



FDA Tightens Safety Rules for Radiation Therapy Machines

Posted On: April 8, 2010 by [Patrick A. Malone](#)

The Food and Drug Administration has canceled its policy of giving rubber-stamp approval to marketing of powerful new radiation therapy equipment like linear accelerators. From now on, the manufacturer of the machine is going to have to prove the equipment has proper safety checks to prevent dangerous overdoses of radiation to patients.

The New York Times ran a series in January 2010 that exposed some horrific tragedies that occurred, particularly when hospitals rushed into operation new and complicated equipment without thorough safety checks and training of technicians. The series also showed that the equipment often lacked simple fail-safe devices such as a way of preventing the machine from delivering a walloping overdose of radiation even if one had been inadvertently programmed by a technician.

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But since the FDA only has power over manufacturers and not over hospitals themselves, it still will be possible for poorly trained technicians to cause errors that hurt patients by either delivering overdoses or underdoses of radiation.

In a [follow-up article](#), the New York Times' Walt Bogdanich quotes Dr. Howard I. Amols, chief of clinical physics at Memorial Sloan-Kettering Cancer Center in New York, as saying the more serious problems stem from shortcomings in staffing, personnel competency and hospital quality assurance programs:

“I’d also caution that however commendable tougher standards for premarket approval of software may be, its not clear that F.D.A. has the expertise to police this,” Dr. Amols said. “In fact, I’m not sure anybody does. That’s one of the big problems with software. It comes down to a qualified user recognizing that something is amiss.”

While the government regulators are getting their act together, my advice for patients is to always make sure you get radiation therapy at only a leading center that has been doing it for a long time. Make sure the center employs licensed, certified technicians to operate the therapy machines. Don't be dazzled by the new smell and clean look of a spanking-new therapy center. That could be a sign that people aren't well trained yet to keep you safe.

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