

Medical Devices

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

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.

Summary of Problem and Scope

At the time of the Oct. 8, 2009 Initial Communication, the FDA knew of 206 patients exposed to excess radiation at one facility, the Cedars-Sinai Medical Center. As of October 26, 2010, the agency is aware of approximately 385 patients from six hospitals who were exposed to excess radiation during CT brain perfusion scans.

Some patients reported obvious signs of excessive radiation exposure following their scans, such as hair loss or skin redness, which called attention to the problem. It is important to note that 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. Over time, excessive radiation exposure can place patients at increased risk for long-term radiation effects, such as cancer.

Patients should follow their doctors' recommendations for receiving CT scans. A medically-needed CT scan that does not expose the patient to unnecessary radiation has benefits that far outweigh the radiation risks.

Follow-up Investigation

The reported cases of radiation overdose involved scanners manufactured by GE Healthcare and Toshiba America Medical Systems. FDA inspections of these companies found there were no violations of FDA laws and regulations. The FDA evaluated the manufacturers' specifications for multi-slice CT scanners and found that when these scanners were used according to the manufacturers' specifications, they did not result in overexposure. The FDA also reviewed literature that supports that the manufacturer-defined protocols do provide reasonable and appropriate image quality and dose. Further, the FDA found no evidence that the manufacturers were involved in modifying any of the hospitals' scanning protocols so as to cause the overexposures.

However, FDA's investigation did reveal improvements that industry could make to its equipment, user information and training in order to improve the safety of their equipment and reduce the likelihood of overexposures. The FDA is working with manufacturers of CT scanners to improve their instructions and training programs for this complex equipment, and to provide software safety checks that would prevent unreasonably high radiation doses from being delivered unintentionally. [In a letter dated Nov. 8, 2010](#)⁴, FDA communicated to industry a need for better instructions for use and more information to users about manufacturers' default protocols.

Clarification of "expected level"

FDA's Initial Communication of Oct. 8, 2009 used the term "expected level" to describe a typical radiation dose of 0.5 Gy for a CT brain perfusion scan. The FDA would like to clarify two points:

1. This value referred to a measurement of peak skin dose for the unmodified Cedars Sinai brain perfusion protocol, and this dose value was also found to be within the range expected from the literature. This value did not refer to a computed tomography dose index (CTDI) measurement.
2. Imaging professionals responsible for conducting CT procedures must define the equipment parameters needed to provide an adequate image at the lowest dose possible. Many factors play into the scanner parameters and dose used, such as patient size and age, condition of the patient, scanner design, etc., and so there may be a range of parameters and doses that are considered reasonable and appropriate. While it is inappropriate to designate a maximum dose, dose limit or universal optimal dose for brain perfusion exams or diagnostic imaging procedures in general, the FDA provides information on [how to determine if the dose associated with a given protocol is reasonable](#)⁵.

The American Association of Physicists in Medicine (AAPM) is working with CT manufacturers to specify protocols for common exams as well as for particular exams, such as brain perfusion studies, which may require relatively higher doses. The AAPM protocols, in addition to those recommended by manufacturers, may be used by facilities, to optimize their own procedures. The AAPM protocols can be accessed by [AAPM members online](#).^{6,7}

Updated Recommendations for Facilities and Practitioners

In the Initial Communication of Oct. 8, 2009, the FDA encouraged CT facilities to review their protocols and make sure that the values displayed on the control panel corresponded to the doses normally associated with the protocol. We continue to urge this practice for all protocols.

Based on its investigation to date, the FDA also recommends that facilities take the following actions, some of which are safety practices critical for all CT procedures:

- 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 dose is planned for each study. Any change to the default protocol should be cleared through the facility's quality assurance program and be approved for image quality and dose by the radiologist and physicist.
- If more than one study is performed on a patient during one CT perfusion imaging session adjust the dose of radiation so it is appropriate

for each study.

- Implement quality control procedures to ensure that dosing protocols are followed every time, and that 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 appropriate for the individual patient.
- Be certain and document that radiologic technologists are trained on the specific scanner and for the specific imaging protocol they are using. They should understand the meaning of the dose index reported on the CT control screen, as well as the expected ranges for each imaging protocol and body scan region.
- CT operators should be specifically trained on dose-saving features such as automatic exposure control (AEC) before using them. If the user activates AEC without carefully reviewing and adjusting the associated parameters, the pre-populated ("default") values may not be appropriate for that scan, which could lead to an overexposure with more radiation dose than intended or an underexposure with poor image quality. Protocols using AEC should be reviewed by a radiologist and physicist.

The FDA recommends that each facility set its own alert level for brain perfusion studies beyond which further review by a physicist, radiologist, and quality assurance committee may be necessary. Based on FDA's review of the literature, a reasonable alert level could be set at 1 Gy CTDI_{vol}. Any alert level should not be misinterpreted as a cutoff or limit, as there may be good reasons for exceeding it.

The FDA has provided information to manufacturers that may improve user training, instructions to health care facilities, and surveillance systems to identify problems quickly.

The FDA is engaged in a broad-based ["Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging."](#)⁸ Specific activities the FDA is pursuing are described on our initiative web page.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the 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](#)⁹.

Device manufacturers and device user facilities, which include many health care facilities, must comply with the [Medical Device Reporting \(MDR\) Regulations of 21 CFR Part 803](#)^{10, 1}.

Health care personnel employed by facilities that are subject to [FDA's user facility reporting requirements](#)¹¹ should follow the reporting procedures established by their facilities.

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_{vol}, 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, 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.

Additional Resources

- [Safety Investigation of CT Brain Perfusion Scans: Initial Notification](#)¹²
- [Safety Investigation of CT Brain Perfusion Scans - Update 12/8/2009](#)¹³

Links on this page:

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. <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm232551.htm>
5. <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm232550.htm>
6. <http://www.aapm.org/pubs/CTProtocols/>
7. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
8. <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199904.htm>
9. <http://www.fda.gov/Safety/MedWatch/default.htm>
10. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
11. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
12. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm>
13. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm232560.htm>