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

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President, 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

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 23, 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

http://www.jointcommission.org/sentinel_event.aspx
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.
“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.
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
- 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
  - GC 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

- 12:00 – 12:30 Closing Comments, Preliminary Report

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

### Actions suggested by the Joint Commission

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<thead>
<tr>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.2.10</td>
<td>Improve radiation protection risk communication to both personnel and patients.</td>
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<td>2.2.5</td>
<td>Ensure compliance with NRC and FDA regulations.</td>
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<td>Implement radiation safety audit program.</td>
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### Radiation Safety Audit

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# Radiation Safety Audit

## Action Items

### Required

1. Check the equipment and diagnostic imaging equipment to ensure they are operating properly.
2. Ensure all equipment is certified and in good working condition.
3. Review the operating procedures for each piece of equipment.
4. Review the radiation safety policies and procedures.
5. Train all staff on the proper use of the equipment.
6. Review the radiation safety protocols and procedures for each procedure.
7. Review the radiation safety policies and procedures for each patient.
8. Review the radiation safety policies and procedures for each department.
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### Recommended

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## Suggested Priorities

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<td>1.1</td>
<td>Audit should be focused on overall patient care and identify potential areas for improvement.</td>
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<td>Radiology staff should review appropriate criteria and provide oversight for the radiology policy and procedures.</td>
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<td>Clinical staff should be able to identify appropriate criteria used in radiology cases.</td>
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## A few final examples of findings...

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<th>Action(s) suggested by the Joint Commission</th>
<th>Good Practice (GP), Recommendation (R), and Comment</th>
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Learn more about how LANDAUER Medical Physics can help you.

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