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THE RADIATION BOOM

# As Technology Surges, Radiation Safeguards Lag

By WALT BOGDANICH

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In New Jersey, 36 <u>cancer</u> patients at a veterans hospital in East Orange were overradiated — and 20 more received substandard treatment — by a medical team that lacked experience in using a machine that generated high-powered beams of radiation. The mistakes, which have not been publicly reported, continued for months because the hospital had no system in place to catch the errors.



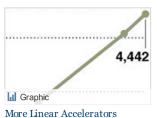
Chang W. Lee/The New York Time Lorraine Raymond, a radiation therapist, raised concerns about overradiation in the treatment of Frederick Stein at a Veterans Affairs hospital in New Jersey in 2006. More Photos »

# The Radiation Boom

Protecting Patients
Articles in this series examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.

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Diffuse Regulation, If Any



In Louisiana, Landreaux A. Donaldson received 38 straight overdoses of radiation, each nearly twice the prescribed amount, while undergoing treatment for prostate cancer. He was treated with a machine so new that

the hospital made a miscalculation even with training instructors still on site.

In Texas, George Garst now wears two external bags — one for urine and one for fecal matter — because of severe radiation injuries he suffered after a medical physicist who said he was overworked failed to detect a mistake. The overdose was never reported to the authorities because rules did not require it.

These mistakes and the failure of hospitals to quickly identify them offer a rare look into the vulnerability of patient safeguards at a time when increasingly complex, computer-controlled devices are fundamentally changing medical radiation, delivering higher doses in less time with greater precision than ever before.

Serious radiation injuries are still infrequent, and the new equipment is undeniably successful in diagnosing and fighting disease. But the technology introduces its own risks: it has created new avenues for error in software and operation, and those mistakes can be more difficult to detect. As a result, a single error that becomes embedded in a treatment plan can be repeated in multiple radiation sessions.

Many of these mistakes could have been caught had basic checking protocols been followed, accident reports show. But there is also a growing realization among those who work with this new technology that some safety procedures are outdated.

"Scientific societies haven't been able to keep up with the

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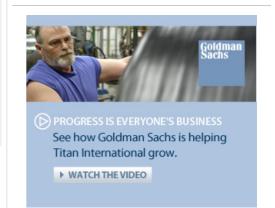
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New Risks for Medical Radiation

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HEALTH.

Radiation Safety Falls Behind As medical radiation technology advances, a

patients from radiation injury.

patchwork of regulations does not always protect

rapid pace of technical improvements," said <u>Jeffrey F.</u> <u>Williamson</u>, a professor of radiation oncology, who leads the medical physics division at the Massey Cancer Center at <u>Virginia Commonwealth University</u> in Richmond.

Hospitals, too, are lagging, sometimes failing to provide the necessary financial support to operate the sophisticated devices safely, according to accident reports and medical physicists, who set up and monitor radiological devices. And manufacturers sometimes sell machines before all the software bugs are identified and removed, records show.

At a 2007 conference on radiation safety, medical physicists went so far as to warn that radiation oncology "does indeed face a crisis." The gap between advancing technology and outdated safety protocols leaves "physicists and radiation oncologists without a clear strategy for maintaining the quality and safety of treatment," the group reported.

Government regulators have been slow to respond. Radiation accidents are chronically underreported, and a patchwork of laws to protect patients from harm are weak or unevenly applied, creating an environment where the new technology has outpaced its oversight, where hospitals that violate safety rules, injure patients and fail to report mistakes often face little or no <u>punishment</u>, The New York Times has found.

In this largely unregulated marketplace, manufacturers compete by offering the latest in technology, with only a

cursory review by the government, and hospitals buy the equipment to lure patients and treat them more quickly. Radiation-generating machines are so ubiquitous that used ones are even sold on eBay.

"Vendors are selling to anyone," said Eric E. Klein, a medical physicist and professor of radiation oncology at Washington University in St. Louis. "New technologies were coming into the clinics without people thinking through from Step 1 to Step 112 to make sure everything is going to be done right."

A national testing service recently found

unacceptable variations in doses delivered by a now common form of machine-generated radiation called Intensity Modulated Radiation Therapy, or I.M.R.T. To help institutions achieve more consistency, an association of medical physicists issued new I.M.R.T. guidelines in November.

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The problems also extend to equipment used to diagnose disease.

More than 300 patients in four hospitals — and possibly many more — were overradiated by powerful CT scans used to detect strokes, government health officials announced late last year. The overdoses were first discovered at Cedars-Sinai Medical Center, a major Los Angeles hospital, where 260 patients received up to eight times as much radiation as intended.

Those errors continued for 18 months and were detected only after patients started losing their hair. The federal <u>Food and Drug Administration</u> is still struggling to understand and untangle the physics underlying the flawed protocols. The F.D.A. has issued a nationwide

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alert for hospitals to be especially careful when using CT scans on possible stroke victims.

Although the overdoses at Cedars-Sinai were displayed on computer screens, technicians administering the scans did not notice. In New York City, technologists who also did not watch their treatment computers contributed to two devastating radiation injuries documented in an article in The Times on Sunday.

The incidents not only highlight the peril of placing too much trust in computers, they also raise questions about the training and oversight of medical physicists and radiation therapists.

Despite the pivotal role medical physicists play in ensuring patient safety, at least 16 states and the District of Columbia do not require licensing or registration. "States can be either very tough or very lax," said Dr. <u>Paul E. Wallner</u>, a director of the American Board of Radiology.

Eight states allow technologists to perform medical imaging other than mammographies with no credentials or educational requirements.

In those states, said <u>Robert Pizzutiello</u>, a medical physicist in New York who is part of a movement to license all medical physicists, "you could drive a truck in the morning and operate an <u>X-ray</u> in the afternoon."

### Turmoil at the V.A.

Frederick Stein, an Army veteran from New Jersey, was already suffering from a delayed diagnosis of <a href="laryngeal cancer">laryngeal cancer</a> when he began radiation treatments in late September 2006 at the Veterans Affairs Medical Center in East Orange. Within weeks of starting <a href="radiotherapy">radiotherapy</a>, his <a href="sore throat">sore throat</a> worsened and a rash appeared along with other skin problems, according to Mr. Stein's family.

Swallowing became more difficult, causing him to lose weight. His skin eruptions worsened. Mr. Stein's pain became so severe, he needed an injection of morphine. More painkillers followed. The hospital stopped <u>chemotherapy</u>, figuring it was causing his problems. But his condition continued to deteriorate.



Reporting was contributed by Simon Akam, Renee Feltz, Andrew Lehren, Kristina Rebelo and Rebecca R. Ruiz.

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