# Safety

# CT Brain Perfusion Scans Safety Investigation: Initial Notification

**Audience**: Radiological, Neurological and emergency medicine healthcare professionals

[UPDATED 12/07/2009] The FDA, working with state and local health authorities, has identified at least 50 additional patients who were exposed to excess radiation of up to eight times the expected level during their CT perfusion scans. These cases so far involve more than one manufacturer of CT scanners. Some of these patients reported hair loss or skin redness following their scans. High doses of radiation can cause cataracts and increase the risk of some forms of cancer.

On the basis of its investigation to date, the FDA is providing interim recommendations for imaging facilities, radiologists, and radiologic technologists to help prevent additional cases of excess exposure.

These recommendations include:

- Facilities assess whether patients who underwent CT perfusion scans received excess radiation.
- Facilities review their radiation dosing protocols for all CT perfusion studies to ensure that the correct dosing is planned for each study.
- Facilities implement quality control procedures to ensure that dosing protocols are followed every time and the planned amount of radiation is administered.
- Radiologic technologists check the CT scanner display panel before performing a study 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, practitioners should adjust the dose of radiation so it is appropriate for each study.

[Posted 10/09/2009] FDA notified healthcare professionals that it has become aware of radiation overexposures during perfusion CT imaging performed to aid in the diagnosis of stroke at a particular facility, the patients receiving radiation doses that were approximately eight times the expected level. While this event involved a single kind of diagnostic test at one facility, the magnitude of these overdoses and their impact on the affected patients were significant. This situation may reflect more widespread problems with CT quality assurance programs and may not be isolated to this particular facility or this imaging procedure (CT brain perfusion). 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.

FDA encourages every facility performing CT imaging to review its CT protocols and be aware of the dose indices normally displayed on the control panel. These indices include the volume computed tomography dose index and the dose-length product. For each protocol selected, and before scanning the patient, carefully monitor the dose indices displayed on the control panel. To prevent accidental overexposure, make sure that the values displayed reasonably correspond to the doses normally associated with the protocol. Confirm this again after the patient has been scanned. Patients should follow their doctor's recommendations for receiving CT scans. While unnecessary radiation exposure should be avoided, a medically-needed CT scan has benefits that outweigh the radiation risks.

[12/07/2009 - News Release- FDA]

[10/08/2009 - Safety Investigation of CT Brain Perfusion Scans: Initial Notification - FDA]