Safety Investigation of CT Brain Perfusion Scans: Update 11/9/2010

U.S. Food & Drug Administration

Date Issued: Nov. 9, 2010

Audience: CT facilities, Emergency Medicine Physicians, Radiologists, Neurologists, Neurosurgeons, Radiologic Technologists, Medical Physicists, Radiation Safety Officers

Medical Specialties: Emergency Medicine, Radiology, Neuroradiology

Device: Multi-slice CT machines

On Oct. 8, 2009, the FDA issued an Initial Communication [1] about excess radiation during CT brain perfusion scans, which are used to aid in the diagnosis and treatment of stroke. The FDA issued an update on this communication [2] on Dec. 8, 2009. These communications included a summary of the problem to date and safety recommendations for radiology facilities.

The FDA is issuing this update to inform you of the findings of its investigation of the manufacturers of CT scanners that were the subject of the earlier communications as well as updated recommendations. In addition, this communication summarizes the information the FDA is providing to manufacturers and professional organizations on ways to create programs and training that would help address these problems in the future. These efforts to avoid overdoses of radiation reflect the goals of the agency's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging *[3]*. In this initiative, the FDA is advocating the universal adoption of two principles of radiation protection: appropriate justification for ordering each procedure, and careful optimization of the radiation dose used during each procedure. Each patient should get the right imaging exam, at the right time, with the right radiation dose.

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@CDRH.FDA.GOV [4], 800-638-2041 or 301-796-7100.

**This document reflects FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.*

[1] A device user facility is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility

which is not a physician's office.

SOURCE [5]

Source URL (retrieved on *03/10/2014 - 10:22am*):
http://www.mdtmag.com/news/2010/11/safety-investigation-ct-brain-perfusion-scans-update-11/9/2010

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm
[2] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm232560.htm
[3] http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199904.htm
[4] mailto://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/DSMICA@CDRH.FDA.GOV
[5] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm