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DEPARTMENT OF HEALTH
AND ENVIRONMENT

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Division of Health

October 21, 2009

Kansas Information Notice 09-06

Computed Tomography(CT) Overexposure Incident and Protocol Review

Addressees

This notice is addressed to all Kansas registrants of CT Scanners

Purpose

The purpose of this information notice is to provide information related to overexposures due to CT imaging performed with an improperly adjusted patient protocol. Additionally, this information notice provides recommendations from the Conference of Radiation Control Program Directors (CRCPD) to improve quality assurance and prevent potential overexposures in the use of CT imaging.

Description of Circumstances

Thursday, October 8, the Food and Drug Administration(FDA) issued an initial notification on a safety investigation of CT brain perfusion scans. The FDA became aware of radiation overexposures during perfusion CT imaging to aid in the diagnosis and treatment of strokes.

This incident included 206 patients at a single facility involving this one study protocol. However, this may reflect more widespread problems with CT quality assurance programs. The FDA's Safety Investigation of CT Brain Perfusion Scans: Initial Notification can be viewed at:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm>

The Conference of Radiation Control Program Directors, Inc.(CRCPD) issued a position paper titled *Computed Tomography Protocol Review* on October 20, 2009. The CRCPD position paper offers recommendations on quality assurance

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improvement and prevention of such overexposures in the use of CT imaging. The CRCPD position paper can be viewed at:

http://www.crcpd.org/Positions_Resolutions/Healing_Arts/HA27.pdf

The Kansas Department of Health and Environment regulations published in the Kansas Administrative Regulations (KAR), contain the regulatory requirements for X-ray and CT in Kansas. Part 5, Use of X-rays in the healing arts, KAR 28-35-241 through 28-35-256, contain the requirements for X-ray. KAR 28-35-248a contains specific regulations related to computed tomography (CT) X-ray systems. The regulations can be found on the Secretary of State's website at http://www.kssos.org/pubs/pubs_kar.aspx. Click on *2006 K.A.R. Volumes in order by Agency Number* and then scroll down and click on *28-Department of Health and Environment Article 35, 2006 KAR Vol 2A*.

The following regulation, excerpted from the KAR is also applicable to this issue.

KAR 28-35-242a. (a)(8)(B) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

Discussion

The investigation by the FDA and the subsequent issuance of CT protocols by the CRCPD has increased the awareness of potential overexposures and provided suggestions to prevent those overexposures in the future. Kansas Department of Health and Environment recommends that registrants of CT scanners review the *Computed Tomography Protocol Review* from the CRCPD. Completion of the attached [checklist](#) may provide helpful suggestions to assist your facility in demonstrating compliance with KAR 28-35-242a. If you have questions regarding this information notice, please contact the Kansas Department of Health and Environment, Radiation Control Section at 785-296-1560.