Radiation Safety Webinar

on

California State Law &
The Joint Commission
Sentinel Event Alert #47

Lisa Russell, BSRT • Bob Pizzutiello, FACR, FAAPM, FACMP
Radiologic Health Branch

Radiation Safety Education Seminar

California State Law: Dose Recording, Accreditation, and Event Reporting

Lisa Russell, BSRT
How much is too much?

• California law and regulations do not limit how much radiation a patient can receive – medical necessity.

• Society and physicians determine what exposure is considered acceptable.

• Due to publicity involving recent events, patients and their families are starting to ask how much radiation exposure they received.
• SB 1237 - Generated Due to Multiple Incidents Involving CT Scanners in California

  – Head CT - Northern CA Hospital
    • A two year old child received excessive radiation.
    • Manually imaged same location on face 151 times.

  – Brain Perfusion CT – Southern CA Hospital
    • RHB investigation identified five facilities with excessive radiation during brain perfusion scans.
    • 376 patients in California identified as receiving excessive radiation ($\text{CTDI}_{\text{vol}} > 1,000 \text{ mSv}$) from brain perfusion CT studies.
SB 1237, as amended by SB 38 last year, added 3 new sections (115111, 115112, and 115113) to the Health and Safety Code

Prior to SB 1237, California did not require:

– Reporting of events of excess radiation exposure involving machine generated radiation.
– CT dose recording
  • The displayed dose indicators are only an estimation of the dose.
– Accreditation for any imaging service other than mammography
Terminology

• Sievert (Sv) = 100 rem

• Standard CT Phantoms: PMMA (polymethylmethacrylate) approximately 15 cm long with a diameter of either 16 cm or 32 cm
  – Specific phantom used in protocols may or may not be displayed
  – 16 cm phantom is typically used to represent the head and pediatric body
  – 32 cm phantom is typically used to represent the adult abdomen
Terminology

• **CTDI**: Computed Tomography Dose Index
  – Measured in axial scan mode/single rotation
  – Theoretical estimate of multiple contiguous slices

• **CTDI\_vol**
  – Average dose within the scan volume for a standardized phantom; estimates dose to similar volumes
  – Independent of scan length
  – Considers protocol specific information such as pitch and technical parameters

• **DLP**: Dose Length Product
  – Scan length in centimeters x CTDI\_vol
Terminology

• **E**: Effective Dose (mSv)
  – Reflects the risk of a non-uniform exposure in terms of an equivalent whole body dose

• **k**
  – Factors used for estimating effective dose (e.g. AAPM Report 96)
  – Based on computed organ dose in adults

\[ E = k \times DLP \]
Terminology

• **Scan**
  – Axial or helical acquisition

• **Study**
  – Scan(s) of a region of interest intentionally acquired for a single diagnosis

• **Examination**
  – One or more studies performed during a single visit/appointment
  – Does not include repeat imaging due to operator or machine error
Terminology

• **Patient Movement or Interference**
  – A patient moves voluntarily or involuntarily
  – Patient (family or other care giver) interference
    • Interrupted study
    • Set-up disrupted
  – Abnormal patient anatomy
    • Routine procedures followed but area of interest was not adequately imaged

• **Radiology Report**
  – The formal documented interpretation of the diagnostic test
• Health and Safety Code Section 115111
  – Effective July 1, 2012
  – Requires facilities that use CT to record the technical factors and dose of radiation on every CT study.
    • RDSR electronically sent to PACS when the study is complete if the facility has a PACS.
Dose Recording

- **Health and Safety Code Section 115111**
  - Requires that the displayed dose be verified by a medical physicist as accurate to +/- 20% of the measured dose
    - Displayed dose depends on the phantom size used to generate the values.
    - Is only an approximation of the actual radiation dose received by the patient.
    - Not required if facility is accredited
  - Defines dose as either
    - CTDI$_{vol}$ and DLP
    - Dose unit recommended by AAPM
• Health and Safety Code Section 115111
  – Requires facilities to record the dose in the radiology report

  • Dose indicators may be attached or dictated in the report.

  • $\text{CTDI}_{\text{vol}}$ may be summed if the same anatomic region is scanned multiple times.

  • Ensures that dose information is available to the patient and referring physician.
• Health and Safety Code Section 115111
  – Are there any exceptions?
    • Limited to systems performing diagnostic studies.
      – CT defined by federal regulation
    • Limited to systems capable of calculating and displaying the dose.
    • The Department cannot make exemptions to the law.
Accreditation

• Health and Safety Code Section 115112
  – Effective July 1, 2013
  – Requires facilities that provide CT services to be accredited
  – Accreditation organization approved by Medicare and Medicaid Services (CMS) or
    • Agency approved by California Medical Board
    or
    • California Department of Public Health

• MIPPA – Not exactly the same thing
• **Health and Safety Code Section 115113**
  – Effective July 1, 2012
  – Outlines which events must be reported
    • Dose limits
  – States timeframe for initial report

• **Dose calculations of excess exposure**
  – Only calculate patient exposure from CT scans that were not used for the diagnosis (e.g. operator and/or equipment errors)
Event Reporting

• 0.05 Sv (5 rem) effective dose equivalent
  – Whole body exposure, dose equivalent, or TEDE.
    • Partial body exposure is corrected for whole body exposure
• 0.5 Sv (50 rem) organ dose or shallow (skin) dose
• Why?
  – Same as annual radiation worker limits
  – Same as radiopharmaceutical in 10 CFR 35 medical
  – Limit based on increased risk of cancer (other than skin)
  – Biological Effects of Ionizing Radiation (BEIR) VII - 5 rem
    • 400 individual excess solid cancers per 100,000 people – male
    • 650 individual excess solid cancers per 100,000 people – female
    • 205 individual excess cancer deaths per 100,000 people – male
    • 305 individual excess cancer deaths per 100,000 people – female
• Patient movement or interference – **reporting not required.**

  – The obvious reasons include: a patient moves voluntarily or involuntarily, patient, family, or other care giver interferes with the acquisition or set-up, and abnormal patient anatomy or tissue damage interferes if routine procedures are followed.

  – **QUESTION** – Who reviews images or has physician/radiologist approve prior to rescanning patient?
• Health and Safety Code Section 115113(a)(1)
  – “Repeating of a CT examination, unless otherwise ordered by a physician or a radiologist” and if specified dose values are exceeded.

  – Examples:
    • Wrong CT parameters
    • Not administering contrast when required
    • Equipment does not operate properly
• Health and Safety Code Section 115113(a)(2)
  – “CT X-ray irradiation of body part other than that intended by the ordering physician or a radiologist, and if specified dose values are exceeded.

  – Examples:
    • Scan head only when abdominal scan requested
    • Wrong patient

  – Note: We know that certain body parts adjacent to the area of concern will be imaged. This is acceptable.
Event Reporting

• Health and Safety Code Section 115113(a)(3)
  – “CT or therapeutic exposure that results in unanticipated permanent functional damage to an organ or a physiological system, hair loss, or erythema, as determined by a qualified physician.” – reporting required.

• If the patient has received instructions concerning the risks and potential consequences of a procedure, and has given consent prior to the procedure being performed, then the facility has met the definition of an anticipated event.
• Health and Safety Code Section 115113(a)(4)
  – “A CT or therapeutic exposure to the embryo or fetus that is greater than 50 mSv (5 rem) dose equivalent…”
  
  • If the facility knows that the patient is pregnant at the time of irradiation
    
    and
  
    • The embryo or fetus receives 50 mSv (5 rem) exposure
      
      and
  
    • The patient’s physician **did not** approve the CT exam
      
      then **REPORT IT**
Event Reporting

• Health and Safety Code Section 115113(a)(5)
  – “Therapeutic ionizing irradiation of the wrong individual, or wrong treatment site”

• If a geometric miss occurs, it requires reporting.
  – We know that certain body parts adjacent to the treatment volume will be exposed to radiation.

• Wrong person

• Required to be reported if miss occurs for any fraction.
• Health and Safety Code Section 115113(a)(6)
  – “The total dose from therapeutic ionizing radiation delivered differs from the prescribed dose by 20 percent or more”
    • 20% of prescribed dose?
      – Physicians modify dose prescriptions – use latest prescription
    • Final dose - not fractions.

  – Palliative care allowance
    • If the dose given for palliative care exceeds the 20% limit, the referring physician must be notified but not the Department.
Inspection

- Is the facility accredited? By whom?
- Are there appropriate policies and procedures in place?
- Who determines which protocols are used?
- Have staff technologists and physicians received adequate training? Are they certified?
- Did the last medical physicist equipment evaluation identify any issues or concerns?
  - Were these addressed by the facility?
- Have there been any events that met the reporting criteria?
  - Were they reported?
  - Was the reporting done within the required timeframe?
Inspection

- **Observations and Interviews**
  - Is a reference chart available at the console?
  - Does the scanner display the required values?
  - How do they verify patient identification to the related diagnostic protocol or treatment plan?
  - When should the technologist seek guidance or additional authorization? From whom? By what method?
  - Does the PACS system contain the required information?
  - Does the report contain the required information?
Reporting to RHB

• What do we want to know?
  – Identity of the person making the report (name, job title, contact information, etc.)
  – Date(s) of event
  – Facility information
  – Equipment specifics (manufacturer and model, software version, technical settings during the event, etc.)
  – Operator’s name
  – Referring physician’s name and contact information
  – Copy of the physician’s order/prescription for CT or radiation therapy treatment
Reporting to RHB

• What do we want to know?
  – Explanation of the reportable event
  – Patient dose calculations (include methodology)
  – Copies of any internal investigation reports (include cause and corrective action designed to prevent reoccurrence)
  – Copies of letters sent to the patient and the referring physician
Follow-up Investigation

• **What do we want now?**
  – Walk though the event - Go to the location of the event and have the technologist who was involved in the event review what happened
  – Collect copies of images and any documentation that may have been omitted earlier
  – Understand how the corrective action is likely to prevent similar events in the future.
Lessons Learned

• An ounce of prevention...
  – Understand your equipment and protocols.
  – Establish trigger levels to determine when reporting might be required.
  – Know what to do if things aren’t happening as they should.
  – Use amount of radiation necessary to get image.
  – Patient radiation from medical X-rays is still radiation exposure.
Lessons Learned

• Road to Success
  – Hospital Administration support
    • Especially important for cross-functional control
  – RSC/RSO involvement
  – Internal processes
    • Dose reduction committee
    • Internal audit
  – External processes
    • Consultant audit assessment
    • Compliance inspection
Stay Informed

• Latest information
  – Assembly Bill 510 – Active legislation - Senate.ca.gov

  – California Department of Public Health
    • (877) 818-2890
    • RHB_SB1237@cdph.ca.gov
    • Frequently asked questions
Radiation Safety Audit
Based on the Joint Commission
Sentinel Event Alert #47

Bob Pizzutiello, FACR, FAAPM, FACMP
Upstate Medical Physics
A LANDAUER Medical Physics Partner
Bob Pizzutiello has over 30 years of experience as a medical physicist. Bob began practicing medical physics in the Cancer Center at the University of Rochester Medical Center in 1977. In 1979, he became Director of Medical Physics at Rochester General Hospital, where his areas of interest and expertise broadened to include diagnostic imaging physics and teaching medical physics to physicians. In 1987, Bob helped to pilot test the new “ACR Mammography Accreditation Phantom” at several client facilities. In the early 1990’s he became a medical physicist reviewer for phantom images for the ACR-MAP. After more than a decade of work with the ACR and the Conference of Radiation Control Program Directors (CRCPD), Bob was appointed to the FDA’s Mammography Quality Standards Advisory Committee. When Stereotactic Breast Biopsy was introduced in the early 1990’s, Bob worked with the American College of Radiology (ACR) to develop the ACR Stereotactic Breast Biopsy Accreditation program and co-authored the SBB QC manual. Bob continues to serve on several key committees of the AAPM, ACR and ACMP. Bob is an active lecturer, and has been invited to speak at over 100 programs in the last decade across the U.S., in South America and in China. Bob has also served as consultant to many major imaging manufacturers, contributing his knowledge of imaging and broad practical experience to the manufacturing sector. His current special interests include breast imaging, MRI, and cone-beam CT imaging. In 1983, Bob formed a medical physics practice group, which became the largest private practice imaging physics group in New York State. The group joined Landauer Medical Physics in 2010, and Bob assumed and currently occupies a senior role on the clinical leadership team.
Outline

- What is the Sentinel Event Alert #47
  - And why do I care?
- FDA Initiatives
- Why go beyond State and NRC Inspections?
- Audit Topics
- Advance Preparation
- Typical Agenda
- Documents
- Summary - Q&A
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 told his family of a final
Radiation Boom

Articles in the 'Radiation Boom' series by Walt Bogdanich examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.

March 5, 2011
February 28, 2011
December 29, 2010
November 22, 2010
August 1, 2010
February 25, 2010
January 27, 2010
January 24, 2010
December 8, 2009
October 16, 2009
June 30, 2009
June 21, 2009

With follow-up articles in countless local news media
In support of its mission to improve the quality of health care provided to the public, The Joint Commission includes the review of organizations' activities in response to sentinel events in its accreditation process, including all full accreditation surveys and random unannounced 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. For more information see Sentinel Event Policy and Procedures.
Radiation risks of diagnostic imaging

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.\textsuperscript{1,2,3} 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.\textsuperscript{4} The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.\textsuperscript{1,5,6,7} 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.\textsuperscript{1}
“Working together,” said Shuren, “the FDA and other organizations hope to help patients get the right imaging exam, at the right time, with the right radiation dose.”
FDA Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

- FDA is advocating the universal adoption of two principles of radiation protection:
  - appropriate justification for ordering each procedure,
  - careful optimization of the radiation dose used during each procedure.
- Each patient should get the right imaging exam, at the right time, with the right radiation dose.
- In support of this goal, FDA will use our regulatory authority and also collaborate with others in the Federal government and the healthcare professional community to:
  - Promote safe use of medical imaging devices;
  - Support informed clinical decision making; and
  - Increase patient awareness.
Traditionally, radiation safety programs were designed for compliance with State and/or NRC Regulations.

Many states have regulations that have not been updated in more than a decade

- Medical imaging has changed radically in the past decade

When untoward radiation safety events have occurred across the country

Gap Analysis and SEA #47 bring a new emphasis on radiation safety that is commensurate with current practice and risk management
Audit Topics

- Right Test
- Right Dose
- Effective Process
- Safe Technology
- Standards, Policies and Procedures
- Role of Radiation Safety Committee
- Monitoring of adverse events
- Education, staff, physicians and patients
Typical Agenda

- **8:00 – 8:30** Opening remarks, context and plan for the day
  - All

- **8:30 – 9:30** Radiology Team
  - Chief Radiologist
  - Interventional Radiologist
  - Radiology Director
  - Managers and Supervisors (CT, Nuclear medicine, MR)
  - Radiology Nursing
  - Imaging physicist

- **9:30 – 10:00** CT Team
  - Chief Radiologist
  - CT focused Radiologist
  - Radiology Director
  - CT Supervisor
  - Imaging Physicist
  - QC Technologist
- **10:00 – 10:30 Cardiology Team**
  - Chief Cardiologist
  - Cardiology Director
  - Radiologic Technologist or Invasive tech
  - Imaging Physicist

- **11:00 – 11:30 Radiation Safety Team**
  - Chief of Radiology
  - Radiation Safety Officer
  - Chair, Radiation Safety Committee
  - Chair, Environment of Care Committee
  - Facility Risk Management
  - Imaging Physicist

- **11:30 – 12:00 Radiation Oncology Team**
  - Chief Radiation Oncologist
  - Manager, Radiation Oncology
  - Radiation Oncology Physicist
  - Dosimetrist

- **12:00 – 12:30 Closing Comments, Preliminary Report**
  - All
Documents submitted in advance

- Recent inspection reports (from the previous 24 months) from State agencies (or NRC) that regulate the use of x-rays and radioactive material at the facility
- Radiation Safety Committee minutes for the past 2 years
- Medical Physics survey reports for all imaging equipment (2 years)
- Records of fluoroscopy time, DAP or Air Kerma for patients undergoing interventional fluoroscopy procedures
Radiation Safety Policies and Procedures

- Complete Radiation Safety P&P Manual
  - Including both Radiology and Interventional Cardiology labs
  - Policy for credentialing and privileging of fluoroscopy users
  - Policy for gonadal or breast shielding for CT
- Minutes of CT Protocol Review Committee, if applicable
- Records of radiation safety training for applicable personnel
- Occupational exposure reports for the past 24 months
- Records of any radiation related “medical events,” other adverse incidents or that precipitated changes in procedures or corrective actions that were not discussed at the RSC
## Radiation Safety Audit

### Actions suggested by the Joint Commission

**SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011**

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<th>TO-DO LIST</th>
<th>ACTION ITEMS, TIMING AND RESPONSIBLE PEOPLE</th>
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<tr>
<td><strong>RIGHT TEST</strong></td>
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<td>Implement processes that enable radiologists to dialogue with referring physicians regarding the appropriate use of imaging using the ACR’s <em>Appropriateness Criteria.</em></td>
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<td>1. Have your physicians reviewed the <em>Appropriateness Criteria</em>?</td>
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<td>2. Are you considering implementing this on a prospective or spot check retrospective basis?</td>
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<td><strong>RIGHT DOSE</strong></td>
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<td>Adhere to ALARA, <em>Image Gently</em> and <em>Image Wisely</em> guidelines when providing imaging radiation.</td>
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<td>1. <em>Image Gently</em> applies to pediatrics. If you do pediatrics, have you implemented <em>Image Gently</em> dose reduction methodology for CT?</td>
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<td>2. <em>Image Wisely</em> applies to adults.</td>
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<td>a. For example, are you using pulsed fluoro?</td>
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<td>b. Do you perform quality audits of radiographs (collimation, S#, etc.)?</td>
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<td>c. Fluoro dose reduction strategies?</td>
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<td><strong>Provide physicians and technologists with reference doses based on anatomy, purpose of the study and patient size. Establish appropriate dose ranges for imaging studies.</strong></td>
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<td>1. Have you performed analysis by a QMP of ESE, CTDI, administered activity, and compared with published data (NCRP Report on Reference Levels, in process)?</td>
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## Radiation Safety Audit

### Actions suggested by the Joint Commission

**SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011**

### EFFECTIVE PROCESS

**Implement policies delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging.**

1. Have you locked down all default protocols, requiring authorization to change?

**Implement policies that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients.**

1. Have you implemented gonadal shielding policy?
2. Policy to collimate to region of interest?
3. Have you instituted compliance audits to show these policies are being followed?

**Expand the radiation safety officer’s roles to explicitly include patient safety and involve the officer in the organization's patient safety committee.**

1. RSO and RSC to include both radioactive materials and x-ray producing equipment
2. RSO to report to Patient Safety (Environment of Care) Committee

### Comments and Recommendations

**R10.** Recommend implementing password protection for all protocols (CR, DR, CT, interventional) in order to permanently save changes. Authorization (and password) should be the responsibility of department manager.

**R11.** Recommend developing a written policy on gonadal shielding. (Gonadal shielding is used at this time.)

**R12.** Recommend developing a written policy relative to collimation to the region of interest.

**R13.** Recommend including an audit of shielding and collimation as part of the patient dose audit.

**Diagnostic imaging issues are discussed at the RSC meetings.**

**R14.** Recommend developing a charge for the RSC which clearly includes oversight of diagnostic imaging patient radiation doses in the responsibilities of the RSC.

**R15.** Recommend that the RSO and Chair of RSC be part of, or report to, the Patient Safety (Environment of Care) Committee.
Summary

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- Documents
- Q&A
Learn more about how LANDAUER Medical Physics can help you.

Contact us at (866) 537-2234 or mlevandoski@landauersales.com