Investigation Of CT Radiation Overexposure Continues

Reuters

Regulators are probing more cases of patients who were exposed to excess radiation from brain scans performed with equipment from General Electric and Toshiba, government officials said. The Food and Drug Administration said some patients received up to eight times the normal amount of radiation, which could cause cataracts and increase the risk of some forms of cancer.

In October the FDA said it was investigating 206 cases at Cedars-Sinai Medical Center in Los Angeles during an 18-month period. The agency reported identifying at least 50 more cases at Cedars-Sinai and two other California hospitals, as well as incidents in Alabama.

The excess radiation caused skin redness and hair loss in some patients, but the FDA has not determined if there were problems with the machines or with how they were used, Dr. Jeffrey Shuren, acting director of the FDA's device center, told reporters on a conference call. The FDA issued guidelines on Monday meant to help avoid future problems.

GE Healthcare spokesman Arvind Gopalratnam said that while the company continues to investigate, “we confirm that there were no malfunctions or defects in any of the GE Healthcare equipment involved.” Toshiba said the FDA had informed the company of one site where potential over-radiation occurred with the company's equipment. “We are cooperating fully with the FDA and working with them to investigate this matter,” said Paul Biggins, head of regulatory affairs for Toshiba America Medical Systems.

New guidelines urge imaging centers to review protocols for CT perfusion scans of the brain and heart, and advised technicians to check the display panel before use to make sure the right amount of radiation would be delivered. “While we do not know yet the full scope of the concern, facilities should take reasonable steps to double-check their approach to CT perfusion studies and take special care with these imaging tests,” the FDA’s Shuren said in a statement.

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