What is a Joint Commission (JC) Sentinel Event?

- A sentinel event (SE) is an **unexpected occurrence involving death or serious injury, or the risk thereof**
- Sentinel events **signal the need for immediate investigation and response**
- Sentinel event and medical error are not the same; a sentinel event may not be an error and an error may not result in a sentinel event

www.jointcommission.org/SentinelEvents/PolicyandProcedures/
More About Sentinel Events

• Goals of SE response action include reducing the probability of SE in the future and developing strategies to prevent them
• Each institution is expected to develop its own definitions of SEs, but there are 10 types of event that the Joint Commission specifically names as "Reportable"; the fluoroscopic event is one of these

What an Institution Must Do in Response to a Sentinel Event

• Conduct a timely, thorough, and credible root cause analysis (RCA)
• Develop an action plan to implement improvements to reduce risk
• Implement the improvements
• Monitor the effectiveness of those improvements
Root Cause Analysis

- Focuses on systems and processes, not on individual performance (no witch hunts)
- Examines clinical and organizational processes to identify potential improvements to decrease the likelihood of such SEs in the future or determine, after analysis, that no such opportunities exist
- Patient and care-givers are anonymized in any reports to JC

More About Root Cause Analysis

- The JC encourages, but does not require, notification when a SE occurs
- Two strategies
  - Self-report (i.e. notify the JC after SE)
  - Do RCA and have report available on request
- The RCA must occur within 45 days of the hospital becoming aware of the event (day of procedure)
- Failure to pursue an adequate RCA within the proper time frame and produce an action plan can result in loss of accreditation
What Is the Radiologic Sentinel Event (Nov 2005)?

- Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

The JC Fleshes Out the Fluoroscopic Sentinel Event with an FAQ Page

- "Cumulative dose > 1500 rads" is the peak skin dose, taking overlap of different fields (all runs, all fluoro) into consideration
- Cumulative dose, for the JC, refers neither to a single procedure nor to a lifetime; they indicate "...monitoring cumulative dose over a period of six months to a year would be reasonable."

www.jointcommission.org/SentinelEvents, Radiation Overdose FAQ's
Problems

• Terminology
  – Cumulative Dose (CD), to the medical physicist, is the air kerma at the international reference point (IRP) (15 cm toward x-ray tube from isocenter) (ICRP, IEC)
  – Cumulative dose, in the JC definition, is essentially a cumulative Peak Skin Dose (PSD), summed for a "reasonable" time

• What to do about
  – Multiple procedures
  – Multiple institutions !!!

Strategy for Detection

• Monitor and record surrogates for skin dose
  – Fluoro time (all machines)
  – Air Kerma (AK) or Dose-Area-Product (DAP) readings on machines so equipped
  – Skin dose software (e.g. Siemens CareGraph) if present

• Establish "threshold" values of the surrogates (and a hospital process) to trigger an investigation

• Threshold should be
  • Low enough to catch all real events
  • High enough to keep workload on physics department within realistic limits
Picking Thresholds: 2006 Thoughts

If we want to trap all events that have a CD (physics!) > 15 Gy, investigate everything > 150 min of fluoro (< 2%)

Data on 2142 interventional procedures, from Miller et al. J Vasc Interv Radiol 2003; 14:977–990

Picking Thresholds: 2006 Thoughts

Final threshold choices:

> 150 min fluoro

> 6000 mGy on AK meter sum planes for biplanes

Data on 2142 interventional procedures, from Miller et al. J Vasc Interv Radiol 2003; 14:977–990
A Gratifying Coincidence --
What Others Are Doing

Literature specific to Fluoroscopic Sentinel Events is limited:

Dauer et al. JVIR 20(6):782-8, 2009

**Mahesh** (JACR 5(4):601-3, 2008) addresses practical aspects of identifying sentinel events and suggests threshold levels for medical physics evaluation of

- **Fluoro Time:** 150 minutes
- **Air Kerma:** 6000 mGy

Further Thoughts: Can we rely on using a high AK threshold?

This data shows that on average the PSD is 1/2 the reported cumulative (physics) dose, leading some to suggest that cases in which the CD is less than 15 Gy are very unlikely to be SEs

709 "high-dose" cases with PSD monitoring

Further Thoughts: Can we rely on using a high AK threshold?

BUT NOTE
- Embolization cases (two circled are in that class) can have CD=PSD
- No cardiac, EP cases included in set
- Assumes good practice (not always a good assumption)

709 "high-dose" cases with PSD monitoring

Possible Implementation

Check database for dose history
Notify physician of cumulative dose
Procedure starts
Update physician on status during procedure
Remedial actions during procedure
Procedure ends

New dose data logged in DB
If cumulative threshold passed, notify RSO, Event System
Physics investigation

>15 Gy
Yes
Report to RSO, Medical Director

No
Whew!
Case Study 1: Cerebral Aneurysm With No AK Monitor

- Cerebral arteriogram with embolization procedure for an ACOMM (anterior communicating) arterial aneurysm
- Fluoroscopy time exceeded the investigational limit of 150 min.
- Bi-plane c-arm fluoroscope not equipped with an air kerma monitor.
Case 1: Basic Information

- No cumulative dose (AK) data available.
- 22 frontal and lateral runs, ~20 frames each
- 1 rotational run.
- No DICOM information for fluoroscopy
- 154 minutes of fluoroscopy recorded by staff (also available on unit)

"Just the Facts,"
Sgt. Joe Friday in Dragnet

Case 1: Information Collection

- DSA images obtained from modality (not all image sets sent to PACS !)
- DSA images:
  - Number, type of runs
  - Technique factors
  - Table position
  - C-arm angulation
- Staff interview:
  - Patient positioning
  - Fluoro details (fluoro FOV, etc.)
- CT images:
  - Patient size
- Note: Patient had more procedures after this one!

<table>
<thead>
<tr>
<th>Information</th>
<th>Fluoro Unit</th>
<th>PACS</th>
<th>HIS/RIS</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro Details</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fluoro Time</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>Images</td>
<td>✓</td>
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<td>Body Habitus</td>
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<td>✓</td>
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<tr>
<td>Exam Notes</td>
<td></td>
<td>✓</td>
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</table>
Phantom Measurements

- Phantom measurements to measure output exposure factors for:
  - Fluoroscopy
  - DSA runs
  - Rotational DSA
- Fixed SID (1 m) with phantom at isocenter
- Exposure and technique (kVp/mA or kVp/mAs per pulse) determined for each FOV
- X-ray filters appropriate for the exam

Calculations

- Spread sheet calculation
- Simplify: ignore tube angulation, divide into frontal and lateral fields
- DSA and rotational run exposures scaled for patient position (1/r^2), and technique factors (kVp^2, mAs)
- Fluoroscopy exposure calculated for average position from run data

<table>
<thead>
<tr>
<th>Skin Exposure Contributions (R)*</th>
<th>Frontal</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>DA Runs</td>
<td>167 (~9 R/run)</td>
<td>105 (~6 R/run)</td>
</tr>
<tr>
<td>Rotational</td>
<td>7 (7 R/rot)</td>
<td>7 (7 R/rot)</td>
</tr>
<tr>
<td>Fluoro</td>
<td>438 (7 R/min)</td>
<td>240 (4 R/min)</td>
</tr>
<tr>
<td>Total</td>
<td>612 R</td>
<td>352 R</td>
</tr>
</tbody>
</table>

*Corrected for SSD and technique

Patient Skin Dose (Rads)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontal</td>
<td>735</td>
</tr>
<tr>
<td>Lateral</td>
<td>423</td>
</tr>
<tr>
<td>Max Overlap</td>
<td>1159</td>
</tr>
</tbody>
</table>

RESULT: Frontal and lateral doses do not exceed 1500 Rad, even with 100% overlap
Case Study 2: Dural Arteriovenous Fistulas With AK Monitor

- Transvenous embolization for dural arteriovenous fistulas
- Fluoroscopy time and air kerma exceeded the investigational limits of 150 min and 6 Gy.
- Bi-plane c-arm fluoroscope equipped with an Air Kerma Monitor

Case 2: Basic Information

- Unit Equipped with a Dose Monitor
- 18 runs, ~20 frames each
- Cumulative dose (IRP) and fluoro time in Performed Procedure Step file
- Frontal AK$_{IRP}$ 10 Gy, fluoro time 182 min
- Lateral AK$_{IRP}$ 0.5 Gy, fluoro time 10 min
- DICOM tags provided run details
  - DAP per run
  - Technique factors
  - Patient (table) to source distance
  - C-arm angulation
- Fluoroscopy dose preceding DSA run included with run DAP in DICOM tag
- Air Kerma monitor calibration checked

"Just the Facts,"
Sgt. Joe Friday in Dragnet
Case 2: Calculations

- Spread sheet calculation
- Patient skin dose calculated from DAP data in DSA run DICOM tag
- For each run & associated fluoro:
  - Dose = DAP x FOV (at patient)
- c-arm angulation and overlap considered (minor effects)

RESULT: Maximum skin dose does not exceed 1500 Rad

<table>
<thead>
<tr>
<th>Skin Dose Contributions (Rad_{Ab})*</th>
<th>Frontal</th>
<th>Lateral</th>
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</thead>
<tbody>
<tr>
<td>Fluoro + DSA Runs</td>
<td>970</td>
<td>40</td>
</tr>
<tr>
<td>Rotational</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>970</td>
<td>40</td>
</tr>
</tbody>
</table>

*Corrected for SSD, angulation

Tissue/Air Conversion
TAR(0) \approx 1.3 \text{ Rad}_{ts}/\text{Rad}_{air}

<table>
<thead>
<tr>
<th>Patient Skin Dose (Rad_{ts})</th>
<th>Frontal</th>
<th>Lateral</th>
<th>Max Field</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1270</td>
<td>60</td>
<td>1330</td>
</tr>
</tbody>
</table>

But Wait!

Keep digging at the evidence!
Case 2: The Rest of the Story!

- Image sets in PACS revealed 5 other fluoroscopic procedures within a period of 2-3 months
- Cumulative Peak Skin Dose for all procedures estimated to be close to 3000 Rad
- MORAL: You need a monitoring system that keeps track of all procedures!

Practical Tidbits: AK Accuracy

- After 2006, fluoro equipment must have AKR meters; accuracy of reported air kerma at reference point must be +/- 35% (pretty loose!). Best check the calibration!
- Pre 2006, AKR meter may be present; no FDA requirement for accuracy (you may be surprised how bad it can get)
Practical Tidbits: DICOM Data

- Wide variations over vendors -- need to check conformance statement and verify against data
- Some dose report numbers (provided for DA or DSA runs) associated with images include fluoro preceding run, some do not;
- Some dose reports are not in the DICOM image headers, but are associated with DICOM Modality Performed Procedure Step data
- PACS may not be configured to save needed private tags
- Not all image sets may be on PACS

Practical Tidbits: Miscellaneous

- Interview staff regarding operational practices
- Check assumptions regarding table positioning (patient may not be isocentric)
- Check assumptions regarding patient positioning on table (positioning blocks, pads may considerably elevate patient above the table)
Resources for Communication with Physicians, Administration
