

## Medical Devices

### Safety Investigation of CT Brain Perfusion Scans: Update 12/8/2009

Date Issued: December 8, 2009

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

**Medical Specialties:** Emergency Medicine, Radiology

**Device:** Multi-slice CT machines.

#### Summary of Problem and Scope:

On October 8, FDA issued an [Initial Communication](#)<sup>1</sup> about excess radiation during perfusion CT imaging to aid in the diagnosis and treatment of stroke. At that time, we knew of 206 patients who had been exposed to excess radiation at one facility.

Together with state and local health authorities, FDA has identified at least 50 additional patients who were exposed to excess radiation during CT perfusion scans. These cases involved more than one manufacturer of CT scanners. FDA has also received reports of possible excess exposures at facilities in other states. Some patients reported hair loss or skin redness following their scans.

If patient doses are higher than the expected level, but not high enough to produce obvious signs of radiation injury, the problem may go undetected and unreported, putting patients at increased risk for long-term radiation effects including cataracts.

While unnecessary radiation exposure should be avoided, a medically-needed CT scan has benefits that outweigh the radiation risks. **Patients should follow their doctor's recommendations for receiving CT scans.**

#### Updated Recommendations for Facilities and Practitioners:

In [our previous communication](#)<sup>2</sup>, FDA encouraged CT facilities to review their protocols and make sure that the values displayed on the control panel corresponded reasonably to the doses normally associated with the protocol.

On the basis of our investigation to date, FDA now recommends that facilities, radiologists, and technologists take the following actions:

- Assess whether any of your patients received excess radiation during CT perfusion scans.
- Review your radiation dosing protocols for all CT perfusion scans to ensure that the correct dosing is planned for each study.
- Implement quality control procedures to ensure that dosing protocols are followed every time and the planned amount of radiation is administered.
- Check the display panel before performing each scan to make sure the amount of radiation to be delivered is at the appropriate level for the individual patient.
- If more than one study is performed on a patient during one imaging session, adjust the dose of radiation so it is appropriate for each study.

In addition, FDA has advised manufacturers to review their training for users, reassess information provided to healthcare facilities, and put into place new surveillance systems to identify problems quickly.

#### FDA Activities:

FDA is continuing to work with manufacturers, professional organizations, and state and local public health authorities to investigate the scope and causes of these excess exposures and their potential public health impact. As FDA obtains more information that better defines the problem, we will be better able to determine if there are more widespread risks. We will provide this information as it becomes available.

#### Reporting Problems to FDA:

Prompt reporting of adverse events can help FDA identify and better understand the risks associated with medical devices. If you suspect a problem with a CT device, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting Program](#)<sup>3</sup>.

Healthcare personnel employed by facilities that are subject to [FDA's user facility reporting requirements](#)<sup>4</sup> should follow the reporting procedures established by their facilities.

Device manufacturers must comply with the [Medical Device Reporting \(MDR\) Regulations](#).<sup>5</sup>

To help us learn as much as possible about the adverse events associated with CT overexposure and assess its public health impact, please include the following information in your reports, if available:

- The protocol you were following during the event
- The CT conditions of operation (i.e. technical parameters including kVp, mA, time per rotation, mAs, mode, etc.)
- The dose-index values displayed (CTDI<sub>vol</sub>, DLP).

#### Contact Information:

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

*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. The nature, magnitude and possible public health impact of this situation are not yet clear.*

#### Additional Resources

- [Safety Investigation of CT Brain Perfusion Scans: Initial Notification](#)<sup>6</sup>

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#### Links on this page:

1. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm>
2. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm>

3. <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>
4. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
6. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm>