Legislative Committee on New Licensing Boards

Medical Imaging and Radiation Therapy

Submitted by Brenda Greenberg RT(R)(CT)
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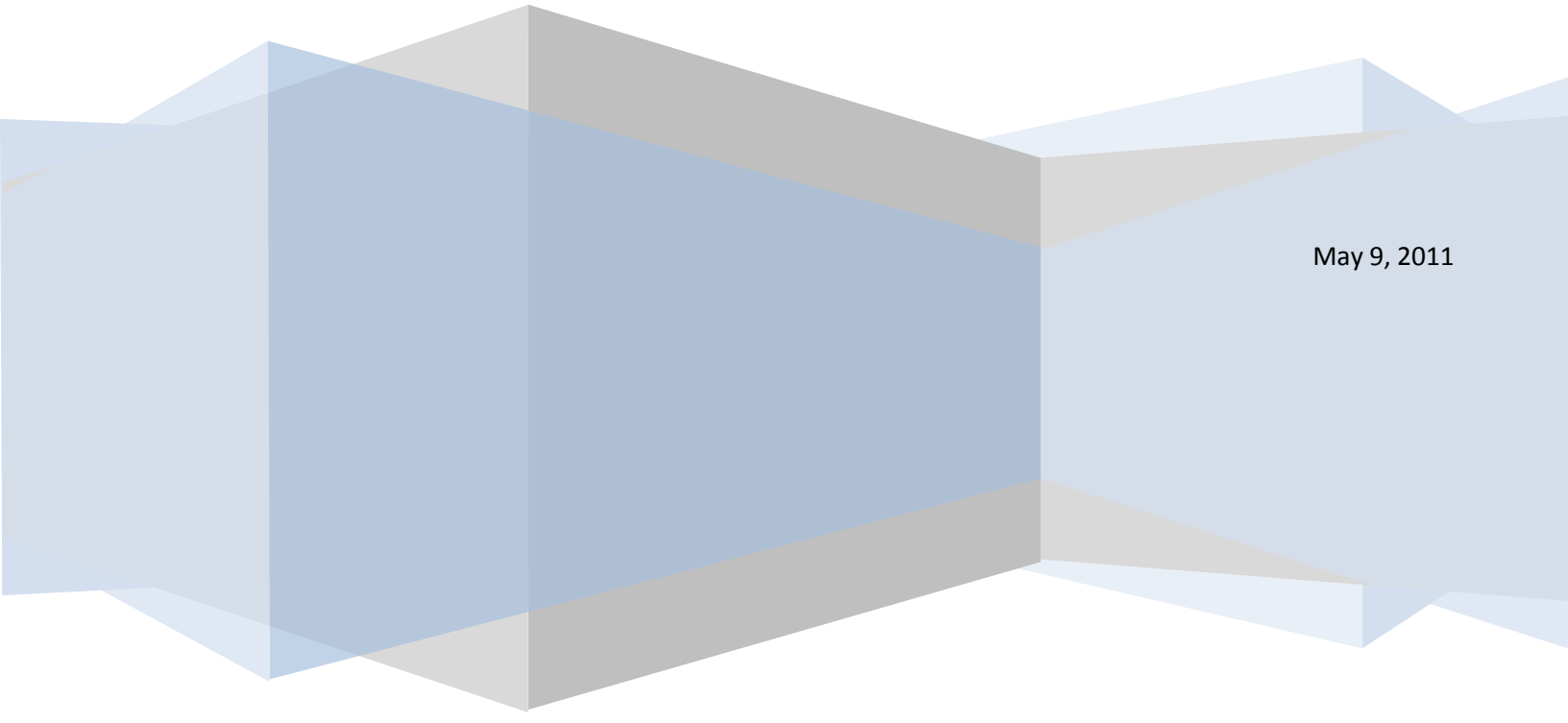

May 9, 2011

1) In what ways has the marketplace failed to regulate adequately the profession or occupation?

Market place failure to regulate: While most hospitals do regulate the profession, there are still individuals performing imaging procedures in physicians 'offices who are neither educated nor licensed in our field. These individuals are dispensing radiation to the public and making anatomical images without proper radiation or anatomy skill sets. It takes and educated individual to calculate safe dose and to be able to make the proper adjustments to the image to display anatomical features that will lead the physician to a proper diagnosis.

2) Have there been any complaints about the unregulated profession or occupation? *Please give specific examples including (unless confidentiality must be maintained) complainants' names and addresses.*

The complaints by patients cannot be disclosed due to HIPPA. The consequences of suboptimal images are found in malpractice laws suits and physician dictations while interpreting such images. Another complaint about the lack of regulation of the profession comes from the 10,000 + educated and professionally trained, ARRT registered technologists. Knowing what it takes to practice safely and efficiently without unnecessary harm to the public is what makes the lack of regulations unacceptable. The hair stylist, the nail stylist, cosmetologists, sigh language interpreters are all required to be licensed by the State of NC. Professionals administering medical radiation are not required minimal standards regulated by licensure in the state of North Carolina. It makes absolutely no sense that that state finds it very important that our hair and nails are done by a standard, but our safety and health does not need it.

3) In what ways has the public health, safety, or welfare sustained harm or is in imminent danger of harm because of the lack of state regulation? *Please give specific examples.*

Harm to public health, safety, or welfare: Harm may not be seen for years as to the unsafe radiation exposure, and given that dose effects are stochastic may not be traced back to a specific procedure. This does not indicate that harm has not occurred. However, harm due to a misdiagnosis does result in time lost in the treatment of an illness which can be traced to increased health care costs, lost work and wages from illness, and possible loss of life. Any disease is best treated in the onset when intervention is more easily treated and outcome is more favorable.

If left untreated and a disease progresses, the cost of treatment is much higher and the outcome may not be a favorable.

4) Is there potential for substantial harm or danger by the profession or occupation to the public health, safety, or welfare? How can this potential for substantial harm or danger be recognized?

"Someone with no background in anatomy, radiation safety or patient care too often is hired to do procedures that help doctors detect cancer and other life-threatening illnesses. The reason

public outcry is not louder is that most patients have no idea they may be getting substandard care."

Birmingham News
Birmingham, Ala.

"Adoption of the Consumer-Patient Radiation Health and Safety Act of 1981 was made discretionary for each state. As a result, only 39 states voluntarily license, regulate or register radiographers; 34 states license radiation therapists, and 28 states license nuclear medicine technologists. Laws vary from state to state, and some are so weak that they are ineffective in ensuring the competency of personnel who perform medical imaging and radiation therapy procedures. The situation is even worse in the six states that do not have any licensure law at all. In those states and Washington, D.C., individuals may be permitted to perform complex diagnostic procedures after only a few hours of coursework or a couple weeks of on-the-job training Health care workers with as little as one week training by an equipment vendor— and completely untrained in the basics of human anatomy and radiation safety— may, and do, lawfully administer x-rays in New Hampshire. The situation reflects a glaring deficiency in … consumer protection laws that demands immediate public attention".

New Hampshire Business Review

Three years ago, on July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) was passed by Congress. Part of the CARE bill was put into the MIPPA bill, covering computed tomography, magnetic resonance, positron emission tomography and nuclear medicine. These modalities now have mandatory quality standards established by the Secretary of Health and Human Services that will be tied to Medicare reimbursement. The procedures done in these modalities make up only 30 percent of medical imaging provided to Medicare patients in the United States. That leaves the other 70 percent of diagnostic imaging (x-ray, ultrasound, fluoroscopy and radiation therapy) provided to Medicare patients not covered by MIPPA.

So, you can see that by getting the CARE bill passed, we can be assured that any medical imaging and radiation therapy procedure will be done by properly trained, qualified and certified professionals. Oh, don't forget the cost savings!

See Appendices Missed Diagnoses.

5) Has this potential harm or danger to the public been recognized by other states or the federal government through the licensing or certification process? *Please list the other states and any applicable federal law (including citations).*

ASRT Tally of State Licensure, Certification or Recognition Standards by Discipline

Radiography (39 States)

Arizona
Arkansas
California
Colorado
Connecticut
Delaware
Florida
Hawaii
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Minnesota
Mississippi
Montana
Nebraska
New Jersey
New Mexico
New York
North Dakota
Ohio
Oregon
Pennsylvania
Rhode Island
South Carolina
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

Radiation Therapy (35 States)

Arizona
Arkansas
California
Colorado
Connecticut
Delaware
Florida
Hawaii
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Mississippi
New Hampshire
New Jersey
New Mexico
New York
Ohio
Oregon
Pennsylvania
Rhode Island
South Carolina
Tennessee
Texas
Utah
Vermont
Washington
West Virginia
Wisconsin
Wyoming

Limited X-ray Machine Operators (32 States) – Not Permitted to perform fluoroscopy

Arizona
Arkansas
California
Colorado
Delaware
Florida *(fluoro under direct MD supervision)*
Illinois
Indiana
Iowa *(must pass hospital fluoro exam)*
Kentucky
Maine
Minnesota
Mississippi
Montana
Nebraska
New Jersey
New Mexico
North Dakota
Ohio
Oregon
Pennsylvania
Rhode Island
South Carolina
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia (*podiatry only*)
Wisconsin
Wyoming

Nuclear Medicine Technology (31 States)

Arizona
Arkansas
Indiana
Iowa
Mississippi
New Jersey
South Carolina
Texas

California
Colorado
Delaware
Florida
Hawaii
Illinois
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
New Mexico
New York
Ohio
Oregon
Pennsylvania
Rhode Island
Utah
Vermont
Washington
West Virginia
Wyoming

Fusion Imaging (12 States)

Arizona
California
Florida
Iowa
Louisiana
Maryland
Minnesota
Nebraska
New Mexico
Ohio
Oregon
Vermont

Radiologist Assistant (28 States)

Arizona
Arkansas
Colorado
Connecticut
Florida
Georgia
Illinois
Iowa
Kentucky
Maryland
Massachusetts
Minnesota
Mississippi
Montana
New Jersey
New Mexico
New York
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
Tennessee
Vermont
Virginia
Washington
West Virginia
Wyoming

No Standards (6 States)

Alabama
Alaska
District of Columbia
Idaho
Missouri
North Carolina
South Dakota

Magnetic Resonance (3 states)

New Mexico
Oregon
West Virginia

Mammography (distinct from Radiography) (5 States)

Arizona
California
Colorado
Michigan
Nevada

Sonography (2 states)

New Mexico
Oregon

Computed Tomography (distinct from radiography) (3 States)

Colorado
Oregon
Wisconsin

Cardiovascular Technologists (RCIS)

Arkansas
Ohio
Texas

Delaware South Carolina Washington

Fluoroscopy Only (1 state)

Alaska

Data: https://www.asrt.org/Content/GovernmentRelations/TallyofStateLicensure.aspx

6) What will be the economic advantage of licensing to the public?

Economic advantage to the public: The economic advantage to the public as previously stated is that the licensed professional has the training necessary to perform quality images with the lowest possible dose which in turn does increase the health benefits to the public when using imaging services through a reduction in radiation dose and a decrease in misdiagnosis through poor images caused by untrained individuals. As stated earlier--it is far more cost effective to treat an illness in the early stages than the progresses stage.

7) What will be the economic disadvantage of licensing to the public?

The public will only be helped by implementing licensing of radiologic technologist. It will not increase cost to the public, but will better guarantee that they receive optimal imaging resulting in less radiation and a more timely diagnosis.

The ASRT studied radiologic technologists' salaries in Arkansas and South Carolina (recent states to pass radiologic technologist licensure laws). Following the implementation of state licensure, salary levels did not increase above the national norm.

8) What will be the economic advantages of licensing to the practitioners?

Economic advantage to the practitioner: The economic advantage to the imaging practitioner is in the satisfaction that our profession is taken serious by the public and that we know that only quality work should be the outcome from the profession. The vast majorities of imaging professionals do take pride in our work and feel that our images are key in the quality of healthcare our patients receive. We are an important component of the healthcare team and would love to have our profession embraced as such by our fellow healthcare professionals. The imaging community for years has vowed to be viewed as professional, and licensure is a step in that direction.

9) What will be the economic disadvantages of licensing to the practitioners?

Economic disadvantage to the practitioner: The economic disadvantage to licensure to the practitioner would be the additional fee we would submit to the state for the privilege of practicing our profession. However, this fee is far overshadowed by the benefit to both the practitioner on the professional level and the benefit gained by the public through reduced dose and quality of care.

10) Please give other potential benefits to the public of licensing that outweigh the potential harmful effects of licensure such as a decrease in the availability of practitioners and higher cost to the public.

Cost of licensure to the public: Licensure has not historically caused a higher cost to the public. The cost of our services is not set by the imaging professional nor do we receive pay through piecemeal practices. Also, there is a misconception that licensure will cause a decrease in availability of services--North Carolina has educated technologists in the ready to fill any vacancies that may appear. This state is blessed in the fact that there are great educational programs that are willing and able to develop our future imaging professionals, and ensure that these individuals practice and are elevated to the highest standards of the profession.

11) Please detail the specific specialized skills or training that distinguish the occupation or profession from ordinary labor.

Specific skills within the profession:

- Basic and Cross-sectional anatomy
- Procedural skills and anatomical manipulation
- Radiation Biology and Protection
- Electromagnetic physics
- Computer manipulation
- Equipment manipulation
- Patient care skills
- Drug interaction, dose, and injection skills
- Plus basic General Educational skill sets

See Appendices "ASRT Practice Standards for Medical Imaging and Radiation Therapy"

12) What are other qualities of the profession or occupation that distinguish it from ordinary labor

Skill sets that distinguish our profession:

- Commitment to quality images
- Caring and compassion for our patients
- ALARA concept of maintain the lowest possible dose for our Examinations.
- An innate ability to work with and for our physician coworkers
- Teamwork skills to work in conjunction with other healthcare Departments.
- The ability to interpret an order in conjunction with what the Patient tells us and then in turn use what we have learned to question to ensure that the proper exam is performed on our patient
- The ability to communicate effectively

Etc...

See Appendices " ASRT Practice Standards for Medical Imaging and Radiation Therapy"

13) Will licensing requirements cover all practicing members of the occupation or profession? If any practitioners will be exempt, what is the rationale for the exemption?

The imaging profession is differentiated by anatomical modalities and imaging technology used. The modalities which involve ionizing radiation are covered by these licensing requirements. The exempts are made on bases of crossing licensing with other professions, such as licensed dental assistants and hygienists, licensed physicians and physician and radiologists assistants. We are proposing to give the board the ability to evaluate the need for additional licensure as modalities evolve with the new technology.

14) What is the approximate number of persons who will be regulated and the number of persons who are likely to utilize the services of the occupation or profession?

Number of imaging professionals within North Carolina: North Carolina has some 10,000+ technologists with some 15,000+ certifications. The state also has over 30 educational facilities that produce imaging professionals each year to keep our supply at a viable level.

15) What kind of knowledge or experience does the public need to evaluate the services offered by the practitioner?

How the public can evaluate our profession: The public can often evaluate the quality of the services given by the professional demeanor of the practitioner. Did they provide radiation protection, did they do excessive repeats of the procedure, did they explain the exam to them, did they ask questions as to verify the procedure and in the case of young females child bearing events, did they introduce themselves as a certified imaging professional, and could an accurate diagnosis or step in a diagnosis be determined by the exam.

16) Does the occupational group have an established code of ethics, a voluntary certification program, or other measures to ensure a minimum quality of service?

Code of ethics and certification process: There is a code of ethics for each modality within the imaging arena. These can be found on the web sites of our professional organizations, and probably in every imaging school handbook within this state. The educated imaging professional is encouraged to seek certification within a specified time post graduation. Also most hospitals within the state do insist that the imaging professional become certified at a specified time post employment. Once certification is acquired, the imaging professional must obtain a number of continuing educational credits within a specified time period to retain certification. The continuing education credits must fall within the scope of practice for that modality and are policed by the national certification centers per each specialty.

Appendices

1) ASRT Tally of State Licensure, Certification or Recognition Standards by Discipline.
2) ASRT Map of States That Do Not Have Any Licensure or Regulatory Provisions For Radiologic Personnel
3) Alphabet Soup: A Guide to Organizations in Radiologic Technology
4) ASRT Radiologist Technologist: Code of Ethics
5) ASRT Radiation Therapist: Code of Ethics
6) ASRT Practice Standards for Medical Imaging and Radiation Therapy
7) JRCERT http://www.jrcert.org/pdfs/mission_core_values.pdf
8) Missed Diagnosed Cases 1-6

Articles of Interest:

- History of X-Rays: Mary Washington College, 4/14/2003 created by Amy Miller for Dr. Jeffrey McClurken's History of American Technology & Culture

http://www.umw.edu/hisa/resources/Student%20Projects/Amy%20Miller%20--%20X-Ray/students.mwc.edu/_amill4gn/XRAY/PAGES/cont.htm

- The New York Times, X-Rays and Unshielded Infants, 2/27/2011, by Walt Bogdanich and Kristina Rebalo

http://www.nytimes.com/2011/02/28/health/28radiation.html

- NEW YORK TIMES HEALTH FEED : Tuscaloosa News, Radiation Offers New Cures, and Ways to Do Harm, 1/24/2010, Walt Bogdanich

http://www.tuscaloosanews.com/article/20100124/ZNYT04/1243010

- Unintended Over Exposure of Radiation Plaguing Hospitals and Harming Patients, February 18, 2010,
  Eisenberg, Rothweiler, Winkler, Eisenberg & Jeck, P.C. (Lawyer Blog)

http://www.philadelphiapersonalinjurylawyersblog.com/2010/02/unintended-over-exposure-of-ra.html

- Fatal Dose: Radiation Deaths Linked to AECL Computer Errors, June 1994. By Barbara Wade Rose

http://www.ccnr.org/fatal_dose.html

- CT Radiation and Cancer, Parker, Waichman, Alonso LLP,

http://www.cat-scan-radiation-overexposure.com/radiation-overdose-news/ct-radiation-and-cancer/

- Injuries Associated with Over Radiation, Eisenberg, Rothweiler, Winkler, Eisenberg & Jeck, P.C. , March 3, 2010

http://www.philadelphiapersonalinjurylawyersblog.com/cgi-bin/mt-search.cgi?search=radiation&IncludeBlogs=132&search=

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Limited X-ray Machine Operators (32 States) – Not Permitted to perform fluoroscopy

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Oregon
Pennsylvania
Rhode Island
South Carolina
Tennessee
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Utah
Vermont
Virginia
Washington
West Virginia (*podiatry only*)
Wisconsin
Wyoming

Nuclear Medicine Technology (31 States)

Arizona
Arkansas
California
Colorado
Delaware
Florida
Hawaii
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Mississippi
New Jersey
New Mexico
New York
Ohio
Oregon
Pennsylvania
Rhode Island
South Carolina
Texas
Utah
Vermont
Washington
West Virginia
Wyoming

Fusion Imaging (12 States)

Arizona
California
Florida
Iowa
Louisiana
Maryland
Minnesota
Nebraska
New Mexico
Ohio
Oregon
Vermont

Radiologist Assistant (28 States)

Arizona
Arkansas
Colorado
Connecticut
Iowa
Kentucky
Maryland
Massachusetts
New Jersey
New Mexico
New York
Ohio
Rhode Island
Tennessee
Vermont
Virginia

Florida	Minnesota	Oklahoma	Washington
Georgia	Mississippi	Oregon	West Virginia
Illinois	Montana	Pennsylvania	Wyoming

No Standards (6 States)

Alabama	District of Columbia	Missouri	South Dakota
Alaska	Idaho	North Carolina	

Magnetic Resonance (3 states)

New Mexico	Oregon	West Virginia

Mammography (distinct from Radiography) (5 States)

Arizona	Colorado	Michigan	Nevada
California			

Sonography (2 states)

New Mexico	Oregon

Computed Tomography (distinct from radiography) (3 States)

Colorado	Oregon	Wisconsin

Cardiovascular Technologists (RCIS)

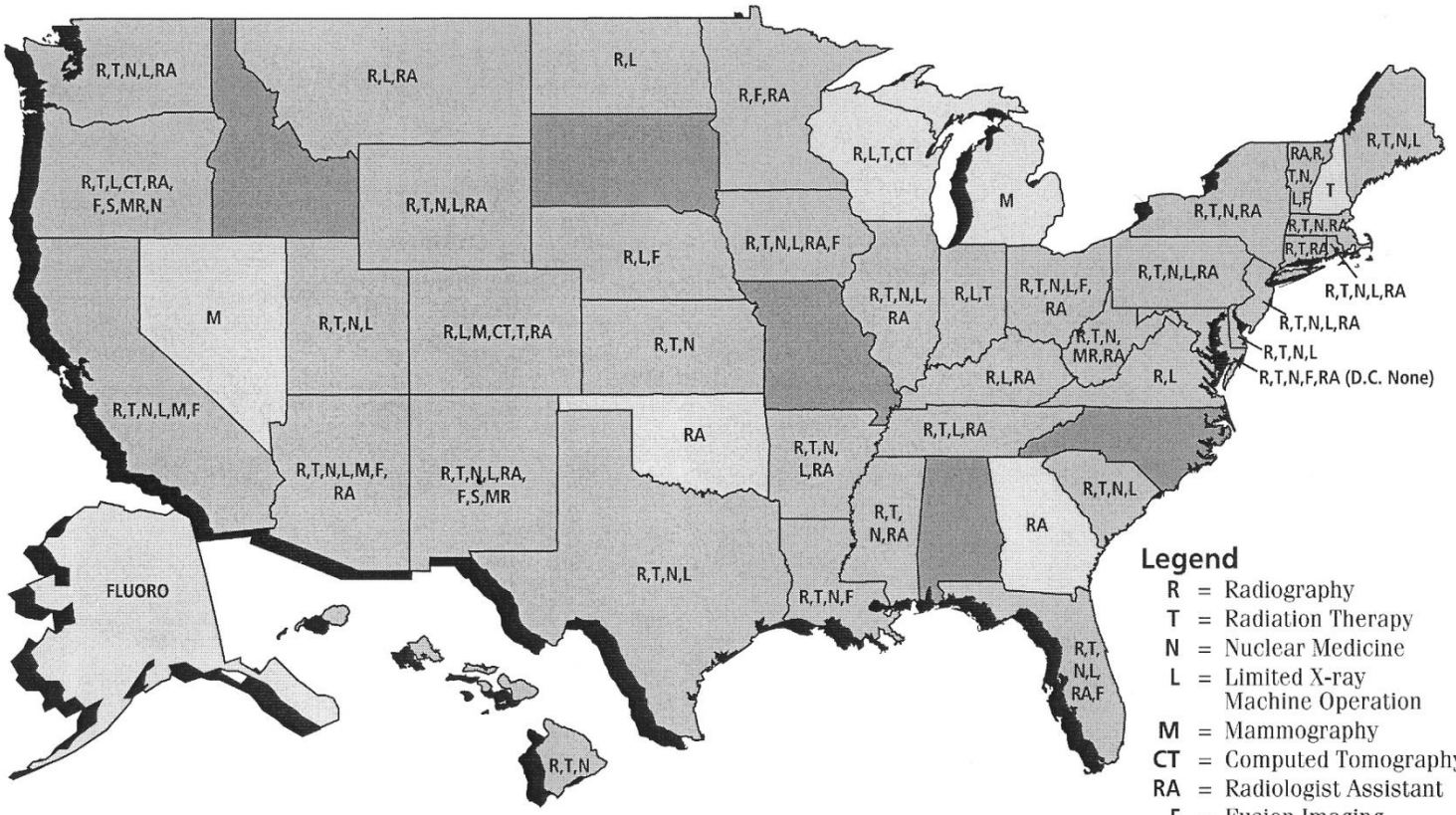
Arkansas	Ohio	Texas
Delaware	South Carolina	Washington

Fluoroscopy Only (1 state)

Alaska

asrt
American Society of Radiologic Technologists

Does Your State Regulate Medical Imaging and Radiation Therapy Technologists?



Legend

R	=	Radiography
T	=	Radiation Therapy
N	=	Nuclear Medicine
L	=	Limited X-ray Machine Operation
M	=	Mammography
CT	=	Computed Tomography
RA	=	Radiologist Assistant
F	=	Fusion Imaging
S	=	Sonography
MR	=	Magnetic Resonance

States That Do Not Have Any Licensure or Regulatory Provisions For Radiologic Personnel*

Alabama	Idaho	North Carolina
	Missouri	South Dakota

*List complete as of July 1, 2010. In addition to the listed states, the District of Columbia also does not regulate radiologic personnel.

States That Regulate

States That Do Not Regulate

States That Partially Regulate

asrt®

American Society of
Radiologic Technologists

Code of Ethics

1 The radiologic technologist conducts herself or himself in a professional manner, responds to patient needs and supports colleagues and associates in providing quality patient care.

2 The radiologic technologist acts to advance the principal objective of the profession to provide services to humanity with full respect for the dignity of mankind.

3 The radiologic technologist delivers patient care and service unrestricted by concerns of personal attributes or the nature of the disease or illness, and without discrimination on the basis of sex, race, creed, religion or socio-economic status.

4 The radiologic technologist practices technology founded upon theoretical knowledge and concepts, uses equipment and accessories consistent with the purpose for which they were designed and employs procedures and techniques appropriately.

5 The radiologic technologist assesses situations; exercises care, discretion and judgment; assumes responsibility for professional decisions; and acts in the best interest of the patient.

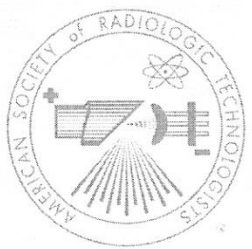
6 The radiologic technologist acts as an agent through observation and communication to obtain pertinent information for the physician to aid in the diagnosis and treatment of the patient and recognizes that interpretation and diagnosis are outside the scope of practice for the profession.

7 The radiologic technologist uses equipment and accessories, employs techniques and procedures, performs services in accordance with an accepted standard of practice and demonstrates expertise in minimizing radiation exposure to the patient, self and other members of the health care team.

8 The radiologic technologist practices ethical conduct appropriate to the profession and protects the patient's right to quality radiologic technology care.

9 The radiologic technologist respects confidences entrusted in the course of professional practice, respects the patient's right to privacy and reveals confidential information only as required by law or to protect the welfare of the individual or the community.

10 The radiologic technologist continually strives to improve knowledge and skills by participating in continuing education and professional activities, sharing knowledge with colleagues and investigating new aspects of professional practice.



Revised and adopted by the American Society of Radiologic Technologists and the American Registry of Radiologic Technologists, February 2003

asrt®

American Society of
Radiologic Technologists

Radiation Therapist
Code of Ethics

1 The radiation therapist advances the principal objective of the profession to provide services to humanity with full respect for the dignity of mankind.

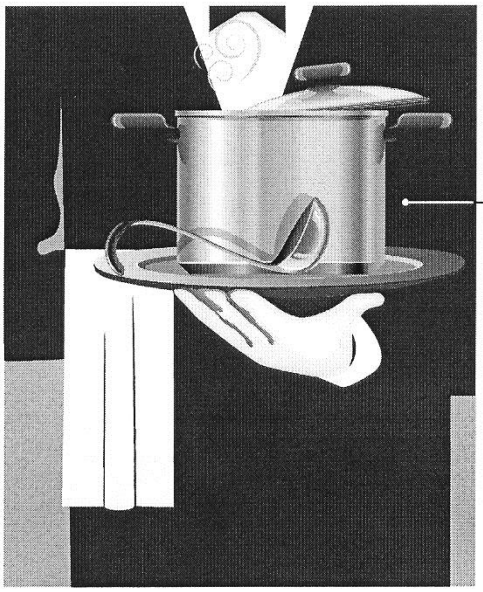
2 The radiation therapist delivers patient care and service unrestricted by concerns of personal attributes or the nature of the disease or illness, and without discrimination on the basis of sex, race, creed, religion or socioeconomic status.

3 The radiation therapist assesses situations; exercises care, discretion and judgment; assumes responsibility for professional decisions and acts in the best interest of the patient.

4 The radiation therapist adheres to the tenets and domains of the scope of practice for radiation therapists.

5 The radiation therapist actively engages in lifelong learning to maintain, improve and enhance professional competence and knowledge.

Revised and adopted by the American Society of Radiologic Technologists, July 1998



Alphabet Soup

A Guide to Organizations In Radiologic Technology

Ingredients: ASRT, JRCNMT, ARRT, JRCERT, ARDMS, AAMD, NMTCB, MDCB, SNMTS, SVU and many more...

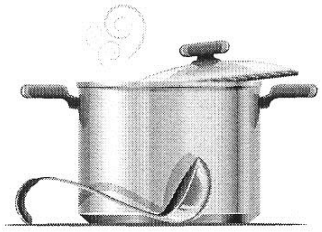
Many organizations play key roles in the professional lives of radiologic technologists. From evaluating the quality of the educational programs they attend to upholding the standards of the profession they've chosen, these organizations provide assistance and support throughout every phase of a radiologic technologist's career.

This brochure was developed by the ASRT as a guide to the different types of organizations that serve the radiologic science community, focusing on their responsibilities to the radiologic technologist as well as their relationships to one another. It also introduces the reader to many of these groups, helping make the "alphabet soup" of radiologic science organizations a little easier to swallow.

To obtain additional copies, contact the ASRT Member Services Department at 800-444-2778, then press 5.

The three primary types of organizations that influence an R.T.'s professional life are **Accreditation** accreditation agencies, certification bodies and membership associations. Working in cooperation with **Certification** one another as well as with educators, employers and government agencies, these groups help define the **Membership** parameters of radiologic technology. Inside, you'll learn more about the roles of each of these types of organizations.

Accreditation Agencies



Accreditation agencies protect radiologic science students by ensuring that the educational programs they attend meet standardized criteria. Typically, an accreditation agency reviews a program's admissions policy, curriculum, academic practices, faculty qualifications and other criteria before deciding whether to grant approval. Although accreditation is voluntary, most of the certification bodies in radiologic technology have made graduation from an accredited program a prerequisite for taking a certification examination.

Educational programs in radiologic technology are housed in universities, community colleges, hospitals, military hospitals and other institutions. They may award a two-year certificate, a two-year associate degree or a four-year baccalaureate degree. Some programs offer postbaccalaureate certificates and master's degrees. Generally, programs must follow a standardized curriculum to earn accredited status. The curriculum usually is developed by the profession's membership associations in consultation with educators and managers.

There are two types of accrediting agencies — regional accreditation agencies and programmatic accreditation agencies. Regional agencies, such as the Middle States Association of Colleges and Schools and the Northwest Association of Schools and Colleges, accredit degree-granting colleges and universities. These agencies examine an institution as a whole rather than specific educational programs within the institution.

Programmatic agencies accredit only the specific programs they are authorized to evaluate. The three programmatic accreditation agencies that evaluate the majority of radiologic science programs are the Joint Review Committee on Education in Radiologic Technology (JRCERT), the Joint Review Committee on Educational Programs in Nuclear Medicine Technology (JRCNMT) and the Joint Review Committee on Education in Diagnostic Medical Sonography (JRC-DMS).

The accreditation process benefits patients as well as students, because it helps ensure that future practitioners graduate with a standard level of competency.

Programs Accredited in 2010

Accredited by JRCERT	
Radiography Programs	629
Radiation Therapy Programs	82
Medical Dosimetry Programs	15
Magnetic Resonance Programs	3
Accredited by JRCNMT	
Nuclear Medicine Programs	99
Accredited by JRC-DMS	
Sonography Programs	185

Certification Bodies

In many ways, certification bodies are the gatekeepers of radiologic technology. Using a standardized examination process, they identify the individuals who are qualified to enter the profession. Some certification bodies also administer "postprimary" examinations, designed to demonstrate a technologist's ability to specialize in a particular area of practice.

To be eligible to take a certification examination, an individual usually must graduate from an accredited educational program and fulfill specific clinical competencies. However, a few certification bodies allow indiviaduals to take a certification examination after they have completed a certain amount of clinical experience, regardless of whether they graduated from a formal educational program in the field.

Examination material is developed by "item writers," volunteer radiologic technologists, educators and administrators specially trained to develop examination questions. Questions then are assembled into examination forms by exam committees. The questions usually are based on specific competencies that an entry-level radiologic technologist should be able to perform.

The three primary certification bodies in medical imaging and the radiologic sciences are the American Registry of Radiologic Technologists (ARRT), the American Registry for Diagnostic Medical Sonography (ARDMS) and the Nuclear Medicine Technology Certification Board (NMTCB). Approximately 300,000 radiologic technologists are certified by the ARRT, 60,000 sonographers and other sonography practitioners are certified by the ARDMS, and 25,000 nuclear medicine technologists are certified by the NMTCB. Other certification bodies in the profession include the Medical Dosimetrist Certification Board (MDCB) and Cardiovascular Credentialing International (CCI), which offers four certification exams.

Certification bodies award credentials to individuals who pass the examinations they administer. For example, a person who passes the ARRT certification examination in radiography earns the right to use the credential "R.T.(R)(ARRT)," while a person who passes the ARDMS certification examination in diagnostic medical sonography is awarded the credential "RDMS." A list of the primary certification examinations and credentials is provided in the box on Page 3.

After radiologic technologists pass their certification examinations, their certificates are "registered" by the awarding certification body. Registrations must be renewed annually, and most certification bodies require technologists to earn continuing education credits to maintain their registrations. Each certification body sets its own CE requirements. The ARRT, which registers the majority of radiologic technologists, mandates that its registrants earn 24 CE credits every two years.

Certification is a voluntary process, but many employers hire only certified technologists. In addition, many states recognize national certification as one of the qualifications for licensure as a radiologic technologist.

Certification Examinations

Administered by ARRT	Credential Awarded
Primary Examinations	
Radiography	R.T.(R)
Radiation Therapy	R.T.(T)
Nuclear Medicine Technology	R.T.(N)
Magnetic Resonance Imaging	R.T.(MR)
Sonography	R.T.(S)
Postprimary Examinations	
Computed Tomography	(CT)
Magnetic Resonance Imaging	(MR)
Mammography	(M)
Quality Management	(QM)
Sonography	(S)
Breast Sonography	(BS)
Vascular Sonography	(VS)
Cardiac-Interventional	(CI)
Vascular-Interventional	(VI)
Bone Densitometry	(BD)
Advanced Practice	
Registered Radiologist Assistant	R.R.A.
Administered by ARDMS	
Diagnostic Medical Sonography	RDMS
Vascular Technology	RVT
Diagnostic Cardiac Sonography	RDCS
Administered by NMTCB	
Nuclear Medicine Technology	CNMT
Nuclear Cardiology Technology	NCT
Positron Emission Technology	PET
Administered by MDCB	
Medical Dosimetry	CMD

Membership Associations

According to the American Society of Association Executives, 70 percent of American adults belong to at least one association, club or society, many of them related to their professional interests or careers. Associations inform, represent and lead their members, but they also provide them with something intangible: They offer their members a sense of belonging by creating a community of individuals with similar needs, desires and interests.

In the radiologic sciences, dozens of professional associations provide their members with everything from newsletters and conferences to practice standards and codes of ethics. These associations work closely with the profession's accreditation agencies and certification bodies to develop curricula, establish entry-level standards and promote radiologic technology as a career.

Many radiologic science associations also provide their members with continuing education materials, assist them with career and practice issues, and monitor state and federal legislation that affects the profession.

Most of the membership associations in the radiologic sciences are governed by officers elected by the membership. Most also appoint individual members to serve on committees or task forces to complete the work of the association. Some of the larger associations also hire professional staff to perform daily operations such as maintaining the society's database, publishing its journals or organizing its educational conferences.

The American Society of Radiologic Technologists (ASRT) is the largest of the profession's membership associations, with more than 140,000 members. It also is the only association that represents all medical imaging technologists, no matter what their area of practice, as well as medical dosimetrists, radiation therapists and radiologic science students, educators and administrators.

Fifty-two associations are affiliates of the ASRT. Affiliates send representatives to ASRT's House of Delegates, the society's legislative arm. Also serving in the House are delegates from each of ASRT's 15 chapters, representing specialty areas of practice.

Other membership associations in the profession focus on serving specific groups of technologists, educators or administrators. They include the American Association of Medical Dosimetrists (AAMD), American Health Care Radiology Administrators (AHRA), American Society of Echocardiography (ASE), Association of Educators in Imaging and Radiologic Sciences (AEIRS), Association of Vascular and Interventional Radiographers (AVIR), Society for Radiation Oncology Administrators (SROA), Society of Diagnostic Medical Sonographers (SDMS), Society of Nuclear Medicine Technologist Section (SNMTS), Society for Vascular Ultrasound (SVU) and many others. Membership in these groups ranges from less than 100 to several thousand.

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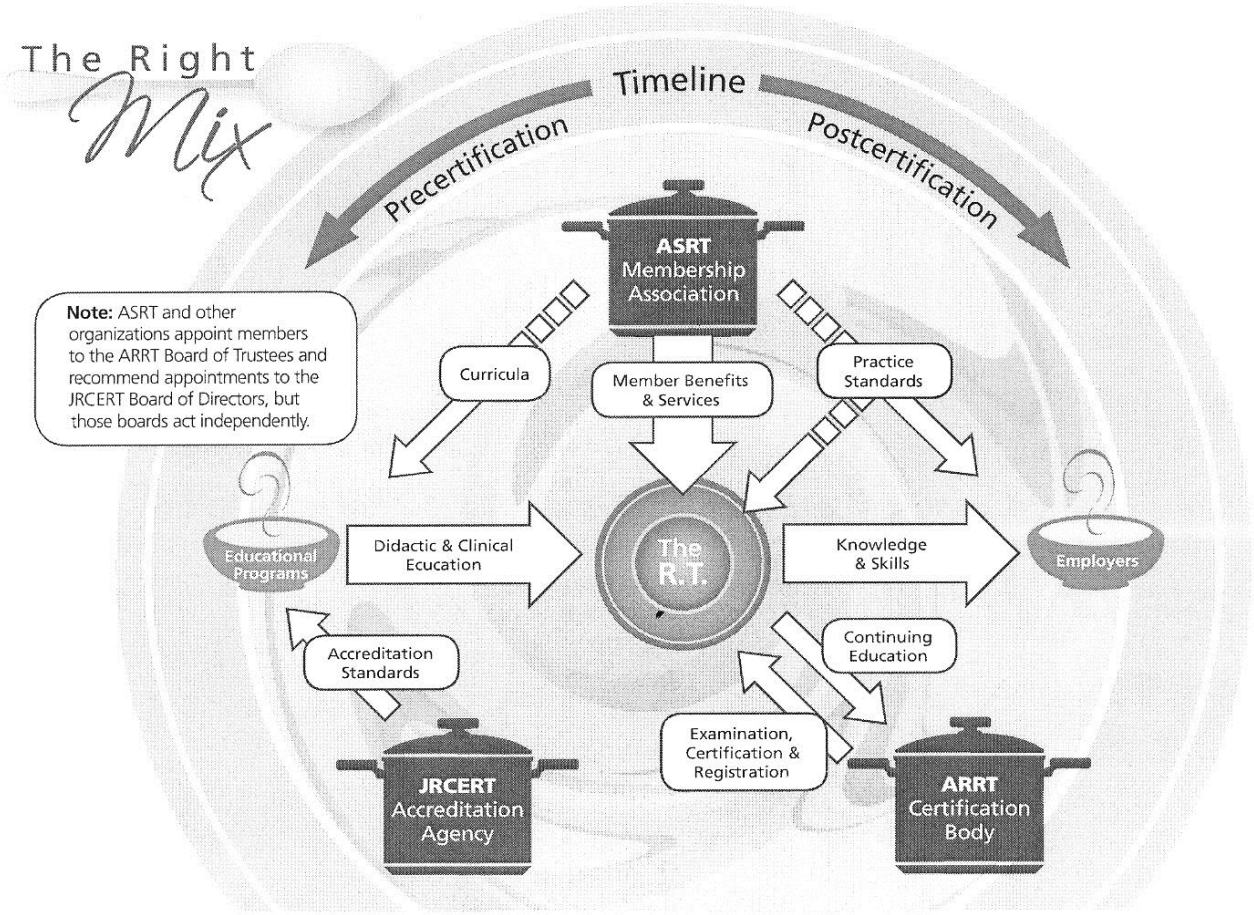

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MembershipAssociations

Membership associations collaborate with one another and with certification bodies and accreditation agencies on a range of projects. For example, the Alliance for Quality Medical Imaging and Radiation Therapy is a coalition of organizations working with Congress to establish federal standards for personnel who perform radiologic procedures.

Working with the profession's certification bodies and accreditation agencies, membership associations help ensure that radiologic technologists provide quality patient care.

asrt
American Society of Radiologic Technologists

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www.asrt.org

A Closer Look at the Roles

The ASRT, ARRT and JRCERT are the largest membership association, certification body and accreditation agency in the radiologic sciences. The graphic above demonstrates a few of the ways these organizations interact with one another as well as with employers, educational programs and the R.T. (Note that the relationships between other membership, certification and accreditation organizations may differ.)

As an example, let's follow the career of a typical radiologic technologist. Jane enrolls in an educational program that has been accredited by the JRCERT and that follows a curriculum developed by the ASRT. When she graduates, she takes the ARRT certification exam in radiography. The content specifications for the exam were developed by the ARRT based on entry-level practice, and her educational program helped her prepare for the exam by assuring that she studied an approved curriculum. Jane passes the exam, entitling her to use the credential "R.T.(R)." She also joins the ASRT.

Jane gets a job as a staff radiographer at a local hospital, where she follows the practice standards developed by the ASRT. To maintain her status as a registered technologist, she earns continuing education credits as mandated by the ARRT. She earns many of these credits by participating in CE programs offered by the ASRT, as well as through CE programs offered by industry and her employer. Her CE credits are tracked by the ASRT as a member service.

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Associated Fractures (comorbidity)

This is a failure to recognise associated pathology

This is sometimes a form of referral failure best illustrated by example- when a patient presents with a widened ankle mortise following trauma, there can be an associated fracture of the upper third of the fibula. Failure to recognise this association can result in a missed diagnosis of Maisonneuve fracture

Case 1

Case 1

This patient presented to the Emergency Department following an injury to his lower leg. He was assessed to have a painful and swollen ankle and was referred for ankle radiography

The ankle images demonstrate a widening of the ankle mortise on the AP image and a fibula fracture is also demonstrated. (os trigonum also noted)

A widened ankle mortise is associated with fractures of the upper third of the fibula. This is known as a Maisonneuve fracture. Failure to assess the upper fibula radiographically can result in a misdiagnoses and inappropriate treatment

The patient's knee was also imaged confirming the diagnosis of Maisonneuve fracture. Note that it is difficult to eliminate the associated upper fibula fracture by clinical examination. Experience has shown that the upper fibula fracture may appear asymptomatic (clinically occult) because of the distracting an

Case 2- Single View Inadequate

This is an AP shoulder image in a patient who was referred for clavicle radiography. There is no displaced clavicle fracture seen.

The dedicated clavicle view demonstrates a fracture which was not visible on the AP shoulder view

Case 3- Two Views Inadequate

This patient presented to the Emergency Department after stubbing her toe on a door frame. She was referred for a foot X-ray examination. The radiographer has performed AP and oblique (DPO) views of the forefoot. No displaced fracture is clearly demonstrated

Is this examination adequate given that the patient has a sore and swollen big toe only?

answer- no

...see below

A lateral toe view was performed and revealed a hyperflexion avulsion fracture of the distal phalanx of the big toe.

You could argue that this is a referral failure given that the referring doctor asked for a foot X-ray examination rather than a toe X-ray examination. I don't see it that way. The radiographer is the expert on radiographic views and should play an advisory role with the referring doctor. The views performed should take into account all of the relevant information including the mechanism of injury and the patient's symptoms

Case 4- Three Views Inadequate

I have included this case in the **Satisfaction Syndrome** section but it could equally belong here. These are three routine views of a trauma ankle. There is a clearly demonstrated spiral fracture of the fibula. The radiographer noted a subtle lucency in the posterior tibia and performed a supplementary off-lateral view.

...see below

If you look closely at the repeat lateral ankle a posterior malleolus tibial fracture is also demonstrated. This is a case where three views were not sufficient to demonstrate all of the bony injuries.

Summary: The number of views required is the number needed to demonstrate all of the demonstratable pathology

Case 5

Neck of Femur Fractures

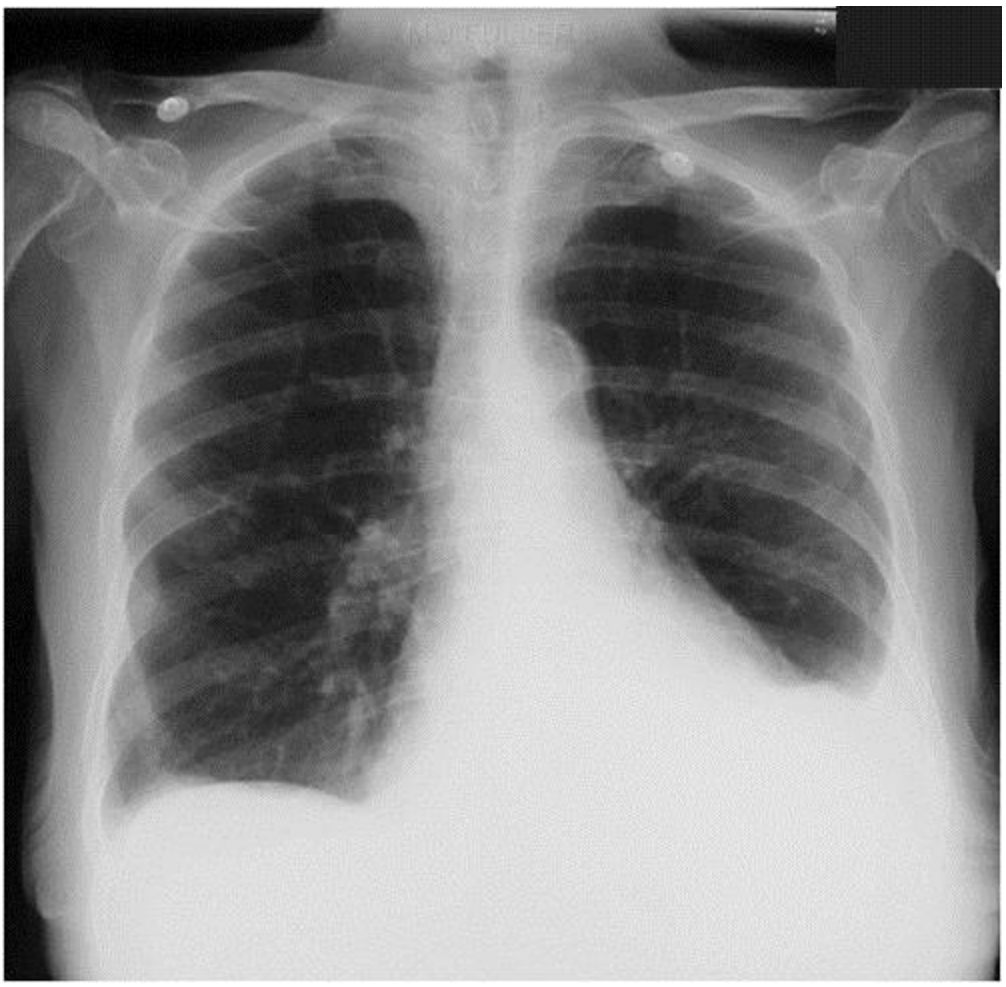
The diagnosis of neck of femur fracture is difficult if the patient's feet are not internally rotated as shown above

External rotation

Artifacts

Artifacts can both obscure pathology and mimic pathology

Case 6



This patient has what appears to be a left pneumothorax. It is actually a skin fold artifact that is caused by the patient's skin puckering up against the X-ray cassette. Skin folds like this one can be misinterpreted as pneumothoraces and treated with

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The Practice Standards for Medical Imaging and Radiation Therapy

Radiography Practice Standards

Effective June 27, 2010 R 2

Introduction to Radiography Practice Standards

The practice of radiography is performed by a segment of health care professionals responsible for the administration of ionizing radiation to humans and animals for diagnostic, therapeutic, or research purposes. A radiographer performs radiographic procedures and related techniques, producing images for the interpretation by, or at the request of, a licensed independent practitioner. The complex nature of disease processes involves multiple imaging modalities. Although an interdisciplinary team of radiologists, radiographers, and support staff plays a critical role in the delivery of health services, it is the radiographer who performs the radiographic examination that creates the images needed for diagnosis. Radiography integrates scientific knowledge, technical skills, patient interaction, and care resulting in diagnostic information. A radiographer recognizes patient conditions essential for successful completion of the procedure and exercises independent professional and ethical judgment.

Radiographer – General Requirements

Radiographers must demonstrate an understanding of human anatomy, physiology, pathology, and medical terminology.

Radiographers must maintain a high degree of accuracy in radiographic positioning and exposure technique. They must maintain knowledge of radiation protection and safety. Radiographers independently perform or assist the licensed independent practitioner in the completion of radiographic procedures. Radiographers prepare, administer, and document activities related to contrast media and medications in accordance with state and federal regulations or lawful institutional policy.

Radiographers are the primary liaison between patients, licensed independent practitioners, and other members of the support team. Radiographers must remain sensitive to the physical and emotional needs of the patient through good communication, patient assessment, patient monitoring, and patient care skills. Radiographers use independent, professional, ethical judgment and critical thinking. Quality improvement and customer service allow the radiographer to be a responsible member of the health care team by continually assessing professional performance. Radiographers engage in continuing education to enhance patient care, public education, knowledge, and technical competence while embracing lifelong learning.

Education and Certification

Radiographers prepare for their role on the interdisciplinary team by successfully completing an accredited educational program in radiologic technology. Two-year certificate, associate degree, and four-year baccalaureate degree programs exist throughout the United States. Accredited programs must meet specific curricular and educational standards.

Upon completion of a course of study in radiologic technology from an accredited program recognized by the American Registry of Radiologic Technologists (ARRT), individuals may apply to take the national certification examination. Those who successfully complete the certification examination in radiography may use the credential R.T.(R) following their name;

the R.T. signifies registered technologist and the (R) indicates radiography. To maintain ARRT certification, radiographers must complete appropriate continuing education requirements in order to sustain a level of expertise and awareness of changes and advances in practice. **Practice Standards** The practice standards define the practice and establish general criteria to determine compliance. Practice standards are authoritative statements established by the profession for judging the quality of practice, service, and education.

Professional practice constantly changes as a result of a number of factors including technological advances, market and economic forces, and statutory and regulatory mandates. While a minimum standard of acceptable performance is appropriate and should be followed by all practitioners, it is inappropriate to assume that professional practice is the same in all regions of the United States.[1] Community custom, state statute or regulation may dictate practice parameters. W*herever there is a conflict between these standards and state or local statutes and regulations, the state or local statutes and regulations supersede these standards*. Recognizing this, the profession has adopted standards that are general in nature. A radiographer should, within the boundaries of all applicable legal requirements and restrictions, exercise individual thought, judgment and discretion in the performance of the procedure. **Format** The Practice Standards are divided into five sections: scope of practice, clinical performance, quality performance, professional performance and advisory opinion. *Scope of Practice*. The scope of practice delineates the parameters of the radiography practice. *Clinical Performance Standards*. The clinical performance standards define the activities of the practitioner in the care of patients and delivery of diagnostic or therapeutic procedures. The section incorporates patient assessment and management with procedural analysis, performance, and evaluation. *Quality Performance Standards*. The quality performance standards define the activities of the practitioner in the technical areas of performance including equipment and material assessment, safety standards, and total quality management. *Professional Performance Standards*. The professional performance standards define the activities of the practitioner in the areas of education, interpersonal relationships, self-assessment, and ethical behavior.

[1] The terms "practice" and "practitioner" are used in all areas of the standards in place of the various names used in medical imaging and radiation therapy, such as radiologic technologist, sonographer, or radiation therapist. Practitioner is defined as any individual practicing in a specific area or discipline. The profession believes that any individual practicing in one of the defined disciplines or specialties should be held to a minimum standard of performance to protect the patients who receive professional services.

Advisory Opinion Statements. The advisory opinions are interpretations of the standards intended for clarification and guidance for specific practice issues.

A profession's practice standards serve as a guide for appropriate practice. Practice standards provide role definition for practitioners that can be used by individual facilities to develop job descriptions and practice parameters. Those outside the imaging, therapeutic, and radiation science community can use the standards as an overview of the role and responsibilities of the practitioner as defined by the profession.

Each section is subdivided into individual standards. The standards are numbered and followed by a term or set of terms that identify the standards, such as "assessment" or "analysis/determination." The next statement is the expected performance of the practitioner when performing the procedure or treatment. A rationale statement follows and explains why a practitioner should adhere to the particular standard of performance.

Criteria. Criteria are used in evaluating a practitioner's performance. Each set is divided into two parts: the general criteria and the specific criteria. Both criteria should be used when evaluating performance.

General Criteria. General criteria are written in a style that applies to imaging and radiation science practitioners. These criteria are the same in all sections of the standards and should be used for the appropriate area of practice.

Specific Criteria. Specific criteria meet the needs of the practitioners in the various areas of professional performance. While many areas of performance within imaging and radiation sciences are similar, others are not. The specific criteria are drafted with these differences in mind.

The Practice Standards for Medical Imaging and Radiation Therapy
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Radiographer Scope of Practice

The scope of practice of the radiographer includes:
1. Performing diagnostic radiographic procedures.

2. Corroborating patient's clinical history with procedure, ensuring information is documented and available for use by a licensed independent practitioner.

3. Maintaining confidentiality of the patient's protected health information in accordance with the Health Insurance Portability and Accountability Act.

4. Preparing the patient for procedures, providing instructions to obtain desired results, gaining cooperation, and minimizing anxiety.

5. Selecting and operating imaging equipment, and/or associated accessories to successfully perform procedures.

6. Positioning patient to best demonstrate anatomic area of interest, respecting patient ability and comfort.

7. Immobilizing patients as required for appropriate examination.

8. Determining radiographic technique exposure factors.

9. Applying principles of radiation protection to minimize exposure to patient, self, and others.

10. Evaluating radiographs or images for technical quality, ensuring proper identification is recorded.

11. Assuming responsibility for provision of physical and psychological needs of patients during procedures.

12. Performing venipunctures where state statute(s) and/or institutional policy permits.

13. Identifying, preparing and/or administering medications as prescribed by a licensed practitioner.

14. Verifying informed consent for, and assisting a licensed independent practitioner with, interventional procedures.

15. Assisting licensed independent practitioner with fluoroscopic and specialized interventional radiography procedures.

16. Performing noninterpretive fluoroscopic procedures as appropriate and consistent with applicable state statutes.

17. Initiating basic life support action when necessary.

18. Providing patient education.

19. Providing input for equipment purchase and supply decisions.

20. Providing practical instruction for students and/or other health care professionals.

21. Participating in the department's quality assessment and improvement plan.

22. Maintaining control of inventory and purchase of supplies for the assigned area.

23. Observing universal precautions.

24. Performing peripherally inserted central catheter placement where state statute(s) and/or lawful institutional policy permits.

25. Applying the principles of patient safety during all aspects of radiographic procedures, including assisting and transporting patients.

26. Starting and maintaining intravenous (IV) access per orders when applicable.

Comprehensive Practice
Radiographic procedures are performed on any or all body organs, systems, or structures. Individuals demonstrate competency to meet state licensure, permit, or certification requirements defined by law for radiography; or maintain appropriate credentials.

The Practice Standards for Medical Imaging and Radiation Therapy

Effective June 27, 2010 R 7

Radiography Clinical Performance Standards

Standard One – Assessment

The practitioner collects pertinent data about the patient and the procedure.

Rationale

Information about the patient's health status is essential in providing appropriate imaging and therapeutic services.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Uses consistent and appropriate techniques to gather relevant information from the patient, medical record, significant others, and health care providers.

2. Reconfirms patient identification and verifies the procedure requested or prescribed.

3. Reviews the patient's medical record to verify the appropriateness of a specific exam or procedure.

4. Verifies the patient's pregnancy status.

5. Determines whether the patient has been prepared for the procedure.

6. Corroborates patient's clinical history with procedure.

7. Assesses factors that may contraindicate the procedure, such as medications, patient history, insufficient patient preparation, or artifacts.

8. Recognizes signs and symptoms of an emergency.

Specific Criteria

The practitioner:

1. Assesses patient risk for allergic reaction to contrast media prior to administration.

2. Locates and reviews previous examinations for comparison.

3. Receives, relays, and documents verbal and/or telephone orders in the patient's chart where state statute and/or lawful institutional policy permit.

4. Identifies and removes artifact-producing objects such as dentures, telemetry units, chest leads, jewelry, and hearing aids.

Standard Two – Analysis/Determination

The practitioner analyzes the information obtained during the assessment phase and develops an action plan for completing the procedure.

Rationale

Determining the most appropriate action plan enhances patient safety and comfort, optimizes diagnostic and therapeutic quality, and improves efficiency.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Selects the most appropriate and efficient action plan after reviewing all pertinent data and assessing the patient's abilities and condition.

2. Uses professional judgment to adapt imaging and therapeutic procedures to improve diagnostic quality and therapeutic outcome.

3. Consults appropriate medical personnel to determine a modified action plan.

4. Determines the need for and selects supplies, accessory equipment, shielding, and immobilization devices.

5. Determines the course of action for an emergency or problem situation.

6. Determines that all procedural requirements are in place to achieve a quality diagnostic or therapeutic procedure.

Specific Criteria

The practitioner:

1. Evaluates lab values prior to administering contrast media and beginning interventional procedures.

2. Determines type and dose of contrast agent to be administered, based on the patient's age, weight, and medical/physical status.

The Practice Standards for Medical Imaging and Radiation Therapy

Effective June 27, 2010 R 9

Standard Three – Patient Education

The practitioner provides information about the procedure and related health issues according to protocol.

Rationale

Communication and education are necessary to establish a positive relationship.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Verifies that the patient has consented to the procedure and fully understands its risks, benefits, alternatives, and follow-up. When appropriate, the practitioner verifies that written or informed consent has been obtained.

2. Provides accurate explanations and instructions at an appropriate time and at a level the patients and their care providers can understand. Addresses patient questions and concerns regarding the procedure.

3. Refers questions about diagnosis, treatment, or prognosis to a licensed independent practitioner.

4. Provides related patient education.

Specific Criteria

The practitioner:

1. Consults with other departments, such as patient transportation and anesthesia, for patient services.

2. Instructs patients regarding preparation prior to imaging procedures, including providing information about oral or bowel preparation and allergy preparation.

3. Explains precautions regarding administration of pharmaceuticals.

The Practice Standards for Medical Imaging and Radiation Therapy Effective June 27, 2010 R 10 Standard Four – Performance

The practitioner performs the action plan.

Rationale

Quality patient services are provided through the safe and accurate performance of a deliberate plan of action.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Performs procedural time-out.

2. Implements an action plan.

3. Explains each step of the action plan to the patient as it occurs and elicits the cooperation of the patient.

4. Uses an integrated team approach.

5. Modifies the action plan according to changes in the clinical situation.

6. Administers first aid or provides basic life support in emergency situations.

7. Uses accessory equipment.

8. Assesses and monitors the patient's physical, emotional, and mental status.

9. Administers oxygen as prescribed.

10. Uses principles of sterile technique.

11. Positions patient for anatomic area of interest, respecting patient ability and comfort.

12. Immobilizes patient for examination.

Specific Criteria

The practitioner:

1. Performs venipuncture, IV patency, and maintenance procedures.
2. Administers pharmaceuticals.
3. Monitors the patient for reactions to pharmaceuticals.
4. Uses radiation shielding devices.
5. Utilizes technical factors according to equipment specifications to minimize radiation exposure to the patient.

The Practice Standards for Medical Imaging and Radiation Therapy

Effective June 27, 2010 R 11

Standard Five – Evaluation

The practitioner determines whether the goals of the action plan have been achieved.

Rationale

Careful examination of the procedure is important to determine that expected outcomes have been met.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Evaluates the patient and the procedure to identify variances that may affect the expected outcome.

2. Completes the evaluation process in a timely, accurate, and comprehensive manner.

3. Measures the procedure against established policies, protocols, and benchmarks.

4. Identifies exceptions to the expected outcome.

5. Documents exceptions in a timely, accurate, and comprehensive manner.

6. Develops a revised action plan if necessary to achieve the intended outcome.

7. Communicates revised action plan to appropriate team members.

Specific Criteria

The practitioner:

1. Evaluates images for positioning, appropriate anatomy, and overall image quality.

2. Reviews images to determine if additional images will enhance the diagnostic value of the procedure.

Standard Six – Implementation

The practitioner implements the revised action plan.

Rationale

It may be necessary to make changes to the action plan to achieve the expected outcome.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Bases the revised plan on the patient's condition and the most appropriate means of achieving the expected outcome.

2. Takes action based on patient and procedural variances.

3. Measures and evaluates the results of the revised action plan.

4. Notifies appropriate health care provider when immediate clinical response is necessary based on procedural findings and patient condition.

Specific Criteria

The practitioner:

1. Performs additional views.

2. Documents justification for additional views.

3. Adjusts imaging parameters, patient procedure, or computer-generated information to improve the outcome.

Standard Seven – Outcomes Measurement

The practitioner reviews and evaluates the outcome of the procedure.
Rationale
To evaluate the quality of care, the practitioner compares the actual outcome with the expected outcome.
General Stipulation
Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.
General Criteria
The practitioner:
1. Reviews all diagnostic or therapeutic data for completeness and accuracy.

2. Determines whether the actual outcome is within established criteria.

3. Evaluates the process and recognizes opportunities for future changes.

4. Assesses the patient's physical, emotional, and mental status prior to discharge from the practitioner's care.

Specific Criteria

Standard Eight – Documentation

The practitioner documents information about patient care, the procedure, and the final outcome.

Rationale

Clear and precise documentation is essential for continuity of care, accuracy of care, and quality assurance.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Documents diagnostic, treatment, and patient data in the record in a timely, accurate, and comprehensive manner.

2. Documents exceptions from the established criteria or procedures.

3. Provides appropriate information to authorized individual(s) involved in the patient's care.

4. Participates in billing and coding procedures.

5. Archives images or data.

Specific Criteria

The practitioner:

1. Documents fluoroscopy time.

2. Documents radiation exposure parameters.

3. Documents procedural time-out.

The Practice Standards for Medical Imaging and Radiation Therapy

Effective June 27, 2010 R 16

Radiography Quality Performance Standards

Standard One – Assessment

The practitioner collects pertinent information regarding equipment, procedures, and the work environment.

Rationale

The planning and provision of safe and effective medical services relies on the collection of pertinent information about equipment, procedures, and the work environment.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Determines that services are performed in a safe environment, free from any potential hazards.

2. Confirms that equipment performance, maintenance, and operation comply with manufacturer's specifications.

3. Verifies that protocol and procedure manuals include recommended criteria and are reviewed and revised.

Specific Criteria

The practitioner:

1. Maintains controlled access to restricted area during radiation exposure.

2. Follows federal and state guidelines to minimize radiation exposure levels.

3. Maintains and performs quality control on radiation safety equipment such as aprons, thyroid shields, etc.

4. Develops and maintains a technique chart for all equipment.

5. Participates in radiation protection, patient safety, risk management, and quality management activities.

Standard Two – Analysis/Determination

The practitioner analyzes information collected during the assessment phase to determine the need for changes to equipment, procedures, or the work environment.

Rationale

Determination of acceptable performance is necessary to provide safe and effective services.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Assesses services, procedures, and environment and adjusts the action plan.

2. Monitors equipment to meet or exceed established standards and adjusts the action plan.

3. Assesses and maintains the integrity of medical supplies such as a lot/expiration, sterility, etc.

Specific Criteria

Standard Three – Education

The practitioner informs the patient, public, and other health care providers about procedures, equipment, and facilities.

Rationale

Open communication promotes safe practices.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Elicits confidence and cooperation from the patient, the public, and other health care providers by providing timely communication and effective instruction.

2. Presents explanations and instructions at the learner's level of understanding.

3. Educates the patient, public, and other health care providers about procedures along with the biological effects of radiation, sound wave, or magnetic field, and protection.

4. Provides information to patients, health care providers, students, and the public concerning the role and responsibilities of individuals in the profession.

Specific Criteria

Standard Four – Performance

The practitioner performs quality assurance activities.

Rationale

Quality assurance activities provide valid and reliable information regarding the performance of equipment, materials, and processes.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Acquires information on equipment, materials, and processes.

2. Performs quality assurance activities.

3. Provides evidence of ongoing quality assurance activities.

4. Verifies performance and results of quality control of imaging and support equipment.

Specific Criteria

The practitioner:

1. Consults with medical physicist in performing and documenting the quality assurance tests.

2. Monitors image production to determine technical acceptability.

3. Performs routine archiving status checks.

The Practice Standards for Medical Imaging and Radiation Therapy

Effective June 27, 2010 R 20

Standard Five – Evaluation

The practitioner evaluates quality assurance results and establishes an appropriate action plan.

Rationale

Equipment, materials, and processes depend on ongoing quality assurance activities that evaluate performance based on established guidelines.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Verifies quality assurance testing conditions and results.

2. Compares quality assurance results to accepted values.

3. Formulates an action plan following the comparison of results.

4. Participates in the institution's quality assessment and improvement plan.

Specific Criteria

None added.Effective June 27, 2010 R 21

Standard Six – Implementation

The practitioner implements the quality assurance action plan for equipment, materials, and processes.

Rationale

Implementation of a quality assurance action plan promotes safe and effective services.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Obtains assistance from qualified personnel to support the quality assurance action plan.

2. Implements the quality assurance action plan.

Specific Criteria

Standard Seven – Outcomes Measurement

The practitioner assesses the outcome of the quality management action plan for equipment, materials, and processes.

Rationale

Outcomes assessment is an integral part of the ongoing quality management action plan to enhance diagnostic and therapeutic services.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Reviews the implementation process for accuracy and validity.

2. Determines that actual outcomes are in compliance with the action plan.

3. Develops and implements a modified action plan.

Specific Criteria

Standard Eight – Documentation

The practitioner documents quality assurance activities and results.

Rationale

Documentation provides evidence of quality assurance activities designed to enhance safety.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Maintains documentation of quality assurance activities, procedures, and results.

2. Provides timely, accurate, and comprehensive documentation.

3. Provides documentation that adheres to protocol, policy, and procedures.

4. Reports the need for equipment maintenance and repair.

Specific Criteria

Radiography Professional Performance Standards

Standard One – Quality

The practitioner strives to provide optimal patient care.

Rationale

Patients expect and deserve optimal care during diagnosis and treatment.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Collaborates with others to elevate the quality of care.

2. Participates in quality assurance programs.

3. Adheres to standards, policies, and procedures adopted by the profession and regulated by law.

4. Applies professional judgment and discretion while performing diagnostic study or treatment.

5. Anticipates and responds to patient needs.

6. Respects cultural variations and addresses misconceptions.

Specific Criteria

Standard Two – Self-Assessment

The practitioner evaluates personal performance.

Rationale

Self-assessment is necessary for personal growth and professional development.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Monitors personal work ethics, behaviors, and attitudes.

2. Evaluates performance and recognizes opportunities for self-improvement.

3. Recognizes and applies personal and professional strengths.

4. Performs procedures only when educationally prepared and clinically competent.

5. Recognizes opportunities for educational growth and improvement in technical and problem-solving skills.

6. Actively participates in professional societies and organizations.

Specific Criteria

Standard Three – Education

The practitioner acquires and maintains current knowledge in clinical practice.

Rationale

Advancements in the profession require additional knowledge and skills through education.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Demonstrates completion of education related to clinical practice.

2. Maintains credentials and certification related to clinical practice.

3. Participates in continuing education and case review to maintain and enhance competency and performance.

4. Shares knowledge and expertise with others.

5. Demonstrates understanding of and continued competency in the functions and operations of equipment, accessories, treatment and imaging methods, and protocols.

Specific Criteria

Standard Four – Collaboration and Collegiality

The practitioner promotes a positive, collaborative practice atmosphere with other members of the health care team.

Rationale

To provide quality patient care, all members of the health care team must communicate effectively and work together efficiently.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Shares knowledge and expertise with members of the health care team.

2. Develops collaborative partnerships to enhance diagnostic and therapeutic quality and efficiency.

3. Promotes understanding of the profession.

Specific Criteria

Standard Five – Ethics

The practitioner adheres to the profession's accepted ethical standards.

Rationale

Decisions made and actions taken on behalf of the patient are based on a sound ethical foundation.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Provides health care services with respect for the patient's dignity, age-specific needs, and culture.

2. Acts as a patient advocate to support patients' rights.

3. Takes responsibility for professional decisions made and actions taken.

4. Delivers patient care and service free from bias or discrimination.

5. Respects the patient's right to privacy and confidentiality.

6. Adheres to the established practice standards of the profession.

Specific Criteria

Standard Six – Research and Innovation

The practitioner participates in the acquisition and dissemination of knowledge and the advancement of the profession.

Rationale

Scholarly activities such as research, scientific investigation, presentation, and publication advance the profession.

General Stipulation

Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards. The individual must be educationally prepared and clinically competent as a prerequisite to professional practice.

General Criteria

The practitioner:

1. Reads and critically evaluates research in diagnostic and therapeutic services.

2. Participates in data collection.

3. Investigates innovative methods for application in practice.

4. Shares information with colleagues through publication, presentation, and collaboration.

5. Adopts new best practices.

6. Pursues lifelong learning.

Specific Criteria

Glossary

Action plan – A program or method developed prior to the performance of the examination or treatment.
Advanced-practice radiologic technologist – A registered technologist who has gained additional knowledge and skills through successful completion of an organized program or radiologic technology education that prepares radiologic technologists for advanced practice roles and has been recognized by the national certification organization to engage in the practice of advanced-practice radiologic technology.
Arthrogram – Visualization of a joint by radiographic study after injection of a contrast medium into joint space.
Artifact – A structure or feature produced by the technique used and not occurring naturally.
Assess – To determine the significance, importance, or value.
Assessment – The process by which a patient's condition is appraised or evaluated.
Clinical – Pertaining to or founded on actual observation and treatment of patients.
Competency – Performance in a manner that satisfies the demands of a situation.
Contrast medium – Substance administered to a patient undergoing an imaging procedure that provides a difference in density (contrast) so that the tissue, organ, or pathology can be better visualized.
Contraindicate – To warrant an otherwise advisable procedure or treatment inappropriate.
Cholangiogram – A radiograph of the bile duct(s).
Cystogram – A radiograph of the bladder.
Delegating radiologist - A board-certified radiologist with appropriate clinical privileges.
Disease – A pathological condition of the body that presents a group of clinical signs, symptoms, and laboratory findings peculiar to it and setting the condition apart as an abnormal entity differing from other normal or pathological conditions.
Ductogram – A radiograph of the breast duct after injection of a contrast medium.
Electrocardiogram (ECG) – A record of the electrical activity of the heart.
Esophagram – A series of x-rays of the esophagus. The x-ray images are captured after the patient drinks a solution that coats and outlines the walls of the esophagus. Also called a barium swallow.
Ethical – Conforming to the norms or standards of professional conduct.
Examination preparation – The act of helping to ready a patient for a diagnostic imaging procedure.
Fistulogram – A radiograph of a sinus tract filled with radiopaque contrast medium to determine the range and course of the tract.
Galactogram – A radiograph of the breast duct after injection of a contrast medium.
Hysterosalpingogram – A radiograph of the uterus and oviducts after injection of a contrast medium.
Initial observation – Assessment of technical image quality with pathophysiology correlation communicated to a radiologist.
Interpretation – The process of examining and analyzing all images within a given procedure and integration of the imaging data with appropriate clinical data in order to render an impression or conclusion set forth in a formal written report signed by the radiologist.
Interventional procedures – Percutaneous catheterization for diagnostic and therapeutic purposes.

Licensed independent practitioner – An individual permitted by law to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted privileges (e.g., physician, nurse practitioner, physician assistant).
Loopogram – A radiograph of the ileal conduit following the injection of a contrast medium.
Medication – Any chemical substance intended for use in the medical diagnosis, cure, treatment or prevention of disease.
Myelogram – A radiograph of the spinal cord and associated nerves.
Paracentesis – Puncture of a cavity with removal of fluid.
Pathophysiology – The study of how normal physiological processes are altered by disease.
Pharmaceutical – See Medication.
Protocol – The plan for carrying out a scientific study or a patient's treatment regimen.

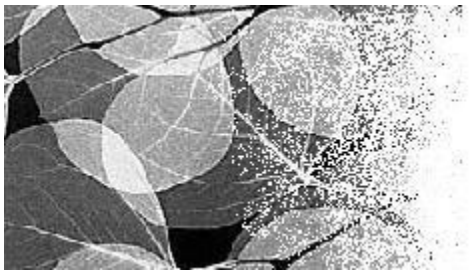
Qualified supervisor – Individual who is educationally prepared, clinically competent, and credentialed in the medical imaging and radiation therapy sciences who provides clinical supervision to the individual.
Quality assurance – Activities and programs designed to achieve a desired degree or grade of care in a defined medical, nursing, or health care setting or program.
Radiation protection – Prophylaxis against injury from ionizing radiation. The only effective preventive measures are shielding the operator, handlers, and patients from the radiation source; maintaining appropriate distance from the source; and limiting the time and amount of exposure.
Radiography – The process of obtaining an image for diagnostic examination using x-rays.
Sinogram – A radiograph of a sinus tract filled with radiopaque contrast medium to determine the range and course of the tract.
T-tube – A device inserted into the biliary duct after removal of the gallbladder.
Thoracentesis – Puncture of the chest wall for removal of fluids, usually done by using a large-bore needle.
Time-out – Immediate preprocedural pause to review procedure and determine the correct procedure is conducted upon the correct patient in the correct manner.
Urethrogram – A radiograph of the urethra after it has been filled with a contrast medium.
Upper GI series – A series of x-rays of the esophagus, stomach, and small intestine (upper gastrointestinal, or GI, tract) that are taken after the patient drinks a barium solution.
Venipuncture – The puncture of a vein.

The Joint Review Committee on Education in Radiologic Technology (JRCERT) promotes excellence in education and elevates the quality and safety of patient care through the accreditation of educational programs in radiography, radiation therapy, magnetic resonance, and medical dosimetry.

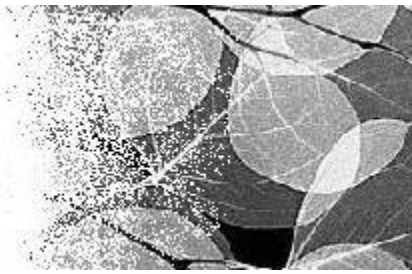
Excellence in education.

- Maintains recognition by the United States Department of Education (USDE) and the Council for Higher Education Accreditation (CHEA) as the only programmatic accreditor for radiologic sciences programs.
- Believes educational quality and integrity cannot be compromised.
- Respects the rights and promotes the welfare of students and patients.
- Appreciates that the programs it serves utilize diverse approaches to quality education.
- Collaborates with other organizations to advance professionalism.

- Exemplifies the highest ethical principles in its actions and decisions.
- Is responsive to the changing needs of the profession.



The History of the X-Ray



Controversies and Problems

Mystery Burns, Radium, and Conspiracy

X-Ray technicians fell victim to the horrible side-effects of radiation. Mihran Kassabian documented and photographed his degeneration, hoping to help later technicians and patients avoid his fate. Copyright Radiology Centennial Inc.[73]

The X-Ray was viewed as a miracle device of the twentieth century;

Americans invested their hopes and dreams of a healthier future in the little tube. Yet the machine was not as wondrous as they thought; the X-Ray's darker side began to raise its ugly head in the early 20th century. Technicians and scientists were struck with burns, cancerous tumors, and lesions where their bodies had been in frequent contact with the machine and its rays. Amateurs stopped experimenting with Crookes tubes after their subjects frequently received burns that would not heal.[74] The discovery of radium in 1898 by the Curies provided an explanation for the dangerous wounds, but the the two ideas were not connected until several years later.[75] Even then the X-Ray community failed to warn the public of the serious dangers they faced every time they were in front of the ray.[76] Meanwhile, the debate over the who should be qualified to take and read the X-Rays raged across America.

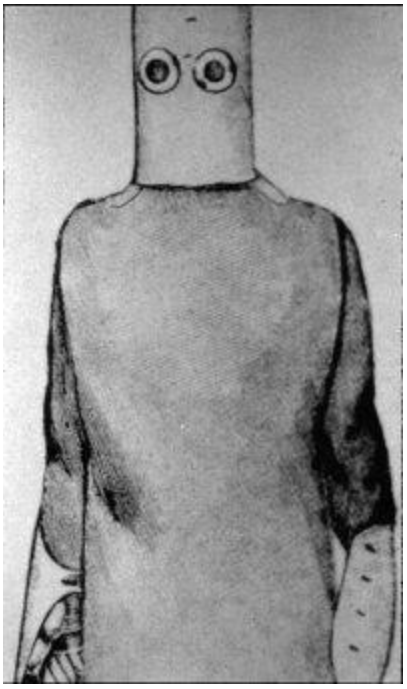
This woman, like thousands of others, suffered from burns, scarring, and cancer after undergoing X-Ray "beauty treatments". Copyright Radiology Centennial Inc.[77]

By the early 1900s, reports of X-Rays damaging skin and killing organic life were widespread.[77] More and more report claimed that X-Rays had caused burns, redness, brown pigmentation, hair loss, and skin cancer.[78] In 1905,13 men w worked with X-Rays for over three years discovered they we impotent.[79] Even Thomas Edison and his assistant were damaged through their work with the rays; Edison complain of sore eyes and skin rashes and his young assistant, Clarence Dally, went through the process of losing all of his hair, every finger, and both hands. The burns had given way to "oozing ulcers measuring three and a half by two and a ha inches across" and he was in constant pain until his death i 1904.[80] A total of 28 Americans died from experimentation alone.[81]

The frightened public looked to scientists and doctors for answers. Phycisians claimed that patients could not be harmed and that these cases were caused by unusual circumstances such as ozone generated by static, excessive heat and moisture, overexposure to electricity, or simply allergies.[83] Scientists cautioned against using X-Rays and advocated the use of lead shields, but their reports were disregarded by most in the medical world. However, a variety of protective suits and zinc salves were placed on the market

to help alleviate the situation.[84] Meanwihle, X-Ray apparatus companies attempted to fix the situation by secretly experimenting with the machines while coating parts of in-use machines with lead, which provided almost no protection whatsoever.[85] The public had no idea of the danger they were in.

A possible explanation emerged in 1898 with the Curie's discovery of radioactivity and radium.[86] This discovery captured the public's imagination as the X-Ray did two years earlier. Radium began to appear everywhere; products such as bottled radium water, toothpaste, suppositories, and glowing radium cocktails along with radioactive hot spring spas were all the rage.[87]However, the fascination was so great that they failed to recognize the dangerous aftermath; only after the death of Marie Curie and other scientists involved in the research of radioactivity was the connection between it and X-Rays made.



Early protective suits made of heavy apro
and metal helmets were introduced into th
market, receiving less than stellar succes
Copyright Radiology Centennial Inc.[82]

Also during this time another problem emerged in the hospital environment. Since their introduction into society, the X-Ray technicians had primarily been photographers, scientists, and engineers.[88] Because the novelty had worn off and the medical world was adopting its use, doctors wanted these technicians who held no medical degrees to either become certified or quit.[89] Special schools were established to train men and women for X-Ray therapy and radiology. Correspondence academies were the most popular among electricians and photographers, allowing them to become "Doctors of Roentology" by mail.[90] Doctors, who were afraid their jobs would be replaced and of malpractice lawsuits, wanted further certification and established the American Roenten Ray Society in 1900, ensuring the reputation of their profession.[91]

Despite all of these problems and solutions, only through the onslaught of WWI and WWII did the X-Ray truly become completely accepted by American culture. More can be learned about this at the Military Impact Page.

The New York Times http://www.nytimes.com/

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February 27, 2011

X-Rays and Unshielded Infants

By WALT BOGDANICH and KRISTINA REBELO

It was well after midnight when Dr. Salvatore J. A. Sclafani finally hit the “send” button.

Soon, colleagues would awake to his e-mail, expressing his anguish and shame over the discovery that the tiniest, most vulnerable of all patients — premature babies — had been over-radiated in the department he ran at State University of New York Downstate Medical Center in Brooklyn.

A day earlier, Dr. Sclafani noticed that a newborn had been irradiated from head to toe — with no gonadal shielding — even though only a simple chest X-rayhad been ordered.

“I was mortified,” he wrote on July 27, 2007. Worse, technologists had given the same baby about 10 of these whole-body X-rays. “Full, unabashed, total irradiation of a neonate,” Dr. Sclafani said, adding, “This poor, defenseless baby.”

And the problems did not end there. Dr. John Amodio, the hospital’s new pediatric radiologist, found that full-body X-rays of premature babies had occurred often, that radiation levels on powerful CT scanners had been set too high for infants, and that babies had been poorly positioned, making it hard for doctors to interpret the images.

The hospital had done the full-body X-rays, known as “babygrams,” even though they had been largely discredited because of concerns about the potential harm of radiation on the young. Dr. Sclafani and Dr. Amodio quickly stopped the babygrams and instituted tight controls on how and when radiation was used on babies, according to doctors who work there. But the hospital never reported the problems in the unit to state health officials as required.

A little over a week ago, after The New York Times asked about the situation at Downstate, the state health commissioner, Dr. Nirav R. Shah, ordered two offices of the department to investigate.

“Our investigators will pull films, they will examine the medical records and they will interview relevant staff,” said Claudia Hutton, the department’s director of public affairs. “Our authority to investigate goes basically as far as we need it to go.”

The New York Times

X-Rays and Unshielded Infants

The errors at Downstate raise broader questions about the competence, training and oversight of technologists who operate radiological equipment that is becoming increasingly complex and powerful. If technologists could not properly take a simple chest X-ray, how can they be expected to safely operate CT scanners or linear accelerators?

With technologists in many states lightly regulated, or not at all, their own professional group is calling for greater oversight and standards. For 12 years, the American Society of Radiologic Technologists has lobbied Congress to pass a bill that would establish minimum educational and certification requirements, not only for technologists, but also for medical physicists and people in 10 other occupations in medical imaging and radiation therapy.

Yet even with broad bipartisan support, the association said, and the backing of 26 organizations representing more than 500,000 health professionals, Congress has yet to pass what has become known as the CARE bill because, supporters say, it lacks a powerful legislator to champion its cause.

In December 2006, the Senate passed the bill, but Congress adjourned before the House could vote. At the time, the House bill had 135 co-sponsors.

“I would think the public would be outraged that Congress was sitting on what could reduce their radiation exposure,” said Dr. Fred Mettler, a radiologist who has investigated and written extensively about radiation accidents.

Individual states decide what standards, if any, radiological workers must meet. Radiation therapists are unregulated in 15 states, imaging technologists in 11 states and medical physicists in 18 states, according to the technologists association. “There are individuals,” said Dr. Jerry Reid, executive director of a group that certifies technologists, “who are performing medical imaging and radiation therapy who are not qualified. It is happening right now.”

Two months ago, in Michigan — which sets no minimum standards for technologists — the Nuclear Regulatory Commission reported that a large hospital had irradiated the healthy tissue of four cancer patients, three of whom suffered burns, because a technologist repeatedly used the wrong radiological device. “It’s amazing to us, knowing the complexity of medical imaging, that there are states that require massage therapists and hairdressers to be licensed, but they have no standards in place for exposing patients to ionizing radiation,” said Christine Lung, the technologist association’s vice president of government relations.

In New York State, technologists must be licensed and prove that they have passed a professional examination. But there were no continuing education requirements — a provision

of the CARE bill — until last year, and regulators usually let hospitals decide whether to discipline technologists. Over the last 10 years, New York health officials say they have not disciplined any of the 20,000 or so licensed technologists for work-related problems.

Children Are Most at Risk

Like many hospitals, SUNY Downstate Medical Center had come to realize that children needed special protection from unnecessary radiation.

Because their cells divide quickly, children are more vulnerable to radiation’s effects. And as new ways are found to use radiation in diagnosing and treating injuries and disease, children face an ever-increasing number of radiological procedures. One recent

study found that by the age of 18, the average child will have already received more than seven radiological exams.

While the procedures save lives, they are also a source of concern because most scientists believe that the effects of radiation are cumulative — the more radiation a patient receives, the greater the chances of developing cancer. In premature infants, minimizing radiation exposure is especially important because they may require multiple radiological exams for problems like underdeveloped respiratory systems.

In 2007, Dr. Sclafani, the radiology chairman, brought in Dr. Amodio, a highly regarded pediatric radiologist, to oversee diagnostic imaging for children and to evaluate existing practices at Downstate, a large teaching hospital that serves mostly the poor.

Dr. Amodio did not like what he saw. “I have started to compile a list of obvious problems with respect to pediatric images, especially in the neonatal population,” he said in a July 26 e-mail to Dr. Sclafani.

A guiding principle for any imaging procedure, regardless of age, is that radiation should be limited — or “coned” — to the area being examined. Yet technologists at Downstate did not always follow that rule. “Improper coning — often entire baby is on radiograph,” Dr. Amodio wrote in the first of several bullet points summarizing his findings.

Full-body X-rays of babies are rarely done. “We don’t do those anymore,” said Dr. Marta Hernanz-Schulman, director of pediatric radiology at Vanderbilt University Medical Center. “If I had an image like that, it would most likely have been a stillborn baby.”

Dr. Donald Frush, chief of pediatric radiology at the Duke University School of Medicine, said that failing to properly cone, or collimate, the radiation was rare. “The collimation issue is

something that technologists are quite aware of and has been emphasized for decades,” Dr. Frush said.

Downstate officials did not say how many inappropriate babygrams were taken. In an interview, Dr. Amodio said he did not know why the technologists had failed to protect the infants, but he surmised that because premature babies are especially fragile, technologists might have been afraid to touch them and "do what was really necessary" to administer proper X-rays. "It is a normal human response," he said.

Asked about the case, Dr. David Keys, a board member of the American College of Medical Physics, said, "It takes less than 15 seconds to collimate a baby," adding: "It could be that the techs at Downstate were too busy. It could be that they were just sloppy or maybe they forgot their training."

In his 2007 e-mail, Dr. Amodio said technologists also failed to shield the gonads, a radiosensitive organ. City and state health codes require shielding for young patients, unless it interferes with a diagnosis, which did not appear to be the case at Downstate.

Other problems, according to Dr. Amodio's e-mail, included using the wrong setting on a radiological device, which caused some premature babies to be "significantly overirradiated."

When Dr. Amodio's findings were reported to the hospital's patient safety committee, its chairman, Dr. Eugene M. Edynak, quickly grasped the seriousness of the situation. "Because of the grave nature of these 'findings,' and the need for immediate correction," Dr. Edynak wrote, "I would like Radiology to present these issues at the next Patient Safety Committee." At the same time, Dr. Edynak noted that radiology management had already begun addressing the problems.

Dr. Sclafani was clearly unsettled by the events. "The past two weeks have been among the most troubled of my career," he wrote at the beginning of an expansive e-mail, sent to members of his department at 1:36 a.m. on July 27.

His greatest disappointment was directed at residents and supervisors for not speaking up about the improper X-rays. "Every film, all dictated, and no one brought this to my attention," Dr. Sclafani said.

In another e-mail, he said he felt "alarmed and ashamed" upon seeing poor imaging techniques. "Excessively irradiating children is something we must have zero tolerance about."

Dr. Sclafani recently took a leave from Downstate to do research. But in an interview last year, he said that his department, with Dr. Amodio's help, had made significant changes, not only in reducing the amount of radiation in CT scans for infants as well as adults, but also in reducing unnecessary scans.

In the past, Dr. Sclafani said, manufacturers had marketed CT scanners based on high-quality images, which often meant more radiation. Referring to Dr. Amodio, he said, "What we learned from John is that sometimes the pretty picture is not what we need."

Dr. Amodio described other department changes, including the use of breast shields for girls and, when possible, substituting an ultrasound, which uses no radiation, for CT scans. In addition, he said, he must personally approve all pediatric CT scans.

Downstate officials, after initially answering questions from The Times last year, have declined to answer any more. In a statement, Ronald Najman, a hospital spokesman, said: "We are working with the New York State Department of Health to re-evaluate the issues raised by our Department of Radiology in 2007, and to ensure that we are in compliance with national and state standards."

Push for Continuing Education

Supporters of the proposed CARE legislation say its continuing-education requirement will keep radiological workers abreast of technological changes. If it passes, "certification and licensure will no longer be a one-time event," said Dr. Geoffrey S. Ibbott, former director of the Radiological Physics Center, a federally financed group that tests radiotherapy equipment for accuracy.

A continuing-education provision might have prevented the over-radiation of 76 patients at a hospital in Missouri — a state that does not regulate its radiological

workers. The medical physicist there had selected the wrong calibration tool to set up a highly sophisticated linear accelerator.

Ms. Lung, the vice president of the technologists' group, said that while most people knew that radiation could cause cancer and burn holes in patients, "They don't understand that the last person to see that patient, to position that patient, to make sure that procedure is performed safely is the radiological technologist or radiation therapist."

Jerry Reid, executive director of the American Registry of Radiologic Technologists, a group that certifies technologists, said he was optimistic that the proposed legislation, expected to be introduced in March, would finally pass. Congress, he said, "has shown much more interest in this issue over the last year," in the wake of a series of articles in The Times documenting the harm that can result from radiation mistakes.

The New York Times

X-Rays and Unshielded Infants

But even supporters of the bill say much more needs to be done, including making radiological devices safer and requiring that all mistakes be reported to a single national database.

"We still have to address the culture in many radiology and radiation therapy departments where there is reluctance or outright intimidation that prevents people from reporting errors or potential errors," said Dr. Ibbott. "All of our staff must be empowered to identify errors and situations that could lead to errors without fear of retribution."

The American College of Radiology also recommends that all medical radiology units be professionally accredited, yet many are not.

"In my profession, there is very little room for error and no room for unqualified personnel," said Dr. Steve Goetsch, a medical physicist in California who runs training programs in the field.

Radiation Offers New Cures, and Ways to Do Harm

WALT BOGDANICH
Published: Sunday, January 24, 2010 at 3:30 a.m.
Last Modified: Monday, January 25, 2010 at 4:19 a.m.

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days.

Soon after the accident, at St. Vincent's Hospital in Manhattan, state health officials cautioned hospitals to be extra careful with linear accelerators, machines that generate beams of high-energy radiation.

But on the day of the warning, at the State University of New York Downstate Medical Center in Brooklyn, a 32-year-old breast cancer patient named Alexandra Jn-Charles absorbed the first of 27 days of radiation overdoses, each three times the prescribed amount. A linear accelerator with a missing filter would burn a hole in her chest, leaving a gaping wound so painful that this mother of two young children considered suicide.

Ms. Jn-Charles and Mr. Jerome-Parks died a month apart. Both experienced the wonders and the brutality of radiation. It helped diagnose and treat their disease. It also inflicted unspeakable pain.

Yet while Mr. Jerome-Parks had hoped that others might learn from his misfortune, the details of his case — and Ms. Jn-Charles's — have until now been shielded from public view by the government, doctors and the hospital.

Americans today receive far more medical radiation than ever before. The average lifetime dose of diagnostic radiation has increased sevenfold since 1980, and more than half of all cancer patients receive radiation therapy. Without a doubt, radiation saves countless lives, and serious accidents are rare.

But patients often know little about the harm that can result when safety rules are violated and ever more powerful and technologically complex machines go awry. To better understand those risks, The New York Times examined thousands of pages of public and private records and interviewed physicians, medical physicists, researchers and government regulators.

The Times found that while this new technology allows doctors to more accurately attack tumors and reduce certain mistakes, its complexity has created new avenues for error — through software flaws, faulty programming, poor safety procedures or inadequate staffing and training. When those errors occur, they can be crippling.

"Linear accelerators and treatment planning are enormously more complex than 20 years ago," said Dr. Howard I. Amols, chief of clinical physics at Memorial Sloan-Kettering Cancer Center in New York. But hospitals, he said, are often too trusting of the new computer systems and software, relying on them as if they had been tested over time, when in fact they have not.

Regulators and researchers can only guess how often radiotherapy accidents occur. With no single agency overseeing medical radiation, there is no central clearinghouse of cases. Accidents are chronically underreported, records show, and some states do not require that they be reported at all.

In June, The Times reported that a Philadelphia hospital gave the wrong radiation dose to more than 90 patients with prostate cancer — and then kept quiet about it. In 2005, a Florida hospital disclosed that 77 brain cancer patients had received 50 percent more radiation than prescribed because one of the most powerful — and supposedly precise — linear accelerators had been programmed incorrectly for nearly a year.

Radiation Offers New Cures, and Ways to Do Harm

Dr. John J. Feldmeier, a radiation oncologist at the University of Toledo and a leading authority on the treatment of radiation injuries, estimates that 1 in 20 patients will suffer injuries.

Most are normal complications from radiation, not mistakes, Dr. Feldmeier said. But in some cases the line between the two is uncertain and a source of continuing debate.

“My suspicion is that maybe half of the accidents we don’t know about,” said Dr. Fred A. Mettler Jr., who has investigated radiation accidents around the world and has written books on medical radiation.

Identifying radiation injuries can be difficult. Organ damage and radiation-induced cancer might not surface for years or decades, while underdosing is difficult to detect because there is no injury. For these reasons, radiation mishaps seldom result in lawsuits, a barometer of potential problems within an industry.

In 2009, the nation’s largest wound care company treated 3,000 radiation injuries, most of them serious enough to require treatment in hyperbaric oxygen chambers, which use pure, pressurized oxygen to promote healing, said Jeff Nelson, president and chief executive of the company, Diversified Clinical Services.

While the worst accidents can be devastating, most radiation therapy “is very good,” Dr. Mettler said. “And while there are accidents, you wouldn’t want to scare people to death where they don’t get needed radiation therapy.”

Because New York State is a leader in monitoring radiotherapy and collecting data about errors, The Times decided to examine patterns of accidents there and spent months obtaining and analyzing records. Even though many accident details are confidential under state law, the records described 621 mistakes from 2001 to 2008. While most were minor, causing no immediate injury, they nonetheless illuminate underlying problems.

The Times found that on 133 occasions, devices used to shape or modulate radiation beams — contributing factors in the injuries to Mr. Jerome-Parks and Ms. Jn-Charles — were left out, wrongly positioned or otherwise misused.

On 284 occasions, radiation missed all or part of its intended target or treated the wrong body part entirely. In one case, radioactive seeds intended for a man’s cancerous prostate were instead implanted in the base of his

penis. Another patient with stomach cancer was treated for prostate cancer. Fifty patients received radiation intended for someone else, including one brain cancer patient who received radiation intended for breast cancer.

New York health officials became so alarmed about mistakes and the underreporting of accidents that they issued a special alert in December 2004, asking hospitals to be more vigilant.

As this warning circulated, Mr. Jerome-Parks was dealing with what he thought was a nagging sinus infection. He would not know until two months later that cancer had been growing at the base of his tongue. It was a surprising diagnosis for a relatively young man who rarely drank and did not smoke.

In time, his doctors and family came to suspect that his cancer was linked to the neighborhood where he had once worked, on the southern tip of Manhattan, in the shadow of the World Trade Center.

Several years before, he had taken a job there as a computer and systems analyst at CIBC World Markets. His starting date: September 2001.

Diagnosis and Treatment

What Mr. Jerome-Parks most remembered about Sept. 11, his friends say, were bodies falling from the sky, smashing into the pavement around him. He was particularly haunted by the memory of a man dressed in a suit and tie, plummeting to his death.

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In the days and weeks that followed, Mr. Jerome-Parks donated blood, helped a family search for a missing relative and volunteered at the Red Cross, driving search-and-rescue workers back and forth from what became known as “the pile.” Whether toxic dust from the collapsed towers caused his cancer may never be known, though his doctor would later say he believed there was a link.

Mr. Jerome-Parks approached his illness as any careful consumer would, evaluating the varied treatment options in a medical mecca like New York. Yet in the end, what led him to St. Vincent’s, the primary treatment center for Sept. 11 victims, was a recommendation from an acquaintance at his church, which had become an increasingly important part of his life.

The Church of St. Francis Xavier in Manhattan, known for its social advocacy, reflected how much Mr. Jerome-Parks had changed from his days in Gulfport, Miss., where he was raised in a conservative family, eventually moving to Toronto and then New York, where he met his Canadian-born wife, Carmen, a dancer, singer and aspiring actress.

In turning to St. Vincent’s, Mr. Jerome-Parks selected a hospital that had been courting cancer patients as a way to solidify its shaky financial standing.

Its cancer unit, managed by Aptium Oncology, a unit of one of the world's leading pharmaceutical companies, AstraZeneca, was marketing a new linear accelerator as though it had Mr. Jerome-Parks specifically in mind. Its big selling point was so-called smart-beam technology.

"When the C.F.O. of a New York company was diagnosed with a cancerous tumor at the base of his tongue," promotional material for the new accelerator stated, "he also learned that conventional radiation therapy could potentially cure him, but might also cause serious side effects."

The solution, the advertisement said, was a linear accelerator with 120 computer-controlled metal leaves, called a multileaf collimator, which could more precisely shape and modulate the radiation beam. (View an interactive graphic demonstrating how multileaf collimators work, and how problems at St. Vincent's caused a fatal overdose.) This treatment is called Intensity Modulated Radiation Therapy, or I.M.R.T. The unit St. Vincent's had was made by Varian Medical Systems, a leading supplier of radiation equipment.

"The technique is so precise, we can treat areas that would have been considered much too risky before I.M.R.T., too close to important critical structures," Dr. Anthony M. Berson, St. Vincent's chief radiation oncologist, said in a 2001 news release.

The technology addressed a vexing problem in radiation therapy — how to spare healthy cells while killing cancerous ones.

Radiation fights cancer by destroying the genetic material that controls how cells grow and divide. Even under the best of circumstances, though, it carries a risk, much like surgery or chemotherapy.

The most accurate X-ray beams must pass through healthy tissue to penetrate the tumor before exiting the body. Certain body parts and certain people are more sensitive to radiation. According to research by Dr. Eric J. Hall of the Center for Radiological Research at Columbia University, even accurate I.M.R.T. treatments, when compared with less technically advanced linear accelerators, may nearly double the risk of secondary cancer later in life due to radiation leakage.

When therapeutic errors enter the picture, the risk multiplies. An underdose allows the targeted cancer to grow, while an overdose can burn and cause organ damage.

While most radiation burns are mild, comparable to a sunburn, larger doses can damage the cells lining small blood vessels, depriving the skin and soft tissue of nourishment. The result is a wound that resists healing.

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"Not only do you lose the blood vessels, but the tissue becomes chronically inflamed, which can lead to scarring," said Robert Warriner III, chief medical officer of Diversified Clinical Services, the wound care company.

After soft-tissue injury, bone death in the head and jaw is the second most common radiation injury that Diversified Clinical treats.

At their worst, radiation injuries can cause organ failure and death.

Dr. Salvatore M. Caruana, then a head and neck surgeon at St. Vincent's, gave Mr. Jerome-Parks another option: surgery.

"I wanted him to have laser resection," Dr. Caruana, now at New York-Presbyterian Columbia University Medical Center, said in an interview.

In the end, Mr. Jerome-Parks chose radiation, with chemotherapy.

His wife would later tell friends that she wondered whether St. Vincent's was the best place for him, given that the world-renowned Memorial Sloan-Kettering was nearby. But she did not protest. His mind was made up, and there was no time to lose. His cancer was advancing, and smart-beam technology promised to stop it.

A Plan Goes Wrong

On a brisk day in March 2005, Mr. Jerome-Parks prepared for his fifth radiation session at St. Vincent's. The first four had been delivered as prescribed. Now Dr. Berson wanted the plan reworked to give more protection to Mr. Jerome-Parks's teeth.

Radiation can damage saliva glands, and if saliva stops flowing, tooth decay and infections become a significant risk. Coupled with bone weakness from radiation, the simple act of extracting a tooth can lead to destruction of the lower jaw and ultimately its removal, doctors say.

Dr. Edward Golembe, who directs a hyperbaric oxygen chamber at Brookdale University Hospital in Brooklyn, said he had treated serious radiation injuries to the jaw and called them "a horrible, horrible thing to see."

Tasked with carrying out Dr. Berson's new plan was Nina Kalach, a medical physicist. In the world of radiotherapy, medical physicists play a vital role in patient safety — checking the calibration of machines, ensuring that the computer delivers the correct dose to the proper location, as well as assuming other safety tasks.

Creating the best treatment plan takes time. "A few years ago, we had computers that would take overnight to actually come up with a good treatment plan," said Dr. David Pearson, a medical physicist who works with Dr. Feldmeier's radiotherapy team at the University of Toledo. Faster computers have shortened that process.

"But we still need to be able to verify that what the computer has actually come up with is accurate," Dr. Pearson said. "The first time it tries to solve the problem, it may not come up with the best solution, so we tell it, O.K., these are the areas that need to be fixed."

A few months before Mr. Jerome-Parks's treatment, New York State health officials reminded hospitals that I.M.R.T. required a "significant time commitment" on the part of their staffs.

"Staffing levels should be evaluated carefully by each registrant," the state warned, "to ensure that coverage is sufficient to prevent the occurrence of treatment errors and misadministrations."

On the morning of March 14, Ms. Kalach revised Mr. Jerome-Parks's treatment plan using Varian software. Then, with the patient waiting in the wings, a problem arose, state records show.

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Shortly after 11 a.m., as Ms. Kalach was trying to save her work, the computer began seizing up, displaying an error message. The hospital would later say that similar system crashes "are not uncommon with the Varian software, and these issues have been communicated to Varian on numerous occasions."

An error message asked Ms. Kalach if she wanted to save her changes before the program aborted. She answered yes. At 12:24 p.m., Dr. Berson approved the new plan.

Meanwhile, two therapists were prepping Mr. Jerome-Parks for his procedure, placing a molded mask over his face to immobilize his head.

Then the room was sealed, with only Mr. Jerome-Parks inside.

At 12:57 p.m. — six minutes after yet another computer crash — the first of several radioactive beams was turned on.

The next day, there was a second round of radiation.

A friend from church, Paul Bibbo, stopped by the hospital after the second treatment to see how things were going.

Mr. Bibbo did not like what he saw. Walking into a darkened hospital room, he recalled blurting out: " 'My goodness, look at him.' His head and his whole neck were swollen."

Anne Leonard, another friend, saw it, too, on a later visit. "I was shocked because his head was just so blown up," Ms. Leonard said. "He was in the bed, and he was writhing from side to side and moaning."

At a loss for what to do, Ms. Leonard said, "I just stood at the foot of the bed in the dark and prayed."

In a panic, Ms. Jerome-Parks called Tamara Weir-Bryan, a longtime friend from Toronto with nursing experience. Something was not right, she said. Then, as Ms. Weir-Bryan tells it: "She called me again, in agony, 'Please believe me. His face is so blown up. It's dreadful. There is something wrong.' "

At Ms. Jerome-Parks's suggestion, Ms. Weir-Bryan said she called the hospital, identified herself as a nurse and insisted that someone check on Mr. Jerome-Parks. If anything was done, it was not enough.

The next day, the hospital sent a psychiatrist to speak to Ms. Jerome-Parks, according to the hospital. A couple of hours later, her husband received yet another round of radiation.

Overdosed on Radiation

The Times has pieced together this account of what happened to Mr. Jerome-Parks largely from interviews with doctors who had been consulted on the case, six friends who cared for and comforted him, contemporaneous e-mail messages and Internet postings, and previously sealed government records. His wife declined to be interviewed about the case, as did Ms. Kalach, the medical physicist, and representatives of Aptium, Varian and St. Vincent's.

In a statement, the hospital called the case an “unfortunate event” that “occurred as a result of a unique and unanticipated combination of issues.”

On the afternoon of March 16, several hours after Mr. Jerome-Parks received his third treatment under the modified plan, Ms. Kalach decided to see if he

was being radiated correctly.

So at 6:29 p.m., she ran a test to verify that the treatment plan was carried out as prescribed. What she saw was horrifying: the multileaf collimator, which was supposed to focus the beam precisely on his tumor, was wide open.

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A little more than a half-hour later, she tried again. Same result.

Finally, at 8:15 p.m., Ms. Kalach ran a third test. It was consistent with the first two. A frightful mistake had been made: the patient’s entire neck, from the base of his skull to his larynx, had been exposed.

Early the next afternoon, as Mr. Jerome-Parks and his wife were waiting with friends for his fourth modified treatment, Dr. Berson unexpectedly appeared in the hospital room. There was something he had to tell them. For privacy, he took Mr. Jerome-Parks and his wife to a lounge on the 16th floor, where he explained that there would be no more radiation.

Mr. Jerome-Parks had been seriously overdosed, they were told, and because of the mistake, his prognosis was dire.

Stunned and distraught, Ms. Jerome-Parks left the hospital and went to their church, a few blocks away. “She didn’t know where else to go,” recalled Ms. Leonard, their friend.

The next day, Ms. Jerome-Parks asked two other friends, Nancy Lorence and Linda Giuliano, a social worker, to sit in on a meeting with Dr. Berson and other hospital officials.

During the meeting, the medical team took responsibility for what happened but could only speculate about the patient’s fate. They knew the short-term effects of acute radiation toxicity: burned skin, nausea, dry mouth, difficulty swallowing, loss of taste, swelling of the tongue, ear pain and hair loss. Beyond that, it was anyone’s guess when the more serious life-threatening symptoms would emerge.

“They were really holding their breath because it was the brain stem and he could end up a paraplegic and on a respirator,” Ms. Giuliano said.

Ms. Lorence added: “I don’t really think they expected Scott to live more than two months or three months.”

The group was told that doctors were already searching for tips on how to manage what promised to be a harrowing journey not only for the patient and his family, but also for the physicians and staff members involved in his care.

The full investigation into why Mr. Jerome-Parks had received seven times his prescribed dose would come later. For now, there was nothing left to say.

As Dr. Berson rose to leave the room, Ms. Lorence noticed that his back was soaked in sweat.

A Warning Goes Unheeded

Rene Jn-Charles remembers where he was and how she looked on that joyful day — his wife, Alexandra, the mother of their two young children, in brown jeans and a brown top, standing in front of him at the corner of Lincoln Place and Utica Avenue in the Crown Heights neighborhood of Brooklyn.

“Babes,” she said. “I have no cancer. I am free.”

Her doctor had called with the good news, she said. A seemingly unbearable weight had been lifted. Now after breast surgery and chemotherapy, she faced only radiation, although 28 days of it.

Ms. Jn-Charles had been treated for an aggressive form of breast cancer at a hospital with a very different patient profile from the one selected by Mr. Jerome-Parks. Unlike St. Vincent’s, on the edge of Greenwich Village, the Downstate Medical Center’s University Hospital of Brooklyn is owned by the state and draws patients from some of Brooklyn’s poorer neighborhoods.

Ms. Jn-Charles’s treatment plan also called for a linear accelerator. But instead of a multileaf collimator, it used a simpler beam-modifying device called a wedge, a metallic block that acts as a filter.

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In the four years before Ms. Jn-Charles began treatment, 21 accidents in New York State were linked to beam-modifying devices, including wedges, records show.

On April 19, 2005, the day Ms. Jn-Charles showed up for her first radiation treatment, state health officials were still so worried about what had happened to Mr. Jerome-Parks that they issued an alert, reminding operators of linear accelerators “of the absolute necessity to verify that the radiation field is of the appropriate size and shape prior to the patient’s first treatment.”

In legal papers before she died, Ms. Jn-Charles explained how the radiation therapist had told her not to worry. “It’s not painful — that it’s just like an X-ray,” she said she was told. “There may be a little reaction to the skin. It may break out a little, and that was basically it.”

‘A Big Hole in My Chest’

For a while, all seemed well. Then, toward the end of therapy, Ms. Jn-Charles began to develop a sore on her chest. It seemed to get worse by the day. “I noticed skin breaking out,” she would later say. “It was peeling. It started small but it quickly increased.”

When Ms. Jn-Charles showed up for her 28th and final treatment, the therapist took her to see Dr. Alan Schulsinger, a radiation oncologist. “He just said that they wouldn’t give me any radiation today, and he gave me the ointment and stuff and said go home and come back in a couple of days,” Ms. Jn-Charles said.

A couple of days later, she returned. “More skin was peeling off, and going down into the flesh,” Ms. Jn-Charles said. Once again, she was told to go home and return later.

On June 8, 2005, the hospital called her at home, requesting that she come in because the doctors needed to talk to her. Fourteen days after her last treatment, the hospital decided to look into the possible causes of her injury, hospital records show.

It did not take long. The linear accelerator was missing a vital command — to insert the wedge. Without it, the oncology team had been mistakenly scalding Ms. Jn-Charles with three and a half times the prescribed radiation dose during each session.

At the hospital, doctors gave her the bad news, and later sent a letter to her home. “I am writing to offer our deepest apologies once again for the devastating events that occurred,” Dr. Richard W. Freeman, chief medical officer, said in the June 17 letter. “There is now a risk of injury to your chest wall, including your skin, muscle, bone and a small portion of lung tissue.”

Ms. Jn-Charles had been harmed by a baffling series of missteps, records show.

One therapist mistakenly programmed the computer for “wedge out” rather than “wedge in,” as the plan required. Another therapist failed to catch the error. And the physics staff repeatedly failed to notice it during their weekly checks of treatment records.

Even worse, therapists failed to notice that during treatment, their computer screen clearly showed that the wedge was missing. Only weeks earlier, state health officials had sent a notice, reminding hospitals that therapists “must closely monitor” their computer screens.

“The fact that therapists failed to notice ‘wedge OUT’ on 27 occasions is disturbing,” Dr. Tobias Lickerman, director of the city’s Radioactive Materials Division, wrote in a report on the incident. The hospital declined to discuss the case.

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The overdose resulted in a wound that would not heal. Instead, it grew, despite dozens of sessions in a hyperbaric oxygen chamber. Doctors tried surgery. The wound would not close. So they operated a second, a

third and a fourth time. In one operation, Ms. Jn-Charles's chest wall was reconstructed using muscle from her back and skin from her leg.

"I just had a big hole in my chest," she would say. "You could just see my ribs in there."

She saw herself falling away. "I can't even dress myself, pretty much," she said. "I used to be able to take care of my kids and do stuff for them, and I can't do these things anymore."

Her husband remembers one night when the children heard their mother crying. They came running, frightened, pleading: "Tell me, Daddy, what happened to Mommy? Say she's O.K., she's O.K."

For more than a year, Ms. Jn-Charles was repeatedly hospitalized for pain and lived with the odor of her festering wound. Meanwhile, her cancer returned with a vengeance.

Several months after her wound had finally healed, she died.

No Fail-Safe Mechanism

The investigation into what happened to Mr. Jerome-Parks quickly turned to the Varian software that powered the linear accelerator.

The software required that three essential programming instructions be saved in sequence: first, the quantity or dose of radiation in the beam; then a digital image of the treatment area; and finally, instructions that guide the multileaf collimator.

When the computer kept crashing, Ms. Kalach, the medical physicist, did not realize that her instructions for the collimator had not been saved, state records show. She proceeded as though the problem had been fixed.

"We were just stunned that a company could make technology that could administer that amount of radiation — that extreme amount of radiation — without some fail-safe mechanism," said Ms. Weir-Bryan, Ms. Jerome-Parks's friend from Toronto. "It's always something we keep harkening back to: How could this happen? What accountability do these companies have to create something safe?"

Even so, there were still opportunities to catch the mistake.

It was customary — though not mandatory — that the physicist would run a test before the first treatment to make sure that the computer had been programmed correctly. Yet that was not done until after the third overdose.

State officials said they were told that the hospital waited so long to run the test because it was experiencing "a staffing shortage as training was being provided for the medical physicists," according to a confidential internal state memorandum on the accident.

There was still one final chance to intervene before the overdose. All the therapists had to do was watch the computer screen — it showed that the collimator was open. But they were not watching the screen, and in fact hospital rules included no specific instructions that they do so. Instead, their eyes were fastened on Mr. Jerome-Parks, out of concern that he might vomit into the mask that stabilized his head. Earlier, he had been given a drug known to produce nausea, to protect his salivary glands.

Government investigators ended up blaming both St. Vincent's, for failing to catch the error, and Varian, for its flawed software.

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The hospital said it "acted swiftly and effectively to respond to the event, and worked closely with the equipment manufacturer and the regulatory agencies."

Timothy E. Guertin, Varian's president and chief executive, said in an interview that after the accident, the company warned users to be especially careful when using their equipment, and then distributed new software, with a fail-safe provision, "all over the world."

But the software fix did not arrive in time to help a woman who, several months later, was being radiated for cancer of the larynx. According to F.D.A. records, which did not identify the hospital or the patient, therapists tried to save a file on Varian equipment when "the system's computer screen froze."

The hospital went ahead and radiated the patient, only to discover later that the multileaf collimator had been wide open. The patient received nearly six times her prescribed dose. In this case, the overdose was caught after one treatment and the patient was not injured, according to Mr. Guertin, who declined to identify the hospital.

"The event at the hospital happened before the modification was released," he said.

Mr. Guertin said Varian did 35 million treatments a year, and in 2008 had to file only about 70 reports of potential problems with the Food and Drug Administration.

Accidents and Accountability

Patients who wish to vet New York radiotherapy centers before selecting one cannot do so, because the state will not disclose where or how often medical mistakes occur.

To encourage hospitals to report medical mistakes, the State Legislature — with the support of the hospital industry — agreed in the 1980s to shield the identity of institutions making those mistakes. The law is so strict that even federal officials who regulate certain forms of radiotherapy cannot, under normal circumstances, have access to those names.

Even with this special protection, the strongest in the country, many radiation accidents go unreported in New York City and around the state. After The Times began asking about radiation accidents, the city's Department of Health and Mental Hygiene reminded hospitals in July of their reporting obligation under the law. Studies of radiotherapy accidents, the city pointed out, "appear to be several orders of magnitude higher than what is being reported in New York City, indicating serious underreporting of these events."

The Times collected summaries of radiation accidents that were reported to government regulators, along with some that were not. Those records show that inadequate staffing and training, failing to follow a good quality-assurance plan and software glitches have contributed to mistakes that affected patients of varying ages and ailments.

For example, a 14-year-old girl received double her prescribed dose for 10 treatments because the facility made a faulty calculation and then did not follow its policy to verify the dose. A prostate cancer patient was radiated in the wrong spot on 32 of 38 treatments, while another prostate patient at the same institution received 19 misguided treatments — all because the hospital did not test a piece of equipment after repairs.

In March 2007, at Clifton Springs Hospital and Clinic in upstate New York, a 31-year-old vaginal cancer patient was overradiated by more than 80 percent by an inexperienced radiotherapy team, putting her at risk for a fistula formation between the rectum and vagina. Afterward, she received antibiotics and treatments in a hyperbaric oxygen chamber.

In 2008, at Stony Brook University Medical Center on Long Island, Barbara Valenza-Gorman, 63, received 10 times as much radiation as prescribed in one spot, and one-tenth of her prescribed dose in another. Ms. Valenza-Gorman was too sick to continue her chemotherapy and died of cancer several months later, a family member said. The therapist who made those mistakes was later reprimanded in another case for failing to document treatment properly.

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The therapist not only continues to work at the hospital, but has also trained other workers, according to records and hospital employees. A spokeswoman for Stony Brook said privacy laws precluded her from discussing specifics about patient care or employees.

Other therapists have had problems, too.

Montefiore Medical Center in the Bronx fired a therapist, Annette Porter, accusing her of three mistakes, including irradiating the wrong patient, according to a government report on June 1, 2007. Ms. Porter retains her license.

“We know nothing about that person — zero,” said John O’Connell, an associate radiologic technology specialist with the State Bureau of Environmental Radiation Protection, the agency that licenses technologists.

Montefiore declined to comment. Ms. Porter, through her lawyer, denied making the three mistakes.

Fines or license revocations are rarely used to enforce safety rules. Over the previous eight years, despite hundreds of mistakes, the state issued just three fines against radiotherapy centers, the largest of which was $8,000.

Stephen M. Gavitt, who directs the state’s radiation division, said if mistakes did not involve violations of state law, fines were not proper. The state does require radiotherapy centers to identify the underlying causes of accidents and make appropriate changes to their quality-assurance programs. And state officials said New York had taken a leadership role in requiring that each facility undergo an external audit by a professional not connected to the institution.

Two years ago, the state warned medical physicists attending a national conference that an over-reliance on computer programs might be leading to mistakes, including patient mix-ups. “You have to be ever-vigilant,” Mr. O’Connell said.

The state imposed no punishment for the overdoses of Mr. Jerome-Parks or Ms. Jn-Charles. The city levied fines of $1,000 against St. Vincent's and $1,500 against University Hospital of Brooklyn.

Irreparable Damage

Mr. Jerome-Parks needed powerful pain medicine soon after his overdose.

Yet pain was hardly the worst of it. Apart from barely being able to sleep or swallow, he had to endure incessant hiccupping, vomiting, a feeding tube, a 24-hour stream of drugs and supplements. And apart from all that, he had to confront the hard truth about serious radiation injuries: there is no magic bullet, no drug, no surgery that can fix the problem.

"The cells damaged in that area are not reparable," Ms. Jerome-Parks reported to friends in an e-mail message shortly after the accident. National radiation specialists who were consulted could offer no comfort. Hyperbaric oxygen treatments may have helped slightly, but it was hard to tell.

"He got so much radiation — I mean this was, in the order of magnitude, a big mistake," said Dr. Jerome B. Posner, a neurologist at Memorial Sloan-Kettering who consulted on the case at the request of the family. "There are no valid treatments."

Though he had been grievously harmed, Mr. Jerome-Parks bore no bitterness or anger.

"You don't really get to know somebody," said Ms. Leonard, the friend from church, "until you see them go through something like this, and he was just a pillar of strength for all of us."

Mr. Jerome-Parks appreciated the irony of his situation: that someone who earned a living solving computer problems would be struck down by one.

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He grew closer to his oncologist, Dr. Berson, who had overseen the team that caused his injury. "He and Dr. Berson had very realistically talked about what was going to happen to him," said his father, James Parks.

Ms. Jerome-Parks, who was providing her husband round-the-clock care, refused to surrender. "Prayer is stronger than radiation," she wrote in the subject line of an e-mail message sent to friends. Prayer groups were formed, and Mass was celebrated in his hospital room on their wedding anniversary.

Yet there was no stopping his inevitable slide toward death.

"Gradually, you began to see things happening," said Ms. Weir-Bryan, the friend from Toronto, who helped care for him. "His eyes started to go, his hearing went, his balance."

Ms. Giuliano, another of the couple's friends, believed that Mr. Jerome-Parks knew prayer would not be enough.

“At some point, he had to turn the corner, and he knew he wasn’t going to make it,” Ms. Giuliano said. “His hope was, ‘My death will not be for nothing.’ He didn’t say it that way, because that would take too much ego, and Scott didn’t have that kind of ego, but I think it would be really important to him to know that he didn’t die for nothing.”

Eventually the couple was offered a financial settlement, though it was not a moment to celebrate because it came at a price: silence. With neither of them working and expenses mounting, they accepted the offer.

“I cried and cried and cried, like I’d lost Scott in another way,” Ms. Jerome-Parks wrote in an e-mail message on April 26, 2006. “Gag order required.”

Now, the story of what happened to Mr. Jerome-Parks would have to be told by his doctors and the hospital, neither of which were part of the settlement. The identities of those who settled were not revealed.

“He didn’t want to throw the hospital under the bus,” Ms. Leonard said, “but he wanted to move forward, to see if his treatment could help someone else.”

Dr. Caruana, the physician who had recommended surgery over radiation, added: “He said to let people know about it.”

Friends say the couple sought and received assurances that his story would be told.

Mr. Jerome-Parks’s parents were in Gulfport in February 2007, waiting for their house to be rebuilt after it was destroyed by Hurricane Katrina, when they got the news that their son had died.

Afterward, they received a handwritten note from Dr. Berson, who said in part: “I never got to know any patient as well as I knew Scott, and I never bonded with any patient in the same way. Scott was a gentleman who handled his illness with utmost dignity, and with concern not only for himself but also for those around him.”

He ended by saying: “I commit to you, and as I promised Scott, everything we learned about the error that caused Scott’s injury will be shared across the country, so that nobody else is ever hurt in this way. On a personal level, I will never forget what Scott gave me.”

Dr. Berson no longer treats patients, said Dr. Josh Torgovnick, a neurologist who helped care for Mr. Jerome-Parks after the accident. “It drove him to retire,” he said, referring to the fatal overdose. The hospital disputes that, saying Dr. Berson still sees patients at the hospital.

Dr. Berson did not respond to several messages seeking an interview about the case. Citing privacy concerns, a spokesman for St. Vincent’s, Michael Fagan, said neither the hospital nor Dr. Berson would grant an interview.

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In July, Mr. Jerome-Parks’s father stood across from the beach in Gulfport where his son’s friends had scooped up the sand they sent for his final Christmas.

“He taught us how to die,” Mr. Parks said. “He did it gracefully and thoughtfully and took care of everything. Most of us would lose it. He didn’t. He just did everything that he had to do, and then he let himself die.”

Mr. Parks said he had thought about starting a campaign to make medical mistakes public — but he never did. Nothing would ever come of it, he concluded.

Unintended Over Exposure of Radiation Plaguing Hospitals and Harming Patients

February 18, 2010

Posted In: Personal Injury

By Eisenberg, Rothweiler, Winkler, Eisenberg & Jeck, P.C. on February 18, 2010 10:06 AM | Permalink

The Food and Drug Administration has launched an investigation to reports that patients in Philadelphia hospitals and other hospitals nationwide have been over exposed to radiation during routine tests and procedures.

A typical CT scan exposes patients to radiation levels about equal to 400 X-rays but reports have surfaced that in some cases patients have received radiation levels equivalent of 3,200 X-rays. None of the patients knew about the overexposure until they begun to lose their hair.

The increasing popularity and effectiveness of diagnostic tests that involve radiation has exposed more people to more radiation then in the past. In the last thirty years a typical person's exposure to medical radiation has increased seven-fold. Ionizing radiation, which is used in imaging exams, increases the patient's lifetime cancer risk and can also cause skin burns, hair loss and cataracts.

The FDA is increasing oversight into CT scans, nuclear medicine studies, and fluoroscopies. CT scans are the most common form of radiation imaging that provides medical professionals with 3-dimensional images of the bodies. In a nuclear medicine study a radioactive substance is passed through the patient's body and monitored by doctors and a fluoroscopy is a diagnostic tool that provides doctors with a continuous internal image through the help of a radiation-emitting device.

Currently there are no indicators on any radiation emitting device that informs doctors or technologists that the patient is receiving inappropriate amounts of radiation. The industry has failed to implement a failsafe system and unfortunately patients are paying the price.

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FATAL DOSE

Radiation Deaths linked to
AECL Computer Errors

In 1985 a Canadian-built
radiation-treatment device began
blasting holes through patients' bodies.

How a series of simple computer errors
sabotaged a state-of-the-art medical wonder.

- by Barbara Wade Rose

from Saturday Night,
June 1994

Radiation Therapy Gone Wrong

On a day early in June, 1985, Katie Yarborough drove to the Kennestone Regional Oncology Center in Marietta, Georgia, for her twelfth cancer treatment. The sixty-one-year-old manicurist who worked at a local hair salon had had a lump successfully removed from her left breast a few months earlier. She needed a dose of radiation treatment in the adjacent lymph nodes to make sure there would be no recurrence. The machine being used to treat Yarborough was a recent acquisition at Kennestone: a state-of-the-art linear accelerator called the Therac-25, which had already successfully performed 20,000 irradiations on the region's cancer patients. Designed and developed

by AECL Medical, a division of Atomic Energy of Canada Ltd., the Therac-25 could speed up electrons and turn them into a high-energy beam that destroyed surface tumours on the skin, or else convert the electrons into x-rays to penetrate tumours deeper in the body.

Yarborough took off her top and her bra and settled in the treatment room for an electron treatment beamed high on the left side of her chest. The usual treatment delivered a dose of around 200 rads: rads are the commonly accepted measurement of radioactive energy -- a chest x-ray, for example, gives off a fraction of one rad.

It would last only a few seconds, during which Yarborough would feel nothing. But this day, when the technician activated the machine, Yarborough said she immediately felt this red-hot sensation. "You burned me," she told the technician, who replied that it wasn't possible. Yarborough's oncologist and Tim Still, the medical physicist at Kennestone, both examined her. Yarborough's skin looked fine, although it felt slightly warm. "I can't understand what might have done it," Still said to her. But he did his duty, and telephoned AECL up in Ottawa to ask whether a Therac-25 could ever project the electron beam without spreading it properly as the machine was supposed to do. They said they'd get back to him. Not possible, he was told three days later.

Yarborough returned in two weeks. She said she felt tingling inside her body and growing pain. There was a red mark the size of a dime on her chest. There was also a larger pink circle of skin high on the left side of her back. Still's stomach turned over when he saw it. "That looks like the exit dose made by an electron beam," he said to Yarborough and her doctor. The damage done by radiation depends upon its strength, what proportion of the body is exposed, and whether it strikes any vital organs. One thousand rads can be fatal if it is spread over the entire body. Physicist Still later estimated that Yarborough probably received between 15,000 and 20,000 rads on that dime-sized space.

That night Still stayed late after work and tried to reproduce a beam that could have gone through a patient's body with such obvious force. He shot beams into water and into the air of the treatment room. Whenever he changed any component of Yarborough's prescribed treatment on the computer console, the beam collapsed, shut off by the Therac-25's safety system. So the technician couldn't have done anything wrong. The machine worked fine.

But Still, a forty-year-old Georgian with a broad southern drawl, describes himself as "a troublemaker. I make a lot of noise." He was already frustrated by what he saw as AECL's lack of interest in fixing problems he'd had with another of their medical machines and this time he let his colleagues and a professional organization,

Pharmacopeia, know about the anomaly. There were, Still says, unpleasant results. "I got this intimidating phone call from AECL," he says. "I got told that this kind of talk was libel unless I had proof and that I'd better stop." At the time there were five Therac-25s installed in hospitals in the U.S. and six in Canada.

Over the next few weeks Katie Yarborough's body began to look as if a slow motion gunshot had gone through her chest and our her back. The site where the beam had entered was now a hole. Over the next few months surgeons twice tried to graft healthy skin over the wound but each time the grafted skin rotted and died. Her left arm became paralyzed except when it spasmed. Yarborough hired a Georgia lawyer named Bill Bird and sued AECL and the hospital in October of 1985. "We never got a good deal of information from AECL," Bird recalls. "We hadn't got a lot of response to our written questions so we filed notice of deposition -- where we could call them in and force them to respond to interviews with a court reporter present. At that point they settled." Bird describes Yarborough as "a remarkable woman" who continued to drive despite a useless left arm. She died in 1990 when her car was hit by a truck on the highway near Marietta.

Katie Yarborough was the first of the Therac-25 accidents.

Twice Burned, Once Shy

Radiation-treatment machines were in enormous demand in hospitals throughout North America, and AECL Medical's equipment was widely considered the best in a growing field. The Therac-25 looked like a giant version of one of those kitchen electric mixers, with a treatment table slid underneath in the bowl position. The machine was seven feet high and took up about twelve feet of space -- less than conventional linear accelerators. Just as technicians leave the room to operate x-ray equipment in hospitals and dentists' offices, operators ran the Therac-25 from a computer console outside the treatment area. There had been several earlier versions of Theracs -- the 6, the 20 -- developed by AECL in cooperation with a French company, CGR, in a business relationship that ended in 1981. But the Therac-25 was better. First of all, it was a double-pass accelerator, which meant the beam doubled back through an electromagnet and that streamlined the machine. Second, the Therac-25 used electricity as the power source for its beam rather than pellets of radioactive cobalt, which lose strength over time.

And the Therac-25 was controlled principally by software. Older Theracs relied on hardware to set the machine up for treatment, to position the beam, and to run the safety system. Hardware is the computer itself, its keyboard, casing, microchips, switches -- rusting, dusty, fallible, and mortal. Software is the thousands of lines of written code that allow the computer to do incredible things at a high speed, and that

never breaks down -- invisible and immortal. Hardware and software; Mensch and óbermensch.

There was soon another kind of accident involving another Therac-25. Seven weeks after Katie Yarborough's overexposure, a forty-year-old woman with cervical cancer at the Hamilton Regional Cancer Centre in Ontario received a dose of what was later estimated to be as much as 17,000 rads to her hip. This time, there was a larger patch of swelling and redness, and the woman was hospitalized for her injury on July 30. She died in November from her cancer, but an autopsy report noted that, had she lived, she would have needed a hip replacement because of radiation overexposure. After the accident, AECL notified Therac-25 operators, the federal government's Canadian Radiation Protection Bureau, and the American Food and Drug Administration (FDA), which monitors medical equipment in the U.S., that there had been a problem with the Hamilton machine. Technicians, AECL said, should examine their machines during each treatment to be sure the positioning mechanism -- called the turntable -- was working properly. Patient injury wasn't mentioned, although hospital physicists in Ontario knew from discussions among themselves that an accident had occurred. None of them knew about the earlier accident in Georgia, and AECL didn't mention it.

Engineers from AECL had examined the Hamilton machine in July to determine whether there were problems with the way the Therac-25 turntable worked. A revolving platform rotated by a motor, the turntable locks into two standard positions, one for an electron beam, one for an x-ray beam, and a third position, called the field-light position, which enables the technician to adjust the beam to a precise target. Once in place, microswitches let the computer know the turntable is properly positioned. During its July, 1985, inspection, AECL decided the microswitches for the Therac-25 turntable weren't working properly and modified them. The software was altered within the machines to check continually on the microswitches, and a plunger that locked the turntable into place was modified so that the machine would no longer operate if the turntable was out of position. In September, 1985, in a letter to users, AECL pronounced the Therac-25 safe "with an improvement over the old system by at least five orders of magnitude."

Three months later, in December, 1985, a Therac-25 at Yakima Valley Memorial Hospital in Washington State, which had been modified according to AECL's July specifications, delivered a similar dose, in a way similar to the Hamilton accident, to the hip of another cervical-cancer patient. This time the burn produced a striped pattern on the woman's body. David Judd, a physicist at Yatima, remembers the "five orders safer" letter he had received from AECL before the accident. "Based on that letter we figured it couldn't be the machine," he told me in a telephone interview. Nor was he aware a patient had been injured in Hamilton, Ontario, when he and his

colleagues began casting about for other explanations. "The woman said she regularly lay on a heating pad. So we investigated that."

An accident report was sent to AECL, which wrote back: "After careful consideration, we are of the opinion that this damage could not have been produced by a malfunction of the Therac-25 or by any operator error." Despite the earlier accidents, the letter also stated -- perhaps referring to the striped pattern of irradiated skin on the patient's hip -- that there had "apparently been no other instances of similar damage to this or other patients." The staff at Yakima decided they would never know the cause of the accident and, since the machine seemed to work, turned it back on.

After Hamilton and Yakima, the physicists who were working with Therac-25s at the various sites in Canada and the U.S. began to talk to one another by telephone and memo about their concerns. The physicists agreed they were perplexed by accidents on an otherwise high-quality machine and frustrated br a sense that someone needed to get to the bottom of the problems. Alan Rawlinson, a physicist at Princess Margaret Hospital in Toronto, which installed its Therac-25 in 1986, said that "these accidents really drew people together. AECL was also involved. But in retrospect the courses of action that were followed once these accidents were found and understood were driven largely by the medical-physics community." But it was confusing at first. Without much information forthcoming from AECL, "we were," says Tim Still of Marietta, "all flying blind."

Death through Software

There would be two more deaths before anyone thought to blame the software program and another still before the errors would be solved. Everyone who uses computers knows about glitches. Everyone has heard stories about the multimillion-dollar bank error or the credit-card charge to someone long deceased -- stories that would be funny if they weren't so annoying. The truth is that any software program will probably contain one error for every 500 lines of code. The Therac-25's software program, relatively crude by today's standards, probably contained 101000 lines of code. At one error for every 500 lines, that works out to the possibility of twenty errors. Errors occur partly because it's a human being who wrote the code, partly because it's almost impossible to account for all the ways in which a software program will behave when it is at work in the machine.

Unfortunately, the same tolerances for error acceptable in wiring the software for the computer on your desk are applied to the software used increasingly in equipment that can affect life and death: automobiles, hospital equipment, medical devices. Though the obvious safety-cricical software systems, for example, those in weapons, nuclear power, and airplanes, have always been subject to government approval, elsewhere

there were fewer set rules. Instead we rely on the people use refer to colloquially as technowizards. To understand such sophisticated programs, they must be geniuses, mustn't they? That is to say, we place the same faith in technowizards as we did in the chemists of the 1950s.

Two accidents occurring in rapid succession provided the first clues to what was happening. On March 21, 1986, an oilfield worker named Ray Cox was being irradiated for the ninth time at the East Texas Cancer Center in Tyler, Texas, for a tumour that had been removed from his back. The centre's Therac-25 had already successfully treated more than 500 patients over a two-year period. Cox lay on his stomach on the table in the treatment room, which was connected to the computer console room next door by an intercom and video monitor. On this day the intercom was broken and the video monitor was unplugged. The technician left the treatment room and shut the door. At the computer console she typed in the prescription data for an electron beam of 180 rads, then noticed she'd made an error by typing in command x (for x-ray treatments) instead of e (for electron). She ran the cursor up the screen to change the command x to e, as Cox's prescription required. She verified everything else and turned on the beam. The machine stopped and the computer screen flashed "Malfunction 54," a mysterious message not even mentioned in the Therac-25 manual.

The technicians who operated the Therac-25 were used to computer glitches. Jonathan Jacky is a research scientist who has been developing software for a computer-controlled radiation machine at the University of Washington's School of Medicine in Seattle. In a 1985 essay for The Sciences, he wrote that a therapist at Kennestone reported the Therac-25 typically issued up to four error messages a day. It did so by displaying "Malfunction" plus a number, from 1 through 64. No explanation was offered by the computer nor was there any reference to the malfunction codes in the operator's manual. Technicians could, in most cases, bypass the irritating malfunctions simply by pressing the "p" key, for "proceed." Doing so became a matter of habit.

Inside the treatment room Cox was hit with a powerful shock. He knew from previous treatments this was not supposed to happen. He tried to get up. Not seeing or hearing him because of the broken communications between the rooms, the technician pushed the "p" key, meaning "proceed." Cox was hit again. The treatment finally stopped when Cox stumbled to the door of the room and beat it with his fists.

Cox's injury was similar to Jane Yarborough's -- a dime-sized dose of 16,000 to 15,000 rads. He was sent home but returned to the hospital a few weeks later spitting blood: the doctors diagnosed radiation overexposure. It later paralysed his left arm, both legs, his left vocal chord, and his diaphragm. He died nearly five months later.

Official Reassurances from AECL At the time of the accident, an AECL representative reportedly told the hospital that its modified Therac-25 could not overdose a patient and that AECL knew of no other accidents. "That's what really bothers me," says a source within the hospital who asked not to be identified. "There were [.4ECL] people sitting in our offices telling us it [the Therac-25] couldn't hurt anybody when they knew it could." AECL suggested Cox's accident might have been caused by an electrical shock. The hospital staff hired an independent investigator, who determined that the Therac-25 wasn't capable of delivering one. The machine was checked and tested repeatedly. Nobody, either from AECL or on the hospital staff, could make it do anything wrong. So treatment resumed on April 7, 1986.

Four days later,"Malfunction 54" flashed on the screen again during a treatment, this rime while a sixty-six-year-old bus driver, Verdon Kidd, was receiving therapy at the Tyler cancer centre for skin cancer on his face. He became disoriented and then comatose, and died three weeks later. Kidd's death, which preceded Cox's by nearly four months, made medical history -- the first fatality caused, according to Jacky's research, by an overdose during radiation treatment.

Treatment stopped on the Tyler Therac-25 the day of Verdon Kidd's accident, on a Friday. The hospital staff, physicist Fritz Hager, and his technician, who had worked the machine in both accidents, stayed at the console long after everybody else had gone home for the weekend, typing and retyping the prescription into the computer console, determined to re-create Malfunction 54. They went to the bottom of the screen and then moved the cursor up to change the treatment mode from x to e, over and over, for hours. Finally they did it.

The speed with which the instructions were entered made the difference. According to a computer system's analysis of FDA documents, the computer would not accept new information on a particular phase of treatment (in the case of both Tyler accidents, changing the x-ray mode to electron mode) if the technician made the changes within eight seconds after reaching the end of the prescription data. That's what Malfunction 54 meant. If the changes were made so soon, all the new screen data would look correct to the technician. But inside the computer, the software would already have encoded the old information.

That meant the beam on the Therac-75 would be set for the much stronger dose needed for an x-ray beam while the turn-table was in the electron position. The coded information within the computer apparently included no system to check that various parts of the prescription data agreed with one another.

Thar night, Hager telephoned AECL to let them know the accidents weren't random. He knew how to turn the Therac-25 into a lethal weapon.

A letter immediately went out from AECL to all the users. "Effective immediately, and until further notice, the key used for moving the cursor back through the prescription sequence must ... not be used for editing or any other purpose." The FDA, which was already investigating the safety of the Therac-25 as a result of the first Tyler accident, told AECL that wasn't enough: the letter didn't describe what would result if the "up" cursor was used or mention any of the accidents. "In fact," the FDA's director of compliance, Center for Devices and Radiological Health (CDRH), wrote in a report, "the letter implies the inconvenience to operators outweighs the need to disable the key." In May, 1986, the FDA requested a corrective-action plan (CAP) to eliminate the problem. But the Therac-25 remained in use. "To say 'don't use the machine,'" Gordon Symonds, a physicist with the Canadian Radiarion Protection Buteau, told me, "was to say to a patient,'you can't have your treatment.'"

Facing the Music

An unhappy band of Therac-25 physicists atrended the annual conference of the American Association of Physicisn in Medicine, in Seattle, Washington, in August, 1986. Gradually, they learned from one another in greater depth about the various accidents, including the original one at Marietta, which had just come to light following the Tyler accidents. They found out that the staff at Princess Margaret Hospital in Toronto had decided to take their own precautions and muzzle their machine -- which had not yet been put into clinical use -- by installing a dose-per-pulse monitor, an electronic device that would measure all doses of radiadon in the beam and, in a fraction of a second, stop excessive doses before they could reach the parient. The physicists decided to circulate their own newsletter, consolidating information and recommendations for safety strategy on the Therac-25.

In the meantime, AECL was trying to satisfy the demands of the FDA. AECL had submirred its CAP on June 13, 1986, and then revised it twice before the end of the year to satisfy the FDA's increasingly stringent demands. Part of the CAP ivolved reworked software that told the computer where the "up" cursor was, so that a Malfunction 54 wouldn't happen again. By the end of the year the machines were back in use.

On January 17, 1987. it became sickeningly apparent that the problems with the Therac-25 that had led to the Hamilton and Yakima accidents were not, in fact, fixed. A man went into the Yakima Valley Memorial Hospital for a low dose of eighty-six rads for his carcinoma. He was hit in the chest with 8,000 to 10,000 rads, and the burn later formed the same striped pattern as in the December, 1985, Yakima accident. David Judd, the physicist at Yakima, describes his staff's reaction as "totally paranoid." "We had had that [1985] letter from AECL saying the safety had been

improved but still two patients got over-dosed," he says. "We just stopped using the machine." The man who proved to be the last Therac-25 victim died in April, 1987, from a combination of terminal cancer and complications from an overdose.

It turned our that both Yakima accidents, as well as the one at Hamilton, had been caused by another software error -- different from the Malfunction 54. On the Therac-25, the part of the computer program that is often referred to as the "house-keeper task" continuously checked to see whether the turntable was correctly positioned. A zero on the counter indicated to the technician that the turntable was in the correct position. Any value other than zero meant that it wasn't, and that treatment couldn't begin. The computer would then make the necessary corrections and the counter would reset itself to zero.

But the highest value the counter could register was 255. If the program reached 256 checks, the counter auromatically clicked back to zero, the same way that a car odometer turns over to zero after you've driven more than 99,999.99 kilometres. For that split second, the Therac-25 believed it was safe to proceed when, in fact, it wasn't. If the technician hit the "set" button to begin treatment at that precise moment, the turntable would be in the wrong position and the patient would be struck by a raw beam.

So when AECL fixed the turntable and microswitch problems back in September, 1985, they were improving the machine but they weren't actually correcting the problem that caused these accidents. A professor in computer engineering at the University of Toronto told me that, as a matter of course, his undergraduate students are warned about the risks of incrementing numbers in a computer program.

After the second Yakima accident the FDA requested "that AECL immediately notify all purchasers and recommend that use of the device on patients for routine therapy be discontinued until such time that an amended CAP approved by CDRH is fully completed." The machine was to be used only "if the need for an individual patient's treatment outweighs the potential risk." The Health Protection Branch, a division of Canada's Health and Welfare ministry, directed AECL to tell its customers to discontinue use of the machine until its safe use could be guaranteed. The physicists clamoured for a face-to-face meeting with AECL officials. They all arranged to fly up to Toronto (at the expense of their respective institutions) and meet with AECL representatives at Princess Margaret Hospital in March, 1987. Fearful of lawsuits, some of the physicists were accompanied by lawyers, one having been told by his administration supervisor that the next victim of an accident "would own the centre" in which it occurred.

Putting Safety First

At the meeting each physicist described the accident or accidents in which he had been involved. AECL, which also brought along its legal staff, presented its plans for correction, all of which involved changing the software. The physicists passed a resolution that there needed to be a hardware solution to the problems of the Therac-25 regardless of what software changes were made. They wanted a dose-per-pulse monitor on all the machines. The physicists I interviewed remember the tremendous energy and determination of the meeting at Princess Margaret Hospital, a relief after their frustration and despair. "There was so much momentum," says Tim Still of Marietta. The physicists' recollections of the meeting tend to differ. "The Canadians wanted the machine up and running as quickly as possible," recalls David Judd. "That really upset me. The Americans were more conservative and wanted more changes." According to Alan Rawlinson of Princess Margaret Hospital, who helped set up the meeting, AECL "was looking for guidance from users. That meeting was a final pulling together of what needed to be done."

In the weeks that followed AECL acted swiftly. It sent the FDA two more revisions of its CAP, based largely on the decisions made at the March Princess Margaret Hospital meeting. On]une 6, 1987, AECL informed users that the FDA had verbally approved the CAP and that all Therac-25s would be fixed by the end of the summer. The CAP included twenty-three software changes in addition to those needed to correct the causes of the accidents, and at least six mechanical safety features, including the dose-per-pulse monitor that had been insisted upon by the physicists. Old-fashioned hardware finally came to the rescue of the software-driven Therac-25.

David Judd and his team at Yakima waited until after the AECL engineering team had installed the full set of safety armour on their Therac-25 early that fall. Then he and an AECL representative tried to create an accident. They shot the beam into hard plastic placed on the treatment table. They disconnected the safety mechanisms one by one. They reactivated the "up" cursor key. They reloaded the old software. Even then, the dose-per-pulse monitor shut the machine down.

Since then the Therac-25 machines at Yakima, Princess Margaret Hospital, Marietta, and other hospitals have been in use without a single accident. (East Texas Cancer Center shipped its Therac-25 back to Canada for a refund. Regardless of what was done to their machine, the staff refused to use it.) They are now considered absolutely safe. The Therac-25 is "still an awesome machine," says Tim Still of Marietta. "Ten years since it was made we're not replacing it with anything better."

AECL dissolved AECL Medical in 1988 and renamed it Theratronics International Ltd. The Canadian government has been trying to sell Theratronics to private industry

since 1990, without success, and has transferred ownership to a government holding company, Canada Development investment Corporation. Many of the staff who were with AECL Medical and who were involved with the Theracs and the other linear accelerators are still working at Theratronics.

No Comment from AECL

From the beginning of research for this article I tried to get interviews from staff at AECL in Ottawa or Theratronics in Kanata. Over a two-month period I left phone messages, made explanatory calls, and sent fares. AECL declined to give me any interviews. A spokesman, Egon Frech, said that AECL no longer had any responsibility for Theratronics, though he agreed that AECL should say something because at the time AECL Medical was their division. AECL faxed me a statement approved by their lawyers that was to be their definitive answer to questions about the Therac- 25 accidents.

"When accidents occurred with the Therac-25 during the 1986 to 1988 time-frame," the statement read in part, "AECL Medical reacted quickly to investigate and inform Health and Welfare Canada and the U.S. FDA." Note the phrase "during the 1986 to 1988 time frame." By 1986 three of the six Therac-35 accidents had already occurred.

The AECL statement took issue with an article about the Therac-25 accidents published last July by the Institute of Electrical and Electronics Engineers in the technical journal Computer (the source for much of the information in this story). It was written by the computer scientist Nancy Leveson, a professor at the University of Washingon who served as an expert witness in two of the Therac-25 accident lawsuits, and a computer-science PhD candidate and lawyer, Clark Turner, of the University of California at Irvine, who specializes in legal liability issues involving software safety systems. In their article, Leveson and Turner noted that the Canadian Radiation Protection Bureau asked AECL by letter to install a mechanical interlock on the Therac-25 as early as November, 1985. Leveson and Turner bestowed upon the Therac-25 accidents the dubious distinction of being "the most serious computer-related accidents to date (at least nonmilitary and admitted)."

The AECL statement read, "The article in Computer magazine does not in places accurately describe the events or give appropriate credit to the fast response of AECL Medical at the time the accidents occurred." I telephoned Frech to ask AECL to be more specific about which parts of Leveson's and Turner's article were inaccurate. He declined. "The errors are in the area of detail which we really don't want to get into at this time," he replied. "This happened a long time ago. We regret that this occurred and don't want ro rehash it"

Theratronics also declined to give interviews. After several weeks of not returning my calls, the president of Theratronics, Frank Garland, told me I would be sent another statement. It arrived less than a week after the AECL statement. "Theratronics currently provides service to installed Therac-25s as part of a contractual arrangement with AECL," it read. "The arrangement was put into place at the time AECL Medical was dissolved in 1988. Theratronics does not manufacture linear accelerators, and cannot add to the information already provided by AECL Medical."

Who was the programmer who actually wrote the software used on the Therac-25? What sort of experience did he have? According to Leveson and Turner, it was a man who left AECL in 1986, but neither they nor lawyers connected with any of the lawsuits against AECL were able to obtain further information from the corporation. I can't tell you who he is. So neither can I tell you where he's working now.

As a result of the Therac-25 accidents, the FDA now requires documentation on software for new medical and other products: a paper trail, in other words, that can be examined by an independent body and retraced for flaws. In January, 1995, the International Electrotechnical Commission will recommend software safety standards for medical equipment, standards developed partly as a result of the Therac-25 accidents. Engineers can find their productivity cut nearly in half by such requirements, and there have been complaints in the high-tech community that software documentation is hampering competitiveness. The University of Washington's Jonathan Jacky still feels it's better than relying on what he calls "the stereotype of the eccentric genius programmer." At least, he told me, "the chances of a hazard getting into the community are a lot less. This run of Therac-25 accidents made it clear how wrong thing could go." At the time of the accidents no educational standard was required of computer-software programmers. "That's still true," says Jacky. "The knowledge of people out there Is extremely variable -- some people working on these things are far better than others. That's what documentation on software is supposed to catch."

I asked Katie Yarborough's lawyer, Bill Bird, to reflect upon the accidents after nearly a decade. "The thing that amazes me," he said, "is that the people who develop these machines are surely some of the most brilliant people in the world. This machine was unbelievably sophisticated. Nobody would have,oor hurt if somebody had used common sense. It's almost as if you have a scientific genius design a car and then an ordinary auto mechanic has to tell him how to run it properly."

The FDA, having been seen as too soft on computer safety in the past, is trying to prove to the U.S. Congress that it is tough on high-tech companies. Even though Theratronics no longer makes linear accelerarors and despite passing repeated Canadian safety inspections, the company has suffered through an FDA ban on all its medical equipment as a result of the Therac-25 malfunctions, beginning on July 19, 1991. Marc Schindler, Theratronics's marketing manager, criticized the ban in a 1991 Globe and Mail article. The ban was partially lifted that year and Theratronics received informal notice in April, 1994, that the rest of the ban will be lifted. Surprisingly, physicist Tim Still, the original troublemaker, sympathizes with the company. "After the FDA got rolling, they [Theratronics] got beaten to death." he says. "But their arrogance towards this whole Therac thing aggravated it. They brought it on themselves."
