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# Radiation Safety Audit Based on the Joint Commission Sentinel Event Alert #47



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# Conflict of Interest

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

# Outline

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- “ 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

# Increased media focus



The screenshot shows the top portion of a New York Times article. At the top left is the newspaper's name, 'The New York Times'. To its right is the section title 'Health'. Below these are navigation tabs for 'WORLD', 'U.S.', 'N.Y. / REGION', 'BUSINESS', 'TECHNOLOGY', 'SCIENCE', 'HEALTH', 'SPORTS', and 'OPINION'. The main headline is 'THE RADIATION BOOM' followed by 'Radiation Offers New Cures, and Ways to Do Harm'. The author is listed as 'By WALT BOGDANICH' and the publication date as 'Published: January 23, 2010'. The first paragraph of the article is visible, describing a patient's suffering and his wish to be studied. On the right side of the article, there is a vertical menu with options: 'SIGN IN TO RECOMMEND', 'TWITTER', 'SIGN IN TO E-MAIL', 'PRINT', 'SINGLE PAGE', 'REPRINTS', and 'SHARE'.

**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  
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SINGLE PAGE  
REPRINTS  
SHARE

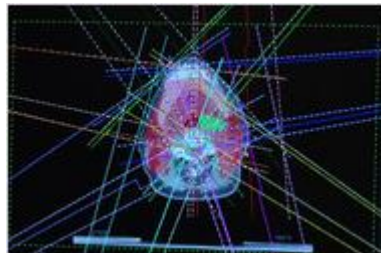


# The New York Times

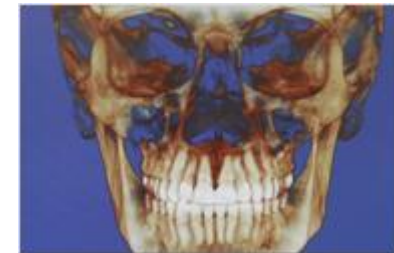
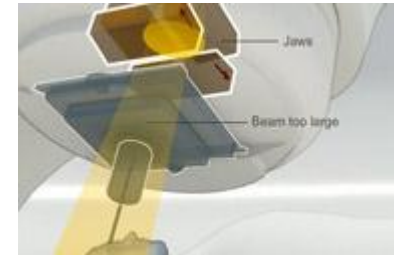
## Radiation Boom



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

## Sentinel Event

### Sentinel Event Alert

- [Sentinel Event Alert Issue 48: Health care worker fatigue and patient safety](#)
- [Sentinel Event Alert, Issue 47: Radiation risks of diagnostic imaging](#)
- [Sentinel Event Alert, Issue 46: A follow-up report on preventing suicide: Focus on medical/surgical units and the emergency department](#)

[View More](#)

### Statistics

- [Sentinel Event Data - Root Causes by Event Type](#)
- [Sentinel Event Data - Event Type by Year](#)
- [Sentinel Event Data - General Information](#)

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](#).

### FAQs

#### Radiation Overdose

- The parameters that specify when these events are reviewable seem very high; in fact, much higher than are specified by the relevant practice guidelines and regulations. Why is that?
- Does "delivery of radiotherapy" apply to radioisotope therapy or radiation producing machines, or both?

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#### Retained Foreign Object After Surgery

- Sometimes a needle or screw will break leaving a fragment behind. Is this a reviewable sentinel event?
- What about a retained sponge following vaginal delivery?
- When, exactly, is "after surgery?"


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### Podcasts

**Sentinel Event Alert, Issue 41: Preventing errors relating to commonly used anticoagulants**

By Joint Commission 

**Sentinel Event Alert, Issue 40: Behaviors that undermine a culture of safety**

By Joint Commission 

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### Forms and Tools

- [Affirmation Statement](#)
- [Alternatives for Sharing Sentinel Event-Related Information with The Joint Commission](#)
- [Framework for Conducting a Root Cause Analysis and Action Plan](#)
- [Self Report Form](#)

# TJC Sentinel Alert



## The Joint Commission Sentinel Event Alert

A complimentary publication of  
The Joint Commission

Issue 47, August 24, 2011

### Radiation risks of diagnostic imaging

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

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.<sup>1,2,3</sup> 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.<sup>4</sup> The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.<sup>1,5,6,7</sup> 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.<sup>1</sup>

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

## *February 9, 2010*

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“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.

# “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.

# “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

# Audit Topics

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- “ 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
- “ 8:30 . 9:30 Radiology Team
  - “All
  - “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

# 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

# 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

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- ” 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

# Summary

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Learn more about how  
LANDAUER Medical Physics can help you.

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