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**January 27, 2010****THE RADIATION BOOM**

As Technology Surges, Radiation Safeguards Lag

By [WALT BOGDANICH](#)

In New Jersey, 36 [cancer](#) 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.

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 But there is also a growing realization among those who work with this new technology that some safety procedures are outdated.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 rapid pace of technical improvements,” said [Jeffrey F. Williamson](#), a professor of radiation oncology, who leads the medical physics division at the Massey Cancer Center at [Virginia Commonwealth University](#) 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 [punishment](#), 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.

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 [Food and Drug Administration](#) is still struggling to understand and untangle the physics underlying the flawed protocols. The F.D.A. has issued a nationwide 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. [Paul E. Wallner](#), 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 [Robert Pizzutiello](#), 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 [X-ray](#) in the afternoon.”

Turmoil at the V.A.

Frederick Stein, an Army veteran from New Jersey, was already suffering from a delayed diagnosis of [laryngeal cancer](#) when he began radiation treatments in late September 2006 at the Veterans Affairs Medical Center in East Orange. Within weeks of starting [radiotherapy](#), his [sore throat](#) 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 [chemotherapy](#), figuring it was causing his problems. But his condition continued to deteriorate.

If Mr. Stein’s skin damage was a mystery to his doctors, two therapists — Alisha High and Lorraine Raymond — had already concluded that he was being overradiated. Ms. High was so concerned that in December 2006 she refused to administer the radiation, records show. The next day, Ms. Raymond expressed her concerns as well.

The protest did not go over well. Their supervisor, Kirk Krickmier, admonished them for questioning doctors and the physics department, and later that month, both therapists were fired by the agency that had placed them in the veterans' hospital, Rosato Associates, according to a lawsuit Ms. High and Ms. Raymond filed against Rosato.

Mr. Stein died of cancer in 2008 at age 71, but not before the hospital admitted that he had been overradiated. His wife, Eileen Stein, said the botched radiation treatments had shortened his life. "Oh, it was just awful," Ms. Stein said in an interview. "They cooked him something terrible. He suffered awful."

Ms. High and Ms. Raymond declined to be interviewed for this article. Steven Menaker, a lawyer who represented Rosato Associates, said his client disputed their account of why they left the hospital. Mr. Krickmier declined to be interviewed about the case, which has been settled.

It turned out that Mr. Stein was not the only victim. Having learned of the therapists' complaints on Dec. 20, 2006, hospital administrators tracked them down a month later and interviewed them, according to Veterans Affairs. A week later, the director of the East Orange facility, Kenneth H. Mizrach, ordered the radiotherapy unit to stop accepting new patients, pending a full investigation.

That investigation found that of 160 cases reviewed, 56 patients were treated incorrectly for cancer of the prostate, head and neck, lung, breast and two other malignancies. Thirty-six had been overradiated and 20 more subjected to "errors in technique," the hospital said. Although the patients were informed, the findings had not been publicly revealed until The Times uncovered them.

According to a confidential report by the American College of Radiology, which had been brought in to study the situation, the hospital's radiotherapy unit was out of control: medical personnel lacked the training and knowledge to safely administer I.M.R.T. treatments, quality control was virtually nonexistent, vital safety procedures were performed by unqualified employees, and patients had little or no follow-up.

"Discontinuation of I.M.R.T. treatment is **STRONGLY** recommended until additional training is obtained by all staff including the physicians," the college said. The reviewers reminded the hospital that the new technology was "VERY labor intensive, and requires not just sophisticated hardware and software, but a lot more training."

The college said medical personnel were "really pushing the envelope of tolerances" and that nonphysicians were apparently approving — in the physician's name — certain steps in the treatment process.

Investigators found that without proper follow-up, there was no way for the hospital to know whether its cancer treatments were successful or whether there were complications. In addition, the college of radiology found no evidence of peer review, quality assurance meetings, outcome studies or mortality and morbidity (known as M&M) conferences, where doctors meet to review cases.

“Several charts reviewed indicated that treatment had been discontinued or at least interrupted by a patient’s worsening condition, or in a few cases death, but there was no M&M review of these issues,” the report said. A spokeswoman for the V.A. said most of the affected patients suffered no apparent harm.

The unit remains closed; it is expected to reopen soon with all new personnel and equipment. “It took a long time to get here — three years in the making,” Mr. Mizrach said. “Without question, this was a dark part of this medical center, but I would hate this to be a defining moment of what this institution is about.”

Checks and Errors

When inspectors from the [Radiological Physics Center](#), a federally financed testing service, arrived at the [Moffitt Cancer Center](#) in Tampa, Fla., in 2005, they uncovered something alarming: a miscalibrated machine that overradiated 77 brain cancer patients by 50 percent in 2004 and 2005.

A new linear accelerator had been set up incorrectly, and the hospital’s routine checks could not detect the error because they merely confirmed that the output had not changed from the first day.

“Errors of this magnitude are very rare,” said Geoffrey S. Ibbott, director of the physics center. But the center’s tests have shown that inaccuracies in the delivery of machine-generated radiation are not uncommon.

Dr. Ibbott’s group also reported in 2008 that among hospitals seeking admission into clinical trials, nearly 30 percent failed to accurately irradiate an object, called a phantom, that mimicked the human head and neck. The hospitals were all using I.M.R.T., which shapes and varies the intensity of radiation beams to more accurately attack the [tumor](#), while sparing healthy tissue.

“This is a sobering statistic, especially considering that this is a sample of those institutions that felt confident enough in their I.M.R.T. planning and delivery process to apply for credentialing and presumably expected to pass,” said a task group investigating I.M.R.T. guidelines for the [American Association of Physicists in Medicine](#).

The group's report, published in November, said the failure rate "strongly suggests" that some clinics had not adequately performed the initial tests to make sure their equipment was set up correctly.

"Errors like the one at Moffitt, and other errors that we have detected at other facilities, would be much less likely to have occurred if, every time a new piece of radiation therapy equipment were installed, there was some sort of independent check of the type that we do," Dr. Ibbott said in an interview last year. "If we had gone to Moffitt eight months earlier, perhaps none of those patients would have received the higher dose."

Another set of tests from 2000 to 2008 found that 15 percent to 20 percent of hospitals using linear accelerators in clinical trials had at least one radiation beam outside the acceptable range.

"We haven't been sufficiently outspoken about this, although we are now in the process of correcting that," said Dr. Ibbott, whose group is based at the M. D. Anderson Cancer Center in Houston.

Hospitals sometimes embrace new technologies before medical personnel can agree on how best to use them.

James Deye, a program director in radiation research at the [National Cancer Institute](#), watched with concern as the popularity of I.M.R.T. exploded before there were national standards. Dr. Deye said he established minimum I.M.R.T. guidelines for institutions wishing to participate in cancer trials. "The community was going along merrily and happily without those guidelines," he said.

Dr. Ibbott's testing service can help clinics improve the performance of their linear accelerators if they are in clinical trials. Operators not in trials can pay to have their units tested by a sister group of the Physics Center. Even so, many do not.

"There are clearly places that don't avail themselves of the service, even though it is well known and very affordable," Dr. Ibbott said. "I guess they don't want someone else checking them for some reason."

In radiotherapy, eschewing an outside, independent review is a calculated gamble.

"If you radiate a person wrong, there's no repeat — you can't say, 'Let's forget about that one and do it correct next time,'" said [George X. Ding](#), a medical physicist at the Vanderbilt Center for Radiation Oncology in Nashville. "It's not like you do a measurement of a phantom and it went wrong and you can do it again."

Steeper Learning Curve

Last fall, in the vast exhibition hall at McCormick Place in Chicago, dozens of companies from around the world displayed their latest radiological weapons in the war on cancer.

“That’s our newest linear accelerator,” said Hans-Jörg Freyer of Siemens Healthcare, standing in front of his company’s Artiste model, which combines imaging with therapy. Sophisticated, yet easy to use, it is capable of treating 80 patients a day, Mr. Freyer said.

Dee Mathieson, of the Swedish company [Elekta](#), said imaging technology in their linear accelerator improved accuracy. “What has changed is the software that allows us to unleash some of these new techniques,” Ms. Mathieson said.

Over the last two decades, the industry has developed generations of machines, each designed to more precisely attack [tumors](#), allowing doctors to administer higher doses of radiation with less risk to healthy tissue.

Linear accelerators once used radioactive beams crudely shaped as blocks or rectangles. Since tumors do not grow in straight lines, healthy tissue was sometimes irradiated along with the cancer. To minimize collateral damage, technicians manually inserted blocks and filters, a task later taken over by computers.

Computers eventually were able to produce three-dimensional images of tumors — a major advancement — and linear accelerators used software that contoured beams to conform to the shape of the tumor. The next step, I.M.R.T., allowed doctors to more precisely tailor the shape and intensity of the beams. The latest generation of machines, which were on display at McCormick Place, incorporates sophisticated imaging.

The F.D.A. waved these advancements through with little review on the grounds that they just extended existing technology. But there are dissenters. “It’s so much more than that,” said Dr. Deye, the National Cancer Institute official. “The issues surrounding advanced technologies are far-reaching.”

Even if the devices work as intended, hospitals face a steep learning curve.

In 2005, when Landreaux A. Donaldson underwent therapy for prostate cancer at Mary Bird Perkins Cancer Center in Baton Rouge, La., the linear accelerator was so new the vendor’s training instructors were still in the hospital, records show. The accelerator delivered radiation in a radically different way, emitting tiny beams of radiation from many points on a spiral encircling the patient.

In treating Mr. Donaldson, the hospital used the wrong type of CT treatment scan for the

machine, prompting medical personnel to compensate by doing what is called “a work around” — a departure from established procedure. But because they were unfamiliar with the treatment planning software, they made a miscalculation that affected all 38 treatments, stretching over two months, according to state records and a lawsuit filed by Mr. Donaldson.

The next year, Mr. Donaldson began experiencing stomach [ulcers](#), [anemia](#) and [urethral stricture](#), which required surgery. He also underwent hyperbaric oxygen treatments, where pure pressurized oxygen is used to promote healing. Neither the hospital nor Mr. Donaldson would comment on the lawsuit, which has been settled.

As therapies become more complex, there is more to check — sometimes too much, say some medical physicists.

“When it exceeds certain levels of complexity, there is not enough time and not enough resources to check the behavior of a complicated device to every possible, conceivable kind of input,” said Dr. Williamson, the medical physicist from Virginia.

As the person most responsible for ensuring that an optimal radiation dose is delivered safely, the medical physicist must make sure that new machines are set up properly; that daily warm-up checks are carried out, along with more extensive monthly and annual evaluations; and that individual treatments are administered as prescribed.

Computers can provide only so much help. In the past, they checked the work of radiotherapists, but now therapists check the computers, said Howard I. Amols, chief of clinical physics at [Memorial Sloan-Kettering Cancer Center](#) in New York.

The problem, Dr. Amols said, is that computers are better at checking humans than humans are at checking computers. “The responsibility on Day 1 to make everything right is much more important than it used to be,” he said. “We are still grappling with how we do that.”

Hospitals sometimes aggravate the problem, buying new technology without adding the employees needed to operate it safely, according to a report issued on a 2007 conference sponsored by two radiological associations and the National Cancer Institute.

And hospitals complain that manufacturers sometimes release new equipment with software that is poorly designed, contains glitches or lacks fail-safe features, records show.

Northwest Medical Physics Equipment in Everett, Wash., had to release seven software patches to fix its image-guided radiation treatments, according to a December 2007 warning letter from the F.D.A. Hospitals reported that the company’s flawed software caused several cancer patients to receive incorrect treatment, government records show.

In another case, an unnamed medical facility told federal officials in 2008 that Philips Healthcare made treatment planning software with an obscure, automatic default setting, causing a patient with tonsil cancer to be mistakenly irradiated 31 times in the optic nerve. “The default occurred without the knowledge of the physician or techs,” the facility said, according to F.D.A. records.

In a statement, Peter Reimer of Philips Healthcare said its software functioned as intended and that operator error caused the mistake.

Patchwork of Regulation

When George Garst was treated in 2004 for prostate cancer at Christus Spohn Hospital in Corpus Christi, Tex., his caregivers were subject to the following regulations:

The first half of his radiation treatment — external beam therapy — was overseen by the state radiological division operating under one set of rules. The second half of his treatment — radioactive seeds — was subject to a second set of rules established by the [Nuclear Regulatory Commission](#), except that the commission passed its responsibility on to the state, which must follow some, but not all, of the commission’s rules. In any case, the second rules differ from the first.

State radiology officials have no enforcement power to punish a clinic if it botched the first half of a procedure like Mr. Garst’s, but they can for the second half. If any radiation equipment failed to work properly, resulting in a serious injury, that must be reported to the federal Food and Drug Administration, the manufacturer and the state.

As it turned out, Mr. Garst was overdosed and seriously injured, destroying his ability to urinate and move his bowels normally. Before two external bags were attached to collect his waste, Mr. Garst’s urine leaked into his rectum because a [fistula](#) had developed. He had so many infections, his doctors had to keep trying new [antibiotics](#) to replace those that no longer worked.

“He was very, very sick from all this,” said Dr. Norbert C. Brehm, one the doctors who treated Mr. Garst after the accident. “He was not sleeping. He had a feeling of worthlessness, hopelessness, appetite disturbance, mood swings.”

And yet, until The Times began investigating Mr. Garst’s injuries, no one in government — not Texas, not the Nuclear Regulatory Commission — was even aware of his overdose or of his devastating injuries.

The state and the commission initially told The Times that they had no jurisdiction in the case since neither the first nor second treatment was by itself an overdose, even though in combination they were. Despite their mandate to protect patients from radiation mistakes, the state and

federal government said in essence that Mr. Garst was someone else's problem.

Had regulators investigated, they would have found reasons for concern.

The medical physicist later said he had been overworked, rarely taking a day off, and that he had complained to hospital officials about staffing issues. Mr. Garst's radiation oncologist failed to prescribe a dosage for the implanted radioactive seeds, and the actual dose ended up being too high, according to a lawsuit filed by Mr. Garst. The physicist then failed to catch the mistake. The oncologist also implanted seeds too close to Mr. Garst's rectum, the physicist delayed performing a post-implant analysis, and the oncologist failed to promptly report the overdose to the patient's doctor.

Mr. Garst said he did not learn of his overdose until about a year later.

In response to inquiries by The Times, the Nuclear Regulatory Commission said the state had opened an investigation into Mr. Garst's care. "They're going to look at why the licensee didn't report it — was there a deficiency in their procedures or training?" said James G. Luehman, a deputy director in the commission.

Last week, Texas reported that its investigation had found no violations of state radiation regulations. The hospital declined to comment on the case, which has been settled.

Mr. Garst said that medically, he was at a dead end. "They couldn't really do anything for me because I'm so burned up," he said.

Last year, health officials in eight states sent a letter to Congress asking for a more rational way to regulate radiation. "There is no national program charged with the protection of the public from all radiation sources," the letter stated. "Federal agencies pressure the states, most of which have comprehensive radiation programs, to provide protection from certain sources of radiation while ignoring other sources."

Kirksey Whatley, director of the Alabama Office of Radiation Control, said radioactive materials, which are overseen by the N.R.C., received most of the government's attention, while the much more common machine-generated radiation was largely unregulated by the federal government.

Thirteen states, including California, do not require that errors involving linear accelerators be reported to state health officials. Texas requires that they be reported, but has no enforcement authority to punish anyone. New York rarely fines radiotherapy units for substandard care, while Florida frequently does.

Part of the problem is that hospitals may skimp on quality assurance because, depending on the state, it is voluntary, medical physicists say.

Jared W. Thompson, an Arkansas radiation official, said he mostly worried about diagnostic radiation. “There are no limits about what can be done, how it can be used, when it is considered unsafe,” Mr. Thompson said.

There are no guarantees, Mr. Whatley said, that radiological devices have been inspected and that its operators are properly trained and qualified. Depending on the state, he added, “you may get two to three times more of the radiation you need.”

Even when overdoses occur, some medical practitioners are reluctant to publicly disclose them. An N.R.C. advisory group underscored that point when in 2005 it recommended that the agency adopt the “industry standard” when responding to a radiation error, called a medical event, or M.E. “Keeping M.E. reports, or at least the licensee’s identity out of the public record, is probably the single most useful improvement N.R.C. could make in this regard,” the advisory committee urged.

The commission rejected that recommendation.

Responding to Mistakes

Under Ohio law, Akron General Hospital was obliged to file a detailed written report no later than 15 days after it overdosed Myra Jean Garman, 76, a [breast cancer](#) patient, with high-dose radioactive seeds.

Instead, Akron General waited five months, records show.

Just two months before Mrs. Garman’s accident, at the same hospital, another patient was overdosed with 111 radioactive seeds that were too powerful. When the Ohio Bureau of Radiation Protection inspected the facility, it found that the hospital’s radiation safety officer was not even aware of the accident. Nor did the hospital’s radiation safety committee discuss the overdose when it met for its regular meeting, state regulators said.

Mrs. Garman’s accident occurred in September 2006, when she received twice her prescribed dose five separate times because a physicist had “entered an incorrect magnification factor into the treatment planning computer,” according to state regulators.

Five months later, she complained of severe pain, and doctors discovered that she had broken ribs, a known side effect of her type of overdose. Mrs. Garman’s daughter, Joyce Lilya, said her mother, who had walked two miles daily before the procedure, could now barely walk two blocks.

Even though her cancer did not reappear, a year after the overdose, Mrs. Garman ended up in intensive care with breathing troubles. No cause could be determined, her daughter said.

A month later, Mrs. Garman took an overdose of Tylenol, tied a plastic bag around her head and killed herself. “I was really trying, but it was too much for me,” she said in a note. “Let me go!!! Please.”

Ms. Lilya said she and her family were stunned, calling her mother a “positive person” who would never hurt herself even though her husband had died several months earlier. Seeking reasons for her mother’s [suicide](#), Ms. Lilya began searching the Internet and reached out with dozens of calls and e-mail messages to professional groups and government agencies.

Only then, she said, did she learn of the radiation overdose. Much to her surprise, the state had cited the hospital only for failing to promptly report the mistake to state authorities. There was no fine. And while Mrs. Garman’s medical records show that she had asked for a written account of her overdose, the hospital could produce no such document nor was one in her medical file.

James Gosky, a spokesman for Akron General, said in a recent interview that Mrs. Garman had been informed of her overdose.

Still, Ms. Lilya said, “none of this made any sense.” So she kept pressing — without success — for a more thorough investigation of her mother’s accident.

In a conference call last summer, she said Lance D. Himes, assistant counsel for the Ohio Department of Health, explained part of the department’s enforcement philosophy.

“He told me they don’t get into assessing penalties because that is what malpractice is for,” she said.

A spokesman for the state said Mr. Himes denied making that statement. And in October 2007, the state did fine the hospital \$4,000 for other infractions — but not for Mrs. Garman’s overdose.

Ms. Lilya said her investigation had taught her much about how hospitals respond when they make a mistake. “It has been a long and tragic journey for my family,” she said, And, she added, “No one was held accountable.”

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

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