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POWERFUL PARTNERSHIPS ADVANCING IMAGING AND THERAPY

# The Joint Commission Sentinel Event Alert #47: Impact and Experience

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## Conflict of Interest

- President of Upstate Medical Physics, P.C.
- Senior Vice President, Imaging – Landauer Medical Physics
- Provides these Audits, fee for service

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## 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

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## Increased media focus

The New York Times

Health

WORLD | U.S. | N.Y. / REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH | SPORTS | OPINION

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

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-

SIGN IN TO RECOMMEND
TWITTER
SIGN IN TO E-MAIL
PRINT
SINGLE PAGE
REPRINTS
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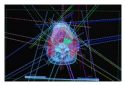
The New York Times

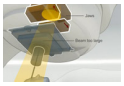
## Radiation Boom

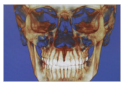

Articles in the 'Radiation Boom' series by Walt Bogdanich examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.



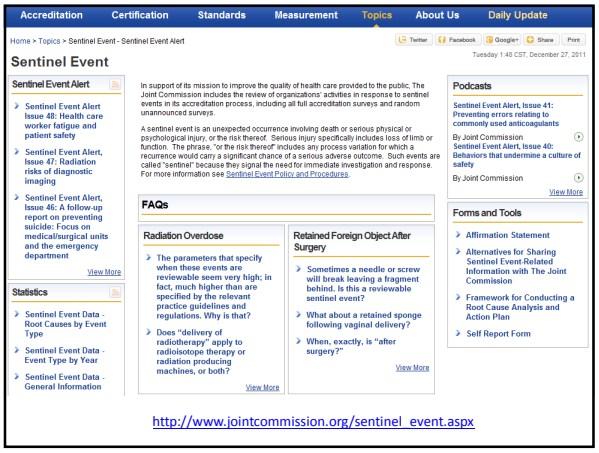
**March 5, 2011**
**February 28, 2011**
**December 29, 2010**
**November 22, 2010**
**August 1, 2010**
**February 25, 2010**
**January 27, 2010**
**January 24, 2010**
**December 8, 2009**
**October 16, 2009**
**June 30, 2009**
**June 21, 2009**

**With follow-up articles in countless local news media**



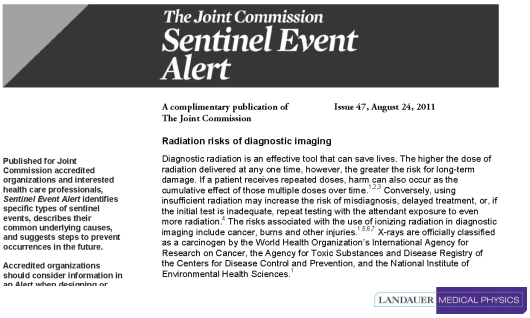


HYSICS




http://www.jointcommission.org/sentinel_event.aspx

## TJC Sentinel Alert



The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 47, August 24, 2011

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or

**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.[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.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[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.[8]

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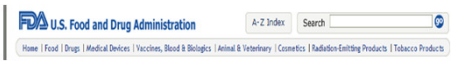
**Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging**

FDA is launching a collaborative *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*, with a focus on the types of imaging procedures that are associated with the highest radiation doses: CT, fluoroscopy, and nuclear medicine.




- …two principles of radiation protection: appropriate *justification* for ordering and performing each procedure, and careful optimization of the radiation dose used during each procedure.
- These types of imaging exams should be conducted only when medically justified.
- When such exams are conducted, patients should be exposed to an optimal radiation dose – no more or less than what is necessary to produce a high-quality image.
- In other words, each patient should get the ***right imaging exam, at the right time, with the right radiation dose.***

## FDA Unveils Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

***February 9, 2010***

"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 gov't and the healthcare professional community to:
  - Promote safe use of medical imaging devices;
  - Support informed clinical decision making;
  - Increase patient awareness.

## "But I don't have any trouble with State Inspections or NRC …"

- Traditional radiation safety programs have been largely limited to compliance with mandatory State requirements,
  - many of which have not been updated to address modern issues in the rapidly changing world of medical imaging.
- When untoward radiation safety events have occurred across the country, facilities have often found that this limited approach to radiation safety has not offered the degree of patient protection and risk mitigation needed in the modern imaging environment.

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## "But I don't have any trouble with State Inspections or NRC …"

- 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

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## 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

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## 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

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## Typical Agenda (continued)

- 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

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## 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

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## 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

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- 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

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| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 |
|---|
| 2.0 RIGHT DOSE |
| **2.1 Adhere to ALARA, *Image Gently* and *Image Wisely* guidelines when providing imaging radiation.** |
| 2.1.1 *Image Gently* applies to pediatrics. If you do pediatrics, have you implemented *Image Gently* dose reduction methodology for CT? |
| 2.2.1 Have you performed analysis by a QMP of ESE, CTDI, administered activity, and compared with published data (NCRP Report on Reference Levels, in process)? |
| **2.3 Institute a process for regular review of all dosing protocols (every 1-2 years). In addition to item above, have you instituted a CT Protocol Review Committee, with a radiologist, RT and QMP?** |
| **2.4 Record the dosage or exposure as part of the study's summary report of findings.** |
| 2.4.1 Has this issue been discussed? |

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 |
|---|
| 3.0 EFFECTIVE PROCESS |
| **3.2 Implement policies that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients.** |
| 3.2.1 Have you implemented gonadal shielding policy? |
| 3.2.2 Policy to collimate to region of interest? |
| 3.2.3 Have you instituted compliance audits to show these policies are being followed? |
| **3.3 Expand the radiation safety officer's roles to explicitly include patient safety and involve the officer in the organization's patient safety committee.** |
| 3.3.1 RSO and RSC to include both radioactive materials and x-ray producing equipment. |
| 3.3.2 RSO to report to Patient Safety (Environment of Care) Committee |
| **3.4 Ensure all physicians and technologists who prescribe diagnostic radiation or use diagnostic radiation equipment receive training on dose and equipment. Institute a process for annual education, review and competency testing.** |
| 3.4.1 Have you instituted privileging of non-radiologist fluoroscopy users every two years, as part of routine medical staff re-credentialing? |

## Radiation Safety Audit

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 | COMPLETE | IN PROCESS | TO-DO LIST | ACTION ITEMS, TIMING AND RESPONSIBLE PEOPLE |
|---|---|---|---|---|
| **RIGHT TEST** | | | | |
| **Implement processes that enable radiologists to dialogue with referring physicians regarding the appropriate use of imaging using the *ACR's Appropriateness Criteria*.**<br>1. Have your physicians reviewed the *Appropriateness Criteria*?<br>2. Are you considering implementing this on a prospective or spot check retrospective basis? | | | √<br>√ | |
| **RIGHT DOSE** | | | | |
| **Adhere to ALARA, *Image Gently* and *Image Wisely* guidelines when providing imaging radiation.**<br>1. *Image Gently* applies to pediatrics. If you do pediatrics, have you implemented *Image Gently* dose reduction methodology for CT?<br>2. *Image Wisely* applies to adults.<br>a. For example, are you using pulsed fluoro?<br>b. Do you perform quality audits of radiographs (collimation, sif, etc.)?<br>c. Fluoro dose reduction strategies? | √ | | √<br>√<br>√ | |
| **Provide physicians and technologists with reference doses based on anatomy, purpose of the study and patient size. Establish appropriate dose ranges for imaging studies.**<br>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)? | | | √ | |

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## Radiation Safety Audit

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 | Comments and Recommendations |
|---|---|
| **EFFECTIVE PROCESS** | |
| **Implement policies delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging.**<br>1. Have you locked down all default protocols, requiring authorization to change? | **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. |
| **Implement policies that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients.**<br>1. Have you implemented gonadal shielding policy?<br>2. Policy to collimate to region of interest?<br>3. Have you instituted compliance audits to show these policies are being followed? | **R11.** Recommend developing a *written* policy on gonadal shielding. (Gonadal shielding is used at this time.)<br>**R12.** Recommend developing a *written* policy relative to collimation to the region of interest.<br>**R13.** Recommend including an audit of shielding and collimation as part of the patient dose audit. |
| **Expand the radiation safety officer's roles to explicitly include patient safety and involve the officer in the organization's patient safety committee.**<br>1. RSO and RSC to include both radioactive materials and x-ray producing equipment<br>2. RSO to report to Patient Safety (Environment of Care) Committee | Diagnostic imaging issues are discussed at the RSC meetings.<br>**R14.** Recommend developing a charge for the RSC which clearly includes oversight of diagnostic imaging patient radiation doses in the responsibilities of the RSC.<br>**R15.** Recommend that the RSO and Chair of RSC be part of, or report to, the Patient Safety (Environment of Care) Committee. |

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**Caduceus Hospital**
**Radiation Safety Gap Analysis - February 6, 2012**

UMP

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 | Good Practices (GP), Recommendations (R), and Comments (C) | | |
|---|---|---|---|
| **1.0 RIGHT TEST** | | | |
| **1.1 Implement processes that enable radiologists to dialogue with referring physicians regarding the appropriate use of imaging using the *ACR's Appropriateness Criteria* .**<br>1.1.1 Have your physicians reviewed the *Appropriateness Criteria* ?<br>1.1.2 Are you considering implementing this on a prospective or spot check retrospective basis? | **GP1.** Dr. C has previously given 2 Med Grand Rounds presentations on ACR White Paper on Rad Dose, creating awareness.<br>**GP2.** CT Technologists have been given copies of ACR *Appropriateness Criteria* .<br>**GP3.** Radiologist available for consult with referring MDs M-F, days. | **R1.** A committee should be formed to oversee and address all patient dose issues, and plan an overall approach to optimizing patient dose.<br>**R2.** Recommend radiology staff review *Appropriateness Criteria* and provide a condensed version for the referring physicians or direct them to on-line search engine application at ACR web-site: http://acsearch.acr.org/.<br>**R3.** Radiology staff should consider presenting an *Appropriateness Criteria* overview and radiation dose reduction methods at medical staff grand rounds. UMP can provide medical physics support.<br>**R4.** Devise method for auditing if the *Appropriateness Criteria* are being used by referring physicians (questionnaire, etc.).<br>**R5.** Radiologists suggest that the "consult radiologist" could be better utilized and more available. We recommend working with the radiologists to create a process to make radiologist consultations more available and better utilized. The goal would be to make referring physicians more aware of alternative imaging exams that may better answer their clinical questions. | **C1.** Radiologists report that exam "Indication" could be more complete in many cases, particularly from ED. |

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 |
|---|
| **4.0 SAFE TECHNOLOGY** |
| **4.1 Perform an organization-wide audit of diagnostic imaging equipment. Implement a system for centralized quality and safety performance monitoring of this equipment under the supervision of a qualified medical physicist and/or the radiation safety** |
| 4.1.1 Is this performed by your medical physics provider(s)? |
| **4.2 Have a qualified medical physicist test all diagnostic imaging equipment initially and at least annually to assure proper installation and calibration and review scanning protocols and** |
| 4.2.1 Is this performed by your medical physics provider(s)? |
| **4.3 Ensure that recommended quality control, testing and preventative maintenance activities are performed. Identify in writing these activities, their frequencies, and who will perform them, in consultation with a medical physicist.** |
| 4.3.1 Is this performed in conjunction with your medical physics provider(s)? |
| **4.4 Invest in technologies that optimize or reduce dose.** |
| 4.4.1 For CT, consider iterative reconstruction software, and/or |

| Actions suggested by the Joint Commission<br>SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 |
|---|
| **5.0 ADDITIONAL GAP ANALYSIS OPPORTUNITIES** |
| **5.1 Is there a uniform standard for Radiation Safety Policies and Procedures and medical physics services across all inpatient and outpatient areas that use radiation within the system?** |
| 5.1.1 Radiation Oncology |
| 5.1.2 Radiology, including CT |
| 5.1.3 Interventional Cardiology |
| 5.1.4 Nuclear Imaging |
| **5.2 Is there a process for periodic independent verification of linear accelerator output and treatment planning system performance? Who monitors these processes?** |

## Suggested Priorities

| Item | Recommendation | Suggested Priority | | |
|---|---|---|---|---|
| 1.0 RIGHT TEST | | 1 | 2 | 3 |
| 1.1 | **R1.** A committee should be formed to oversee and address all patient dose issues, and plan an overall approach to optimizing patient dose. | X | | |
| 1.1 | **R2.** Recommend radiology staff review Appropriateness Criteria and provide a condensed version for the referring physicians or direct them to on-line search engine application at ACR web-site. http://acsearch.acr.org/ | | | X |
| 1.1 | **R3.** Radiology staff should consider presenting an Appropriateness Criteria overview at medical staff meeting. | | | X |
| 1.1 | **R4.** Devise method for auditing if the Appropriateness Criteria are being used by referring physicians (questionnaire, etc.). | | | X |
| 1.1 | **R5.** Radiologists suggest that the "consult radiologist" could be better utilized and more available. We recommend working with the radiologists to create a process to make radiologist consultations more available and better utilized. The goal would be to make referring physicians more aware of alternative imaging exams that may better answer their clinical questions. | X | | |
| 2.0 RIGHT DOSE | | 1 | 2 | 3 |
| 2.1 | **R6.** Implement Image Gently and Image Wisely in 2012 | | X | |
| 2.1 | **R7.** Create P&P to incorporate use of dose reduction practices whenever they do not interfere with the clinical objective of the case, e.g., pulsed fluoroscopy. | X | | |

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## A few final examples of findings…

| Actions suggested by the Joint Commission SENTINEL EVENT ALERT ISSUE 47, AUGUST 24, 2011 | Good Practices (GP), Recommendations (R), and Comment | |
|---|---|---|
| 4.0 SAFE TECHNOLOGY | | |
| **4.1 Perform an organization-wide audit of diagnostic imaging equipment. Implement a system for centralized quality and safety performance monitoring of this equipment under the supervision of a qualified medical physicist and/or the radiation safety** | **GP17.** Fully implemented, with medical physics support from UMP. | |
| 4.1.1 Is this performed by your medical physics provider(s)? | | |
| **4.2 Have a qualified medical physicist test all diagnostic imaging equipment initially and at least annually to assure proper installation and calibration and review scanning protocols and** | **GP18.** Fully implemented, with medical physics support from UMP. | |
| 4.2.1 Is this performed by your medical physics provider(s)? | | |
| **4.3 Ensure that recommended quality control, testing and preventative maintenance activities are performed. Identify in writing these activities, their frequencies, and who will perform them, in consultation with a medical physicist.** | | **R27.** Standardize QC and PM requirements for all sites. Currently requirements vary per state requirements (NY requirements exceed PA requirements). |
| 4.3.1 Is this performed in conjunction with your medical physics provider(s)? | | |
| **4.4 Invest in technologies that optimize or reduce dose.** | **GP28.** Siemen's CareDose 4D is employed on CT scanners. | **R28.** Investigate whether iterative reconstruction capabilities can be added to existing fleet of CT scanners. Plan for future upgrades or replacements based on benefit and cost. |
| 4.4.1 For CT, consider iterative reconstruction software, and/or | | |
| 4.4.2 CT Protocol Committee recommendations to reduce dose. | | |

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**Learn more about how**
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