GE Healthcare Nuclear Medicine Systems: Class I Recall - Serious Injuries or Deaths Could Occur

[Posted 07/29/2013]

AUDIENCE: Nuclear Medicine, Radiology, Risk Manager, Biomedical Engineering

ISSUE: GE Healthcare became aware of an incident at a VA Medical Center facility in the US. A patient died due to injuries sustained while being scanned on an Infinia Hawkeye 4 Nuclear Medicine System. On July 03, 2013 GE notified hospitals that they were recalling several Nuclear Medicine Imaging Systems because serious injuries or deaths could occur due to the failure mode associated with this recall.

BACKGROUND: These Nuclear Medicine systems are used to perform general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient's body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in Oncology, Cardiology, Neurology and other clinical diagnostic imaging applications.

Affected products include: Infinia Nuclear Medicine Systems, VG and VG Hawkeye Nuclear Medicine Systems, Helix Nuclear Medicine Systems, Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670 (refer to the Recall Notice for a list of affected Models).

RECOMMENDATION: Healthcare facilities are instructed to cease use of their Nuclear Medicine system until a GE Healthcare Field Engineer is able to do a complete inspection of the system and perform any necessary repairs at no cost. A GE Healthcare representative will contact the hospitals to arrange for the inspection.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the Recall Notice, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm362963.htm

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You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm