Oregon
Theodore R. Kulongoski, Governor

Department of Human Services
Public Health Division
Environmental Public Health
Radiation Protection Services
800 NE Oregon Street, Suite 640
Portland, OR 97232-2162
Voice 971-673-0490
FAX 971-673-0553
TTY 971-673-0372

DHS oregon department of human services

November 1, 2009

INFORMATION BULLETIN 2009-06

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

From: Terry D. Lindsey
Radiation Protection Services Section

Subject: Radiation overexposure during perfusion CT imaging to aid in the diagnosis and treatment of a stroke.

This informational notice is being resent on behalf of the FDA by Radiation Protection Services.

Summary of Problem and Scope:

FDA has become aware of radiation overexposures during perfusion CT imaging to aid in the diagnosis and treatment of stroke.

Over an 18-month period, 206 patients at a particular facility received radiation doses that were approximately eight times the expected level. In some cases, this excessive dose resulted in hair loss and erythema. The facility has notified all patients who received the overexposure and provided resources for additional information.

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.

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.

Recommendations for Hospitals and CT Facilities:

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 (abbreviated $CTDI_{vol}$, in units of "milligray" or "mGy") and the dose-length product (*DLP*, in units of "milligray-centimeter" or "mGy-cm").
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.

Reporting Problems:

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect reportable adverse events associated with CT devices, you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices and assist in the identification of potential future problems associated with medical devices.
We also encourage you to report any medical device adverse events related to CT devices that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer or to MedWatch, the FDA's voluntary reporting program. This can be done on-line by filing a voluntary report, by phone at 1-800-FDA-1088, or obtain the fillable form online, print it and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.
All reports will help us gather additional information related to CT radiation overexposure and assess its public health impact. To assist us in learning as much as possible about the adverse events associated with CT devices, 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*).

Please also contact your State’s Radiation Protection Services at 971-673-0490.