Attachment: Department of Veterans Affairs Nuclear Medicine Program Office Memorandum dated June 6, 2013: Stand down use of GE Infinia Hawkeye 4 SPECT/CT system

Contacts: The National Center for Patient Safety (NCPS) at (734) 930-5890

Attachment: Department of Veterans Affairs Nuclear Medicine Program Office Memorandum dated June 6, 2013: Stand down use of GE Infinia Hawkeye 4 SPECT/CT system

Department of Veterans Affairs

Memorandum

Date: June 6, 2013

From: National Program Director, Nuclear Medicine and Radiation Safety Service (10P4D)

Subj: Stand down use of GE Infinia Hawkeye 4 SPECT/CT system

To: Chiefs, Nuclear Medicine Diagnostic Services (115)
Supervisory Nuclear Medicine Technologists (115)
Nuclear Medicine Technologists (115)

Thru: Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
Clinical Consultant, Diagnostics (10P4D)

1. We were informed earlier today of a catastrophic equipment failure and the subsequent tragic death of a patient in the process of being imaged on a **GE Infinia Hawkeye 4 SPECT/CT system** at a VA healthcare facility.

2. An investigation is in progress, but until we learn more about this incident **please immediately remove from service** any GE Infinia Hawkeye 4 SPECT/CT system in your nuclear medicine equipment inventory.

3. Please contact our office with the following information:

    a. If you possess a gamma camera(s) of this type
    b. Confirm that you have taken these devices out of service

4. We are collaborating with the National Center for Patient Safety and Center for Engineering and Occupational Safety as to determine the cause(s) of the incident and we will provide this information as it becomes available.

We extend our sincerest condolences to the family of this patient; our thoughts are also with our fellow nuclear medicine staff members who are now coping with the loss of their Veteran patient and this tragic event.

If you have further questions, please feel free to contact Nuclear Medicine program office at (734-845-5961) or by email to debra.blansett@va.gov.

Milton D. Gross, MD