The following slide presentation was presented October 11, 2013 at the joint Fall Seminar of the Penn-Ohio and Ohio River Valley Chapters of AAPM at the Embassy Suites in Beachwood, Ohio. Presented by Ray Kaczur, M.S., DABR
Safety is not an accident: Lessons to be learned from catastrophic events.

Presented by
Ray Kaczur, M.S., DABR
RK Physics Services, Ltd.
Accident Definition

An accident is:

“Any unintended event including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety” (IAEA et al., 1996b). A radiation accident is an unintended or unexpected event occurring with a radiation source or during a practice involving ionizing radiation, which may result in significant human exposure and/or material damage (IAEA and WHO, 1998a; IAEA, 1999a).
Basic Cause of Accidents

Generally due to:

- Weakness in design or implementation in hardware and/or software.
- Weakness in safety practices, training, knowledge of processes or controls.
- Lack of quality assurance measures or inadequacy in a Q.A. program.
Radiation accidents in the U.S.

- Accidents reported in 41 states, District of Columbia, and Puerto Rico: most involving radiation devices.
  
  To include:
  
  - Sealed sources used in Industrial Radiography, Radiotherapy and industrial processes,
  - X-ray generating devices used in medicine, research and industrial processes and
  - Accelerators used in medicine and research.
Improper disposal accidents with sealed sources

Improper disposal of Cs-137 and Co-60 sources used in teletherapy have exposed more than 4,000 persons, contributed to the death of at least 4, and resulted in partial or total demolition of at least 814 buildings.
The greatest number of accidental deaths and significant exposures were associated with diagnostic or therapeutic procedures in medical facilities.
Radiation Injuries

Radiation burn to hand

Intestinal Radiation Injuries
Radiation Injury to the Mandible
Radiation Injury
Radiation Therapy Accidents
Radiation Therapy Accidents

- Reported accidents with most severe consequences were those related to the incorrect calibration of external beam equipment or brachytherapy sources.
- A single mistake in calibration will affect ALL patients treated until the mistake is discovered and corrected.
Radiation Therapy Accidents, cont’d

- This type of accident is normally caused by poor education and training of radiotherapy medical physicists and by a lack of quality assurance which allowed the error to remain undetected over time.
Machine Calibration

- Bend, Oregon, 1980’s
- Incorrect Atmospheric Pressure used in calibration process.
- 13% Overdose on ALL machines

Know expected values, double check if unsure.
Co-60 Teletherapy Accident

- 1974-1976, Columbus, Oh.
- Co-60 improperly decayed.
- No of pts. Affected: 426
- No independent verification of decay charts and dose calculations
- More than 2 yrs without a beam measurement.
- Physics manpower shifted to other tasks, such as a new accelerator.
Co-60 Errors

- Germany, 1986-1987
- No of pts. Affected: 86
- Dose calculations based on erroneous dose tables.
- No independent determination of the dose rate.
Co-60 Errors

- **UK: 1988**
- **No. of pts involved: 207**
- **Error in calibration of a Co-60 therapy unit, 25% overdose.**
Cs-137 Errors

- Error in the identification of Cs-137 brachytherapy sources
- -20% to +10% dosimetry errors.
- No. of patients involved: 22
- No independent determination of source strength.
Linac Error

- Spain, 1990
- 27 pts., 18 deaths from radiation.
- Error in maintenance of clinical linac. Procedures for transferring machine from maintenance to physics not followed. Conflicting signals and displays ignored.
- Procedures for periodic QA not implemented.
- Overdosage from 200% to 700%, Linac repair led to 36 MeV e- beam regardless of the console set-up
Treatment Planning Error

- UK, 1982-1991
- Number of pts. involved: 1,045
- Inappropriate commissioning of a computerized Treatment planning system, distance correction applied twice.
- 5%-30% underdosage, 492 resulted in Tx failure.
- No written procedures for commissioning and use, no clear lines of responsibility, no independent verification, planning system misunderstanding.
Ir-192 HDR Accident

- USA, Nov 16-21, 1992, Indiana, PA.
- Brachytherapy source (HDR) left inside the patient.
- Source dislodged from device.
- Conflicting monitor signals and displays ignored.
- 3.7 Ci (136.9 GBq) Ir-192 source left in patient for 92.75 hours resulting in death of the patient. A total of 95 persons were involved. Multiple persons exposed.
Co-60 Calibration

- San Jose, Costa Rica, Aug and Sept 1996
- Number of patients involved: 115
- At least 17 deaths from radiation
- Error in calculation during the calibration of Co-60 therapy unit.
- Lack of independent calibration and QA
- Recommendations from an external audit were ignored.
- Overdosage about 66%

Child affected by overdoses to brain and spinal cord and lost his ability to speak and walk

Failure to notice treatment times were too long for a new source with a higher activity.
A cobalt source was exchanged for a new one in 1996 in a hospital in Costa Rica. At the subsequent calibration, the medical physicist incorrectly interpreted 0.3 minutes as being 30 seconds (instead of the correct interpretation of 18 seconds). As a consequence, the absorbed dose rate of the new source was underestimated, resulting in treatment times being overestimated by 66%.
The most devastating computer related engineering disaster to date!

"Malfunction 54"
Software Error: Therac 25
“Malfunction 54”

When Software Fails

Perhaps the best-documented example of the harm resulting from poorly designed software involved the Therac-25, an accelerator used in medical radiation therapy. The IEEE Computer Applications in Power reported, "Between June 1985 and January 1987, six known accidents involved massive overdoses by the Therac-25--with resultant deaths and serious injuries" at treatment centers around the U.S. and in Canada.
**Software Error: Therac 25 “Malfunction 54”**

Between the patient and the Therac-25's radiation beam was a turntable that could position a window or an x-ray-mode target between the accelerator and patient, depending on which of two modes of operation was being used. If the window was positioned in the beam's path with the machine set to deliver radiation through the x-ray-mode target, disaster could result because software errors allowed the machine to operate in this configuration.
Conclusion:

“The Therac-25 is one of the most devastating computer related engineering disasters to date. The machine was designed to help people and largely, it did. Yet some sloppy engineering on the part of the AECL led to the death or serious injury of six people. These incidents could have been avoided if the AECL reacted instead of denying responsibility”.

Presented at Penn-Ohio and Ohio River Valley Meeting 10/11/13 by Ray Kaczur, M.S.
Treatment Planning Error
Treatment Planning Error

- Panama City, Panama – Aug 2000-Feb 2001
- 3 techs charged with manslaughter for accidental radiation overdoses of 28 pelvic cancer patients.
- Actual charge: “homicide by imprudence”.
- Modification of radiation therapy protocol by technologists without approval from their supervisors.
- Doses at 20-100% over prescribed.
Treatment Planning Error

- Overexposures as a result of human error in entering data into a treatment planning software program.
- 12 employees involved. Sanctions ranged from written reprimands and suspensions to dismissals.
- Two physicists terminated and permanently barred from practicing.
Treatment Planning Error

• Another physicist was barred from practicing physics for 3 years.
• Additionally one therapist was dismissed with his credentials revoked for 5 years, while 4 other radiation therapists received suspensions. Institute physicians complained they unfairly targeted individual operators instead of procedural failures.
Treatment Planning Error

• Physicians also complained that there was inadequate staffing combined with a heavy workload of more than 100 pts. per day being treated.

• Physicians say that upgrades in equipment and installations will help prevent future accidents.
Treatment Planning Error

- Panama’s Minister of Health, Fernando Garcia, plans to implement a program of qualification, renovation and medical training for all personnel in the x-ray area, including radiologists and physicists.

Time: 1-3 yrs to implement at a cost of $813,000.
Treatment Planning Error

- Of the 28 pelvic cancer patients exposed to radiation overdoses, 12 have died, seven remain hospitalized and the other nine are in guarded condition.

- Eight of the deaths have been directly attributed to radiation overdose.
Tampa, Florida.

- Mistreatment with a Novalis (Brainlab) radiosurgery stereotactic unit.
- Miscalibration of unit using TG-51 protocol.
- No second check or verification using TLD.
- Mistreated over 1 years time. 77 brain patients received 50% overdose. May 2004 to March 2005.
- Caught by RPC review. Dr. Ramesh Taylor
- 100% human error
Glasgow radiotherapy accident, 2006

Date: 5 January-1 February 2006  Location: Glasgow, Scotland, United Kingdom
Type of event: radiation therapy overexposure
Description: A 15-year-old female patient was receiving radiation therapy for a tumor at Beatson Oncology Centre in Glasgow. She was given 17 treatments over a period of time with the first on 5 January. As a result of human error repeated by different operators over the course of the treatments, all 17 treatments were far in excess of the prescribed dose (one report states the doses were 65% too high). The error was not identified until after all treatments were administered, shortly before the patient was informed on 1 February. Symptoms as of early February include large sores on the scalp and ears and permanently higher than normal body temperature. The total dose is reported as potentially fatal; the localized dose to the brain and neck poses a future risk of brain damage, paralysis, or death through damage to blood vessels in nerve tissue. The patient's condition, including damage to the eyes, had improved by late February in response to hyperbaric treatment.

compiled by Wm. Robert Johnston, last modified 14 April 2006
Glasgow, Scotland

As a result of the overdose, she suffered burns on the back of her neck and head, making her unable to lie on her back to sleep.

A teenager who was given 17 overdoses of radiation while being treated for a brain tumor says she feels she is making a "remarkable recovery".
The total dose to Lisa Norris from the Right and Left Lateral head fields was 55.5 Gy (19 x 2.92 Gy) 

She died nine months after the accident
The Hôpital de Rangueil in Toulouse, France

In April 2006, the physicist in the clinic commissioned the new BrainLAB Novalis stereotactic unit

Different measuring devices were used by the physicist

• A measuring device not suitable for calibrating the smallest microbeams was used
• “…an ionisation chamber of inappropriate dimensions…” according to Nuclear Safety Authority (ASN) inspectors
Tolouse, France

- Treatment based on the incorrect data went on for a year (Apr´06 – Apr´07)
- All patients treated with microMLC were affected (145 of 172 stereotactic patients)
Jean Monnet in Epinal, Fr.

• In May 2004 at Centre Hospitalier Jean Monnet in Epinal, France
  • …it was decided to change from static (hard) wedges to dynamic (soft) wedges for prostate cancer patients
• Treatment based on incorrect MU’s went on for over a year (6 May 2004 – 1 Aug 2005)
• At least 23 patients received overdose (20% or more than intended dose)
• Between September 2005 and September 2006, four patients died. At least ten patients show severe radiation complications (symptoms such as intense pain, discharges and fistulas)
New York Times Articles-2010

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO
Published: December 28, 2010.

The initial accident report offered few details, except to say that an unidentified hospital had administered radiation overdoses to three patients during identical medical procedures.

It was not until many months later that the full import of what had happened in the hospital last year began to surface in urgent nationwide warnings, which advised doctors to be extra vigilant when using a particular device that delivers high-intensity, pinpoint radiation to vulnerable parts of the body.

Evanston, Illinois SRS accident due radiation leaking outside the cone.

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10/11/13 by Ray Kaczur, M.S.
As Technology Surges, Radiation Safeguards Lag

In New Jersey, 36 cancer patients at a veterans hospital in East Orange were overirradiated — and 20 more received substandard treatment — by a medical team that lacked experience in using a machine that generated high-powered beams of radiation. The mistakes, which have not been publicly reported, continued for months because the hospital had no system in place to catch the errors.

In Louisiana, Landreaux A. Donaldson received 38 straight overdoses of radiation, each nearly twice the prescribed amount, while undergoing treatment for prostate cancer. He was treated with a machine so new that the hospital made a miscalculation even with training instructors still on site.

In Texas, George Garst now wears two external bags for urine and one for fecal matter — because of severe diarrhea — from a radiation treatment for prostate cancer. The hospital, his wife, and the government have been unable to make him whole.

Lorraine Raymond, a radiation therapist, raised concerns about overirradiation in the treatment of Frederick Stein at a Veterans Affairs hospital in New Jersey in 2008. More
Philadelphia VA Hospital - Prostate seed Incident, substandard implants

At V.A. Hospital, a Rogue Cancer Unit

The Veterans Affairs Medical Center in Philadelphia.
By WALT BOGDANICH
Published: June 23, 2009

Rob Bennett for The New York Times
Dr. Gary D. Kao is responsible for most of the errors, investigators say.

Jessica Kourkounis for The New York Times
NRC fines VA $39,000 over radiation violations in prostate cancer programs

By Josh Goldstein, Inquirer Staff Writer
POSTED: August 24, 2010

The U.S. Nuclear Regulatory Commission on Monday levied a $39,000 fine against the Department of Veterans Affairs for radiation safety violations at prostate cancer programs in 12 VA hospitals nationwide.

The penalty followed a $227,500 fine in March against the veterans agency for failures in the prostate brachytherapy program at the Philadelphia VA Medical Center, where dozens of veterans got incorrect doses of radiation over six years.

Those mistakes prompted investigations at other VA hospitals of brachytherapy, which involves using radiation to kill tumor cells.
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 summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer failed to detect a computer error that directed a linear
Mr. Jerome-Parks
Died at age 43 from a radiation overdose - 2007

NY Times

Presented at Penn-Ohio and Ohio River Valley Meeting
10/11/13 by Ray Kaczur, M.S.
Breast wedge accident in Brooklyn, NY 2007

“But on the day of the warning, at the State University of New York Downstate Medical Center in Brooklyn, a 32-year-old breast cancer patient named Alexandra Jn-Charles absorbed the first of 27 days of radiation overdoses, each three times the prescribed amount. A linear accelerator with a missing filter would burn a hole in her chest, leaving a gaping wound so painful that this mother of two young children considered suicide.”
Safety Features Planned for Radiation Machines

By WALT BOGDANICH
Published: June 9, 2010

GAITHERSBURG, Md. — Manufacturers of radiation therapy equipment said at a patient-safety conference here Wednesday that within the next two years their new equipment and the software that runs it would include fail-safe features to help reduce harmful radiation overdoses and other mistakes.

The absence of these fail-safe features contributed to the fatal radiation overdose of a New York City patient, whose death was the centerpiece of a lengthy article in The New York Times early this year that examined radiation accidents and how complex new technology contributed to those accidents.
Missouri – SRS Error

“In the last five years, SRS systems made by Varian and its frequent German partner, Brainlab, have figured in scores of errors and overdoses, The New York Times has found. Some mistakes were caused by operator error. In Missouri, for example, 76 patients were over radiated because a medical physicist did not realize that the smaller radiation beam used in radiosurgery had to be calibrated differently than the larger beam used for more traditional radiation therapy.”

NY Times
Findings from NY Times

• “Government regulators have been slow to respond. Radiation accidents are chronically underreported, and a patchwork of laws to protect patients from harm are weak or unevenly applied, creating an environment where the new technology has outpaced its oversight, where hospitals that violate safety rules, injure patients and fail to report mistakes often face little or no 

punishment, The New York Times has found.”

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Fluoroscopic Injuries
Fluoroscopy Injury

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Fluoroscopy Injury

6 to 8 wks after procedure

16 to 21 weeks

18 to 21 months, with tissue necrosis

Total fluoro time > 120 min
Fluoroscopy Injury

After skin grafting procedure
X-ray injury: Bi-plane fluoroscopy

At five months post exposure

Cumulative dose approx 25 Gy

Surgical flap in place

Surgical debridement
Potential Causes for Accidents
Causes

- Lack of written procedures and protocols for acceptance tests and commissioning of new equipment has led to use of incorrect values of basic parameters subsequently used in treatment of patients.
- Problem applies not only to irradiation devices but planning equipment.
Error detection

- Underdosage errors are more difficult to detect clinically than overdosages, esp. if the dose deviation is moderate and is undiscovered for a long time.

- Tumor recurrence may already appear.
Error Causes

- Change of personnel without a formal transfer of information relevant to calibration and treatment planning was also among the causes for many reported accidents.
- SSD vs SAD calibrations – inverse square error.
- Double wedge factoring.
Error Causes

Another frequent cause of accidents:

- Misunderstanding of a treatment prescription, of a treatment plan or of data related to the identification of patients.
- Due to ineffective procedures for communication and documentation.
Error Causes

Treatment preparation and delivery requires a high degree of concentration which may be difficult to maintain in a noisy environment and in conditions of a heavy workload.
Error Causes

- Poor maintenance of equipment.
- Use of equipment in an unsafe condition in order to avoid disruption of the patient’s treatment.
Most common radiation therapy errors

1. Blocking of fields
2. Misplacement of fields
3. Miscalculation of fields
4. Transfer of information

“Radiation Therapist”, Fall 2002, Vol. 11 No. 2
Factors contributing to accidents

- Lack of an adequate quality assurance program.
- Verifications omitted, i.e. second checks.
- Deficient training in radiotherapy physics.
- Lack of procedures and written procedures.
- Lack of adequate and proper supervision.
- Inadequate and ineffective management which allowed pts. to be treated without essential institutional policy and provisions of an adequate QA program.
What can we do?

- Leave nothing to chance, but have a structured and systematic approach.
- Ensure a comprehensive quality assurance program is in place.
- Organization of the radiotherapy department.
- Maintenance of equipment. Fault logging.
- Proper staff qualifications and training.
- Auditing provisions.
- Minimize manual entry of data.
Ongoing QA process:
Maintain the level of safety over time!

- Re-evaluate the QA program periodically.
- Look for early warning signs of potential problems.
- Look for slow degradation signs.
- Most accidents involve a combination of failures.
Most accidents involve a combination of failures.

- No prior safety assessment.
- Poor education and lack of training.
- Management pressure (real or perceived) to continue work even when safety systems were inoperable or deficient.
- Poor maintenance program
- Non-investigation of false-alarms. Leads to ignoring warning systems. e.g. Indiana, Pa.
- Lack of management commitment to safety.
Regulatory Affect

- These accidents account for many of the regulatory agency’s federal and state rules that you see today.

- Many of the rules have a story behind them.
- Riverside accident – new Co-60 therapy rules
- P-32 colloidal – misadministration reporting.
The following graph shows the distribution of incidents found at different control points (or checks) in the radiotherapy process.

How medical incidents are found

Ref: ROSIS website
Breakdown of Incident Detection

b) Who did detect or discover the incident?

- Therapist (TU) 70%
- Therapist (Sim/CT) 5%
- Physicist 12%
- Oncologist 6%
- Dosimetrist 4%
- Other 3%
- Tech Main 0%

Notable is that "Others" include two cases when the patient himself draw the attention that something was not correct during the setup/treatment.

Ref: ROSIS website
Ohio Law Requirements

3701:1-66-02

“General administration requirements for handlers of radiation-generating equipment”
Ohio Law: Competency Evaluation

3701:1-66-02 (H)(1),

The registrant shall be responsible for developing safe operating procedures for the operation of the radiation-generating equipment, including any restrictions of the operating technique required for the safe operation of each radiation-generating equipment, and for **documenting the instruction and assuring that all operators are competent in the safe use of the radiation-generating equipment.**
Ohio Law: 3701:1-66-02 (D)(2)

(D) The department may use interview or observation to determine that the handler assures:

… and 

(2) Every individual who is licensed to perform radiologic procedures is adequately instructed in the registrant’s safe operating procedures and can demonstrate competency in the safe use of the equipment.
Pennsylvania Law, § 228.35. Operating procedures.

(5) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence). There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.
Be careful, you do not want an accident waiting to happen!