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DEPARTMENT OF HEALTH
AND ENVIRONMENT

www.kdheks.gov

Division of Environment

July 16, 2008

KANSAS INFORMATION NOTICE 08-01

FDA PRELIMINARY PUBLIC HEALTH NOTIFICATION: POSSIBLE MALFUNCTION OF ELECTRONIC MEDICAL DEVICES CAUSED BY COMPUTED TOMOGRAPHY (CT) SCANNING

Addressees

This notice is addressed to all Kansas registrants of CT scanners.

Purpose

This is to alert you to the possibility that the x-rays used during CT examinations may cause some implanted and external electronic medical devices to malfunction, and to provide recommendations to reduce the potential risk.

Description of Circumstances

The Kansas Department of Health and Environment (KDHE) recognizes the importance of utilization of CT scanning to assist in diagnosis and treatment injury and disease in patients. The Food and Drug Administration Notification, "FDA Preliminary¹ Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning" was released on July 14, 2008 and can be found at: <http://www.fda.gov/cdrh/safety/071408-ctscanning.html>, please see an enclosed copy of the article.

Discussion

The FDA has several recommendations for raising awareness about the possibility that high dose CT may be a cause of a malfunction of electronic medical device. The FDA also gives recommendations for CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, and also for CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

This is solely an informational notice provided to Kansas Radiation registrants of CT scanners and requires no specific response; however please feel free to contact the Kansas Department of Health and Environment Radiation Control Section with any questions at 785-296-1560.

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