Radiological Imaging Risk: Joint Commission Sentinel Alert #47

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Outline

• Medical Radiation Safety
• Recent Events in Imaging & Treatment
• Sentinel Event Alert #47
• Sentinel Events and Medical Events
• ALARA for Patients
• Summary
Medical Radiation Safety: 3 Ps

• Occupational **Personnel**
  – Exposure over long time (decades)
  – Safety comparable to other industries

• General **Public**
  – Maintenance of genetic stability
  – Overall public health and safety

• **Patients**
  – Acute effects: morbidity
  – Long-term effects: 2nd malignancies
Radiation Safety Principles
“Common Sense” + Physics

• **Time**: minimize the exposure time
• **Distance**: maximize the distance
• **Shielding**: use when needed
• **ALARA**: philosophy whereby exposures are kept “As Low As Reasonably Achievable”
  – Cost vs Benefit
  – Occupational, non-occupational, medical(?)
Medical Ionizing Radiation Sources

diverse devices and dose rates

• Linear Accelerators: High dose rate, high energy (MeV)
• Radiography: 60-120 kVp, Rad/Fluoro modes
• Fluoroscopy: 60-120 kVp, high dose rate (15 R/min)
• CT: 60-120 kVp, multi-slice, 4D modes
• Cone-beam CT: ~120 kVp, Rad/Fluoro modes
• HDR: 10 Ci Ir-192 source; high dose rate
• Sealed Sources: Cs-137, Ir-192, I-125, Ra-226, Sr-90 (tubes, LDR spheres, seeds, needles; beta and gamma)
• Liquid Sources: Tc-99m, Kr, I,
# Dose Rates and Dose

<table>
<thead>
<tr>
<th>Radiation Source</th>
<th>Amount</th>
<th>Dose Rate</th>
<th>Doses Deliverable</th>
<th>Scatter/Leakage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Accelerator X Rays</td>
<td>Beam On</td>
<td>400 cGy/min @ 1 m (isocenter)</td>
<td>400 cGy in 1 min</td>
<td>0.75 s for 50 mSv!</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1% (0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R/F Simulator</td>
<td>Beam On</td>
<td>0.076 mGy/mAs @ 1 m</td>
<td>3 cGy/min in fluoro mode (up to 15 rad/min)</td>
<td>0.1% (0.001)</td>
</tr>
<tr>
<td>Radiographic Fluoroscopic</td>
<td>(80 kV, 100 ma)</td>
<td>3.3 cGy/min @ 1 m (74 kV, 8 mA)</td>
<td>1.5 min for 50 mSv!</td>
<td></td>
</tr>
<tr>
<td>Cone-beam CT</td>
<td>Beam On</td>
<td></td>
<td>2 cGy/min per rotation</td>
<td>0.1% (0.001)</td>
</tr>
<tr>
<td>CT Simulator</td>
<td>Beam On</td>
<td>~ 240 cGy/min @ axis (12 mR/mAs)</td>
<td>Per Scan Doses: ~ 1.2 cGy (head) 4.5 – 5.5 cGy (body)</td>
<td>0.1% (0.001) or much less</td>
</tr>
<tr>
<td>Head</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gamma Knife</td>
<td>6000 Ci, 192-201 sources</td>
<td>340 to 200 cGy/min @ focus (40 cm)</td>
<td>300 rad in 1 min</td>
<td>0.1% (0.001), &lt; 2mR/hr @ side; 1 R/hr @ face</td>
</tr>
<tr>
<td>HDR: Ir-192</td>
<td>10 Ci</td>
<td>4.7 cGy/hr @ 1 m (or 78 mcGy/min @ 1 m) 47,000 cGy/hr @ 1 cm (or 783 cGy/min at 1 cm)</td>
<td>1 hour for 5 rem @ 1 m 0.38 s for 50 mSv @ 1 cm (local, not whole body)</td>
<td>By inverse square law</td>
</tr>
<tr>
<td>Sealed, Unsealed Sources for Brachytherapy</td>
<td>1 to 50 to 100 mCi</td>
<td>10 mrad/hr @ 1 m 100 cGy/hr @ 1 cm (or 1.7 cGy/min @ 1 cm)</td>
<td>500 hrs for 50 mSv @ 1 m 3 min for 50 mSv @ 1 cm (local, not whole body)</td>
<td>By inverse square law</td>
</tr>
</tbody>
</table>
Advances in Radiation Technologies and Significance for Radiological Community

- Now available!: Advanced imaging and treatment procedures for benefit of our patients
- New technologies require: higher-level education and training for understanding and operating devices
- Operator roles have changed: from “active, manual mode” to “observer mode”
- Quality Assurance: all steps and devices undergo QA. Now, QA is for processes & software in “black boxes”
- These days: very important to verify initial parameters as correct – they may be used for entire procedure
- Challenge: Tendency that “computer is always right”
- Challenge: Recognizing correct / incorrect operation
Recent Events and Concerns

- NCRP Report 160
- 3 mSv $\rightarrow$ 6 mSv
California RT gives deposition in CT overdose case

By Donna Domino
AuntMinnie.com contributing writer
December 10, 2009

The California radiologic technologist accused of operating the CT scanner that delivered a massive radiation overdose to a 23-month-old boy in 2008 testified last week that she only pushed the CT scan button a few times, and she doesn't understand how the toddler received 151 scans in a single imaging session.

Raven Knickerbocker, who is accused of subjecting Jacoby Roth to more than an hour of continuous scanning, said she only pressed the scan button "two to four times," according to the Roth family’s attorney, Don Stockett, who questioned her during a December 4 deposition in preparation for a civil trial in a lawsuit filed by the boy’s parents.

Knickerbocker testified during the deposition that she performed two scout scans and then tried to start the examination, but the machine did one rotation before it stopped and displayed a fault code, said Stockett, whose practice is based in Folsom, CA. She asserted the scanning procedure lasted only about 20 minutes.

In January 2008, the boy was taken to the emergency room at Mad River Community Hospital in Arcata, a small town 200 miles north of San Francisco, after he fell out of bed and could hardly move his head.

The ER doctor ordered x-rays and CT scans to check for damage to the child’s cervical spine. The boy was taken to the scanning room, where Knickerbocker performed CT scans at C-spine levels C1 through C4 in the same section of the midmaxillary sinuses, midclivus, and posterior fossa. Over the next 68 minutes, the toddler was exposed to 151 scans.

Within a few hours, the child developed a bright red ring around his head from the massive radiation overdose. Photographs of the left side of the boy's face show a clear line extending from the infraorbital ridge backward through the ear and nape of the neck; a similar line extends from the infraorbital ridge through the ear on the right side.

In off-the-record comments, one state official called it the worst case of radiation overdose of a child in the U.S.

Dave Laumann, the head technologist at Mad River at the time, told the state agency that he had stopped in to check on Knickerbocker, saw she was having problems, and suggested that she reboot the scanner. But Knickerbocker testified last week...
Radiation Overdoses Point Up Dangers of CT Scans

By WALT BOGDANICH

At a time when Americans receive far more diagnostic radiation than ever before, two cases under investigation involving a large, well-known Los Angeles hospital, the other a tiny hospital in the northern part of California, point to the risks that powerful CT scans pose when used incorrectly.

A week ago, Cedars-Sinai Medical Center in Los Angeles disclosed that it had mistakenly administered an excessive normal radiation dose to 206 possible stroke victims over an 18-month period during a procedure of the brain. State and federal health officials are investigating the cause.

Hundreds of miles north at Mad River Community Hospital in Arcata, the other case — involving a 20-month-old girl suffering of neck pain after falling off his bed — has led to the revocation of an X-ray technician’s state license, multipling the time of CT scans. The procedure normally takes two or three minutes.
FDA Advisory: CT Brain Perfusion Dose
3-4 Gy (avg 0.5 Gy or 500 mGy) delivered:

Cause: operator error, and training – pre-sets adjusted and stored at higher levels

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm
Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nausea, unable to breathe — be studied and talked about publicly so that others might not have to live the way he did.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His face was ashen. He pointed to the beach where they had played as children so he could touch it, feel it and remember better.

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 would have caused a computer error that would have led to accidental blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive treatments.

Soon after the accident, at St. Vincent’s Hospital in Manhattan, state health officials cautioned...
The Subcommittee on Health held a hearing entitled "Medical Radiation: An Overview of the Issues" on Friday, February 26, 2010, at 10:00 a.m. in room 2123 of the Rayburn House Office Building. This hearing examined the potential benefits and risks of the use of radiation in medicine.

Witnesses

• James and Donna Parks, Gulfport, Mississippi
• Suzanne Lindley, Canton, Texas
• Rebecca Smith-Bindman, M.D., Professor in Residence, Radiology and Epidemiology and Biostatistics, Obstetrics, Gynecology, and Reproductive Medicine, University of California, San Francisco
• Eric E. Klein, Ph.D., Professor of Radiation Oncology, Washington University in St. Louis
• Cynthia H. McCollough, Ph.D., Director, CT Clinical Innovation Center, Department of Radiology, Mayo Clinic, Professor of Radiological Physics, College of Medicine, Mayo Clinic
• CH McCollough, PhD, Mayo
• Tim R Williams, MD, ASTRO
• Michael G Herman, PhD, AAPM
• Sandra Hayden, BS, RT(T), ASRT
• E Steven Amis, Jr., MD, ACR
• Kenneth Mizrach, VA-NJ
• David N Fisher, MITA
• John J Donahue, Medicalis, Inc
House Hearings: Medical Radiation
Other Events

- 77 SRS patients, FL, +50% dose (physics error)
- 76 SRS patients, MO, + 50% dose (physics error)
- Scotland brain irradiation, fatality (calc error)
- IMRT, NY, fatality (software, QA failure)
- GK, MI, wrong side treatment (imaging error)
Classes and Causes of Events

Classes of Errors
- Missed all/part of target 46%
- Wrong dose 41%
- Wrong patient 8%
- Other – eg, technology 5%

Causes of Errors
- QA flawed 28%
- Data entry & calc errors 20%
- Mis-ID: patient, site 14%
- Setup error (blocks, wedges) 11%
- Patients physical setup wrong 8%
- Flawed treatment plan 6%
- Hardware malfunction 5%
- Software/data transfer, software overrides, communication 5%
“Malfunction 54”          US, Canada
The Original Computer Radiation Dose Event: 1985-87

- First “computer-controlled” linear accelerator
- Basic programming language
- Therapist able to out-run the computer program
- Reprogrammed for electron treatment at photon beam energy
- **Result: 250 Gy in ~ 2s**
- Patients injured, died from localized overdoses

**Cause:** inadequate software checks, safety controls

**FATAL DOSE**

Radiation Deaths linked to AECL Computer Errors

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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
Imaging Event (yr 2000)
Imaging Injury At 100 kV

Radiation injury from x-ray exposure during brachytherapy localization B. R. Thomadsen, B. R. Paliwal, D. G. Petereit, and F. N. Ranalloo
University of Wisconsin-Madison, Department of Medical Physics, Madison, Wisconsin 53706

Cause: Training/education and practice issue – “forgot” imaging gives radiation dose; focused on brachytherapy procedure, not imaging process

Cal'd Exp Rate 0.17 mGy/mAs @ 76 cm
ISL correction (76 cm/23 cm)²
Technique Fac 500 mAs/exposure
Exposures / film 12 exposures/film
Films / Rx Course 5.75 films
BSF 1.3
Tot Equiv Dose 83 Gy

Patient 2
0.17 mGy/mAs @ 76 cm
(76 cm/23 cm)²
500 mAs/exposure
12 exposures/film
5.75 films
1.3
29 Gy
Sentinel Events

• Joint Commission – accreditation body for healthcare organizations (www.jointcommission.org)
• Wrote “sentinel event” policy ~ 2006
• Guidelines for reporting of serious events that could result in serious consequences, injury, death, deleterious effects for persons
• Healthcare organizations are to identify, self-report, respond quickly and effectively for correction, etc
Sentinel Event Policy and Procedures

January 4, 2011

In support of its mission to continuously improve the safety and quality of health care provided to the public, The Joint Commission reviews organizations’ activities in response to sentinel events in its accreditation process, including all full accreditation surveys and random unannounced surveys and, as appropriate, for-cause surveys.

- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
- Such events are called “sentinel” because they signal the need for immediate investigation and response.
- The terms “sentinel event” and “medical error” are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.
The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition):
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge
- Unanticipated death of a full-term infant
- Abduction of any patient receiving care, treatment, 
- Discharge of an infant to the wrong family
- Rape
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- **Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose**
TJC List of 10 items as Sentinel Events

1 Radiation Sentinel Event – 3 sub-events

• Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field, or [high imaging dose]

• Any delivery of radiotherapy to the wrong body region, or [wrong site]

• >25% above the planned radiotherapy dose [unintended high treatment dose]
Fluoroscopy

January 8, 2006
By Electronic Transmission

RE: Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Field Review: Candidate 2007 National Patient Safety Goals (NPSGs) and Requirements

1. Modify the event description: “Prolonged high dose imaging procedure with an unanticipated cumulative dose >1,500 rads to a single field in a course of treatment.” This change allows for the planned medically appropriate delivery of such a dose, and further extends the integration time of the dose to account for situations where multiple procedures occur over the period of a few days during a course of treatment.
2. Add language elsewhere in the JCAHO publications that facilitates the effort to properly control patient safety in high dose imaging procedures (and thus avoiding procedure related radiation doses that result in unnecessary or unanticipated adverse skin damage)

2.1. Reference the FDA recommendations for monitoring, recording and patient follow-up for high dose imaging procedures

2.2. Recognize that measurements to achieve compliance with dose monitoring recommendations requires establishing appropriate measurement techniques by a qualified medical physicist to assure that the reported dose measurements correctly reflect the dose received by the patient

2.3. Reinstall the previous JCAHO language regarding credentialing for medical practitioners who use fluoroscopy.

Radiation Treatment

1. “The total dose delivered differs from the prescribed dose by 20 percent or more.” This is consistent with the current NRC requirement for reporting a medical event, and expands the JCAHO requirement to underdoses as well as overdoses.

2. Add a footnote to the “wrong body region” phrase: “Delivery of radiation dose to anatomic regions due to migration of implanted radioactive material or delivery of radiation dose to tissue adjacent to treatment volumes due to normal variations in the treatment process do not rise to the level of a reviewable sentinel event.”
Sentinel Event Alert, Issue 47

- August 24, 2011 - In response to the various radiation events, well-publicized, 2009 and forward, Joint Commission issues a Sentinel Event Alert, Issue 47
  
  “Radiation risks of diagnostic imaging”

- A well-written report: NCRP 160, ECRI reports, FDA, WHO, NIEHS (“radiation a carcinogen”), CMS imaging accreditation
Radiation risks of diagnostic imaging

Correction: The American College of Radiology (ACR) launched its National Radiology Data Registry (NRDR) in 2008. Its Dose Index Registry (DIR), which is part of the NRDR, launched in May 2011 (see fourth paragraph).

Diagnostic radiation is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time. Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation. The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries. X-rays are officially classified as a carcinogen by the World Health Organization’s International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.
Over the past two decades, the U.S. population’s total exposure to ionizing radiation has nearly doubled. Diagnostic imaging can occur in hospitals, imaging centers, physician and dental offices, and any physician can order tests involving exposure to radiation at any frequency, with no knowledge of when the patient was last irradiated or how much radiation the patient received. From the 72 million CT (computerized tomography) scans performed in the U.S. during 2007, one study estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent). Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent. While these studies’ conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information.

As a result of the potential dangers associated with ionizing radiation, the Centers for Medicare & Medicaid Services (CMS) will require the accreditation of facilities providing advanced imaging services (CT, magnetic resonance imaging (MRI), positron emission tomography (PET), nuclear medicine) in non-hospital, freestanding settings beginning January 1, 2012. In addition, the state of California has mandated that facilities that furnish CT X-ray services become accredited by July 1, 2013. This California law also requires the documentation of the dose of
Addressing contributing factors to eliminate avoidable radiation dosing
There are actions that organizations can take to eliminate avoidable radiation. First, staff should be aware of the contributing factors to, and activities that can help eliminate, avoidable radiation doses, which include:
- A comprehensive patient safety program, including education about dosing in imaging departments.

Right test
1. In order to reduce the exposure of the patient to ionizing radiation, use other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level.17

Right dose
3. Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for “as low as reasonably achievable” – making sure doses are as low as possible while achieving the purposes of the study.19
4. Adhere to the Society for Pediatric Radiology’s Image Gently guidelines when providing imaging radiation (or fluoroscopy) to children11,19,20 and for adults, adhere to the

Effective processes
10. Create and implement policies and procedures delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging. Provide

Safety culture
18. Use the following Joint Commission standards to support the use of safe and effective diagnostic radiation: LD.03.01.01, LD.03.04.01, LD.03.05.01, LD.03.06.01 (all programs). The concepts in these standards promote a safety culture, which is necessary for the safe use of diagnostic radiation. A safety culture is expressed in the beliefs, attitudes and values of an organization’s employees regarding the pursuit of safety. It is present in the organization’s structures, practices, controls, and policies, which are used to achieve greater safety. For more information about safety culture, see: Part 1, Part 2

Safe technology
14. Perform an organization-wide audit/survey of diagnostic imaging equipment that have the

13. Ensure all physicians and technologists who prescribe diagnostic radiation or use diagnostic radiation equipment receive dosing education and are trained on the specific model of equipment being used.4,17,21 Institute a process for annual education, review and competency testing.

See relevant Joint Commission requirements:
HR.01.02.01, HR.01.02.05, HR.01.04.01,
HR.01.05.03 (all programs), HR.02.02.01
(ambulatory), MS.03.01.01, MS.03.01.03,
MS.06.01.03 (hospital)
Assessment: Alert Issue 47

- Well-written, with input from medical physicists, and including appropriate references
- Timely based on recent radiological events
- Included the expertise of medical physicists
- Reviews and cautions the medical community about IR from medical imaging procedures
- Five categories: Right test, Right dose, Effective processes, Safe technology, Safety culture
- Specific to diagnostic imaging only, and excludes fluoroscopy and radiation treatment (though these are recognized contributors to Sentinel Events)
Alert Issue 47: Physicist Role

• Joint Commission is very important for credentialing – administrators know the JC
• Thus, review with administrators and clinical and technical directors for impact
  – Highest priorities for patient safety
  – Widespread use and diagnostic benefits of medical imaging – “imaging is a commodity”
Alert Issue 47: One Caution

• Application of ALARA: “ALARA guidelines as required by the Nuclear Regulatory Commission”
  – ALARA is for radiation protection of occupational individuals, not for patients
  – Should not be confused – both involve risk-benefit analysis
  – NRC does not regulate amount of medical radiation dose – accuracy of dose
  – States do not regulate amount of medical radiation dose – accuracy of dose

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Radiation risks of diagnostic imaging

Of interest to the medical physics community is the recent Joint Commission (JC) Sentinel Event Alert, Radiation risks of diagnostic imaging[1]. This important notice from an important organization is well-written, includes input from medical physicists, references appropriate radiological literature, and reviews and cautions the medical community about ionizing radiation dose from diagnostic medical imaging procedures. The Alert's cautions and actions include the five categories of: Right test, Right dose, Effective processes, Safe technology, and Safety culture. The Alert’s recommendations are specific to diagnostic imaging, excluding fluoroscopy and therapeutic radiation, however, in general, the five categories are relevant to all radiological procedures. Medical physicists should review the Alert with their administrators and clinical and technical directors because of the highest priorities for patient safety, the JC’s importance and visibility for credentialing of healthcare organizations, and the widespread use and diagnostic benefits of radiological imaging procedures that impact a large number of patients nationwide.

From the Editor: Following the JC alert, American College of Radiology issued a statement confirming the utility of the alert however, highlighted certain inaccuracies issued in the JC alert. The complete ACR statement on JC’s sentinel event can be found at: http://www.acr.org/HomePageCategories/News/ACRNNewsCenter/ACR-Statement-on-TJC-Sentinel-Alert.aspx
ACR Response: Two Inaccuracies
http://www.acr.org/HomePageCategories/News/ACRNewsCenter/ACR-Statement-on-TJC-Sentinel-Alert.aspx

ACR Statement on TJC Sentinel Alert

On August 24, 2011, The Joint Commission (TJC) issued a Sentinel Event Alert titled “Radiation Risks of Diagnostic Imaging.” Such alerts are issued periodically by TJC to describe underlying causes of these sentinel events and to suggest steps to prevent occurrences in the future.

This alert indicates general agreement that “care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation.” This message concurs with the message that the ACR has been sending to its members, patients and the general public for several years.

However, the alert indicates that the CMS January 2012 requirement for accreditation of CT, MRI, and PET was promulgated “as a result of the potential dangers associated with ionizing radiation.” The ACR, a sponsor of the legislation requiring this accreditation, considers this statement inaccurate, first because the legislation is aimed primarily at ensuring a high level of quality for these modalities, including inspection and evaluation of image quality and, second because MRI, a component of the accreditation requirement, produces no ionizing radiation.
ACR Response: Two Inaccuracies

ACR Statement on TJC Sentinel Alert

A second inaccuracy is the statement that the ACR launched its National Radiology Data Registry (NRDR) in May. In fact, NRDR has been in existence since 2008. In May 2011, the ACR launched its Dose Index Registry (DIR), a national registry that permits facilities to monitor dose from each CT scanner and compare those doses to national benchmarks. The TJC Alert unfortunately makes no specific mention of the existence of the DIR.

We are pleased TJC acknowledges that “experts disagree on the extent of the risks of cancer from diagnostic imaging” but we are concerned with the recommendation for “awareness of the potential dangers from diagnostic radiation among organizational leadership, hospital staff and patients” considering that there is significant scientific disagreement on the magnitude of those dangers.

In general, the ACR applauds TJC’s alert for its comprehensiveness and strong recommendations regarding selection of the right procedure and the right dose, creating effective processes, ensuring safe technology and promoting a safety culture. The College is particularly pleased to have already addressed, through its DIR, recommendation 19 which endorses the creation of a national registry to track radiation doses.
The American Association of Physicists in Medicine (AAPM) acknowledges that medical imaging procedures should be appropriate and conducted at the lowest radiation dose consistent with acquisition of the desired information. Discussion of risks related to radiation dose from medical imaging procedures should be accompanied by acknowledgement of the benefits of the procedures. Risks of medical imaging at effective doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent. Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures. AAPM members continually strive to improve medical imaging by lowering radiation levels and maximizing benefits of imaging procedures involving ionizing radiation.
State Regulations

• Administer licenses to us and others for use of radioactive materials and radiation-producing equipment

• Do not regulate (limit) the amount of dose that can be received by a patient

• Do regulate the accuracy of delivery for diagnostic and therapeutic radiation prescriptions
Quick Links

Staff Directory
Customer Service
Emergency Information
Enforcement
Frequently Asked Questions
Mission
Regulations
Newsletters and Notices
RPS Intranet

Emergency Response/Environmental Monitoring
Environmental Monitoring, Homeland Security, more...

Radioactive Materials
Specific Licensing, Reciprocity, Increased Controls, Forms and Publications, Notices, LLRW, Medical Uses Toolkit, more...

Tanning
Registration Forms, Forms, Service Listings, FAQs, Inspection Check List, Regulations, more...

Guidance and Posting Documents
Mammo Guidance, Specific License Guidance, Radon Testing, Tanning Guidance, Warning signs, X-ray Guides

SECTION FEES
Radioactive Materials (RAM)
X-ray
Tanning

Mammography
Important Info, News, Inspection Help, Mobile, Forms, State Requirements, Education, Processing, more...

Radon
Certified Mitigator List, Certified Measurement Provider List, Training Schedule, Real Estate, more...

X-Ray Program
Registration Forms, Plan Reviews, Service Listings, Written Safety Programs, Top Ten Violations, more...

Licensing and Registration
Mammo Registration, General Licensing, Specific Licensing, Tanning Registration, X-ray Registration

Information Relevant to the Japan Nuclear Incident - click for weekly updates

SAFETY CULTURE BROCHURE
CHAPTER 11 – RADIATION PROTECTION

SECTION .0100 – GENERAL PROVISIONS

Effective November 1, 2007

15A NCAC 11 .0101 SCOPE
(a) Except as otherwise specifically provided these Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.
(b) Nothing in these Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.
(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150.

(79) "Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.
(80) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.
(81) "Member of the public" means any individual except when that individual is receiving an occupational dose.
Medical Events – Not Sentinel Events

15A NCAC 11 .0364

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and
   (A) The total dose delivered differs from the prescribed dose by 20 percent or more;
   (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
   (C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:
   (A) An administration of a wrong radioactive drug containing radioactive material;
   (B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
   (C) An administration of a dose or dosage to a wrong individual or human research subject;
   (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or
   (E) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days of the discovery of the medical event. The written report must include:

1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. What actions, if any, have been taken or are planned to prevent recurrence; and
7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not.

The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that he or she will inform the individual or that based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or responsible
Summary

• Variety of medical radiation sources: high dose rates, automated, and computer controlled
• Recent events show that undesired high exposures for imaging and treatment are possible
• One JC Sentinel Event is defined for medical radiation procedures: both imaging and treatment
• The recent JC Sentinel Event Alert #47 calls attention to possibility of high imaging doses
• Physicists and healthcare administrators should be well-versed on Joint Commission definitions
• Risk-benefit analysis is appropriate, not ALARA
New York: IMRT

• IMRT – individual MLC leaves move to modulate the field intensity

• Field shape changes as a function of time and dose
New York: IMRT

- IMRT – individual MLC leaves move to modulate the field intensity
- Field shape changes as a function of time and dose
New York: IMRT
1st 3 fxs delivered without issue  
Upon IMRT plan revision: “Save All”  
However, not all data saved – computer “crash”  
- Fluence data saved; DRR saved in part  
- MLC control points NOT saved  
No verification plan created (for physics QA)  
- Verification plan would have shown no MLC in use  
Treatment plan has valid MUs  
**but no MLC control points**  
Patient treated for 3 fractions: beams delivered without MLC shapes or motions  
**field was “wide open”**  
We received and reviewed a 9-page letter from the vendor to explain various manners of incorrect program terminations

**What can go wrong in radiation treatment?**

Ola Holmberg, Ph.D., IAEA, Vienna, Austria  
Safety in Radiation Therapy – A Call to Action, June 24-25, 2010
New York: IMRT

- IMRT MUs about 4-5 times higher than 3D-CRT
- High dose received to non-target volumes
  \[3 \times 13 \text{ Gy} = 39 \text{ Gy}\]

Reportedly -
- Plan was revised
- IMRT QA not done
- Overworked and rushed personnel
- Control console not observed
- Patient concerns not listened to
Patient + Scan Orientations

Patient + Scan Label: Supine, Head First

Scan Label: Supine, Feet First

Correct!

Patient: Supine, Head First

Scan Label: Supine, Feet First

Wrong!

True Mirror
What Really Happened

Patient + Scan Label: Supine, Head First

Patient: Supine, Head First
Scan Label: Supine, Feet First

RESULT - 18 mm shift across midline (exaggerated here)
What Really Happened

Patient + Scan Label: Supine, Head First

Patient: Supine, Head First
Scan Label: Supine, Feet First

RESULT - 18 mm shift across midline (exaggerated here)

A Perfect Miss!
The recommendations ... [in this publication] are based on a retrospective analysis of accidental exposures in radiation therapy with past and current types of equipment. There are, however, a number of factors that may cause a change in this picture in the future:

- With the worldwide expansion of radiotherapy there may be more accidents related to inadequate staff training.
- There is a common misperception that modern equipment is safer and will require less quality assurance.
- ...Accidents may occur due to inadequate accelerator maintenance. The increased number of computer-controlled systems may also lead to more computer related accidents, compared to mechanical failures.
- The new technologies of high dose rate (HDR) brachytherapy, “gamma knife” therapy units, multi-leaf collimators, and intensity modulated radiotherapy (IMRT) may produce new types of accidental exposures.
Deviation Rates [~ 1.2- 4.7% per course]

<table>
<thead>
<tr>
<th>Author, year, institution (Ref.)</th>
<th>Deviation rates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang, 2005, Princess Margaret Hospital (1)</td>
<td>1.97% (per treatment course)</td>
</tr>
<tr>
<td></td>
<td>1.28% (per treated volume)</td>
</tr>
<tr>
<td></td>
<td>0.29% (per treatment fraction)</td>
</tr>
<tr>
<td>Yeung, 2005, Northeastern Ontario Regional Cancer Center (5)</td>
<td>4.66% (per treatment course)</td>
</tr>
<tr>
<td></td>
<td>0.25% (per treatment fraction)</td>
</tr>
<tr>
<td>Patton, 2003, University of Utah (3)</td>
<td>3.3% (per treatment course)</td>
</tr>
<tr>
<td></td>
<td>0.17% (per treatment session)</td>
</tr>
<tr>
<td>Barthelemy-Brichant, 1999, Universitaire de Liege (4)</td>
<td>3.22% (per treatment field)</td>
</tr>
<tr>
<td>Fraass, 1998, University of Michigan (2)</td>
<td>1.2% (per treatment course)</td>
</tr>
<tr>
<td></td>
<td>0.13% (per segment)</td>
</tr>
<tr>
<td></td>
<td>0.44% (per treatment session)</td>
</tr>
<tr>
<td>Macklis, 1998, Cleveland Clinic Foundation (6)</td>
<td>3.06% (per treatment course)</td>
</tr>
<tr>
<td></td>
<td>0.18% (per treatment field)</td>
</tr>
<tr>
<td>Current study, 2007, Duke University</td>
<td>0.10% (per treatment sessions)</td>
</tr>
</tbody>
</table>

Huang, Yeung, Patton, and Fraass conducted a retrospective analysis of deviations documented in therapist-reported or QA review. Macklis conducted a prospective and retrospective analysis of deviations documented in therapist-reported or QA review. Barthelemy-Brichant conducted a prospective blinded study comparing recorded parameters entered into record and verify with the prescriptions.

* Some data estimated from published reports

Deviation Rates $[\sim 1.2$- $4.7\% \text{ per course}]$

- Error rate is greater than zero
- Various definitions exist for error rates
- Severity of errors can vary
  - From inconsequential to severe
- Radiation oncology field operates on probability
  - Physics $\sim 3\%$
  - Geometry, positioning $\sim 5\%$
  - Biology $\sim$ variable (site, patient, etc)
  - Goal: Dose delivered within 10\% (biology from there)
Collective Responses

- National Practice Standards: medicine, physics, technology
- National Standards for Education and Training
- Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act of 2010 (CARE Act), S. 3737
- Accreditation: relevant to technology
- National database for reporting of radiation procedure errors - voluntary, self-administered
- Industry – device design and manufacturing
## Impact of Errors

<table>
<thead>
<tr>
<th>Individual</th>
<th>Impact</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>- Individual patient</td>
<td>- Prescription error</td>
</tr>
<tr>
<td></td>
<td>- Class of patients</td>
<td>- Poor brachytherapy technique</td>
</tr>
<tr>
<td>Therapist</td>
<td>- Individual patient</td>
<td>- Wrong isocenter; wrong data</td>
</tr>
<tr>
<td></td>
<td>- Particular technique</td>
<td>- Incorrect beam matching</td>
</tr>
<tr>
<td>Physicist</td>
<td>- Individual patient</td>
<td>- MU calculation error</td>
</tr>
<tr>
<td></td>
<td>- Class of patients</td>
<td>- Incorrect wedge use (RTP)</td>
</tr>
<tr>
<td></td>
<td>- All patients (eg, an irradiation device)</td>
<td>- Linac calibration error</td>
</tr>
</tbody>
</table>

Therapists often assigned blame -
- there is no error in dose delivery until “ON” is pushed
Hospitals With Radioactive Materials Expose Weakness in Antiterror Rules

By MATTHEW L. WALD

WASHINGTON — Ten years into a campaign to make radioactive materials harder for terrorists to steal, Congressional auditors have found one hospital where cesium was kept in a padlocked room but the combination to the lock was written on the door frame and another where radioactive material was in a room with unsecured windows that looked out on a loading dock.

In testimony prepared for delivery on Wednesday to a Senate Homeland Security subcommittee, an official from the Government Accountability Office plans to say that people with responsibility for security told the auditors that they were trained as physicists or radiation health technicians and were being told to enforce regulations “that they did not believe they were fully qualified to interpret.”

The materials in question cannot be used to make a nuclear bomb, but if incorporated into a device with conventional explosives they would make a “dirty bomb” that could contaminate significant areas of a city with measurable amounts of radiation, some of it worrisome.