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

Robert J. Pizzutiello, MS, FAAPM, FACMP
Senior Vice President, Imaging Physics
Upstate Medical Physics – A LANDAUER Medical Physics Partner
Conflict of Interest

• President of Upstate Medical Physics, P.C.
• Senior Vice President, Imaging
  Landauer Medical Physics
• Provides these Audits, fee for service
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
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-Parks wrote to his family from Sand
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.

## 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 radionuclide therapy or radiation producing machines, or both?

### 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”?
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.\(^1\)\(^5\)\(^6\)\(^7\) 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.\(^1\)
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 government and the healthcare professional community to:
- Promote safe use of medical imaging devices;
- Support informed clinical decision making; and
- Increase patient awareness.
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.

“But I don’t have any trouble with State Inspections or NRC...”
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

Å  8:00 ÷ 8:30  Opening remarks, context and plan for the day
  All

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

Å  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


- Including both Radiology and Interventional Cardiology labs
- Policy for credentialing and privileging of fluoroscopy users
- Policy for gonadal or breast shielding for CT
Â Minutes of CT Protocol Review Committee, if applicable
Â Records of radiation safety training for applicable personnel
Â Occupational exposure reports for the past 24 months
Â 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

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

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