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Overview of some major incidents in radiotherapy and their consequences

Hamish Porter

BIR - Radiotherapy Errors and Near Misses September, 2012

In 1966, 3 patients received overdoses during electron therapy on a dual-mode 8 MeV linear accelerator.

Expert committee investigated and concluded that the cause was:
a "very rare combination of circumstances." and
formulated the first UK safety code and recommended the formation of the:

RADIOTHERAPY APPARATUS SAFETY MEASURES PANEL [RASMP] .

"Linear accelerators used to produce therapeutic x-rays operate at maximum power, so any problem leads to an UNDERSDOSE to the patient. This is not possible for electron therapy, so mistakes can lead to an OVERDOSE. In fact a very small change in the current through the filament can lead to a heavy overdose. The relationship between filament current and radiation dose is not known.

The committee take the view that all users should know that, for example, the maximum dose that the linac can deliver is some 70 times the normal operating dose."

Playfair, Spiers & Smithers Report

Technically, two problems were identified:

- **an irregularity of beam current which occurred about once a year for a few days**
- **a failure of the single internal ion chamber**

The incidents occurred when these two events occurred simultaneously.
(*Only one previous incident similar to this had occurred in the early 1950's.*)

The RASMP committee produced two guidance documents:

RASMP 1968 covering linacs and
RASMP 1975 which covered all classes of radiotherapy equipment.

RASMP68 introduced the dual independent electrometer principle leading to the present design of linac monitor ion chambers, incorporated in IEC guidance.

Undoubtedly this design would have prevented this incident.

The Therac-25 Series of Incidents

Between June, 1985 and January, 1987 in the United States and Canada, 6 patients were massively overdosed during treatment with a linear accelerator manufactured by THE ATOMIC ENERGY CANADA LTD COMPANY [AECL]. This therapy accelerator was the THERAC-25.

No operator error was involved and it was eventually identified that two separate **MACHINE ERRORS or MALFUNCTIONS** related to the control system were the primary cause..

However the conclusions, while clearly identifying **software design errors** as a major contribution to these incidents, also identify significant contributions from:

- **failures in equipment design and design testing**
- **operational safety testing**
- **operational quality control**
- **operational procedures and departmental management**
- **lack of communication within and between radiotherapy departments**

Therac-25 was the first medical linac "**designed to use computer-control**".

- **NO STAND-ALONE OPTION**
- **AN INTERNAL COMPUTER WAS INTEGRAL TO ALL PROCESS OPERATIONS**

Some safety features in an earlier model - the Therac-20 - (e.g. hardware circuits for electron beam scanning and hardware interlocks) were now undertaken by a control computer.

Marketing literature: ***more compact - more operational modes - "easier to use".***

AECL did a HAZARD ANALYSIS before the clinical introduction but this did not include the new software .

Operator Comments (before any incidents occurred)

"It was not out of the ordinary for something to stop the machine, say on average 40 dose-rate malfunctions per day. I can't remember all the reasons it would stop, but there was a lot of them."

Most malfunctions were reset by the hospital service technicians or the physicist. There was no written evidence of reports to the AECL of these frequent occurrences.

"We were taught that there were so many safety features on the new accelerator that we understood it was virtually impossible to overdose a patient."

From 1981 to June,1985 eleven Therac-25 systems were installed (6 in Canada and 5 in the U.S.).
No major problems were reported to AECL.

But then in June 1985 the incidents began.

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1. Kennestone Regional Oncology Center, Marietta, Georgia US [Therac-25 installed 6 months].

Incident: June 1985. patient receiving lymph node irradiation [10 MeV] following lumpectomy,
- After treatment patient reported "you burnt me".
- Patient treatment continued to end of prescribed course.

Hospital action:

- Hospital physicist investigated and "wondered if the electron beam had failed to scan leading to an overdose". He raised this possibility with an AECL engineer in a telephone call but **did not report an incident to AECL**..
- There was no hardcopy of the treatment session parameters **as the printer was disabled at the time**.

- Patient eventually showed burn marks at both beam entry and exit sites.
  Patient had received 1 or 2 fractions of 150 - 200 Gy. Breast removed and arm & shoulder were paralysed.
- No records of any investigation by hospital or AECL.
- AECL not explicitly informed by hospital of malfunction or incident.
- Lawsuit settled out of court with no liability admitted. Incident not reported to FDA.

It was not accepted by AECL that an equipment malfunction had caused this incident

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2. Ontario Cancer Centre , Hamilton, Canada [Therac-25 installed 6 months]

Incident: July 1985, patient receiving 24th fraction of photon treatment for cervical cancer.

- Linac faulted 5 times before it stopped operating
- Hospital technician attended but found no fault.
- **Hospital did not notifiy AECL that an incident had occurred**
- Patient complained of "electric tingling shock" in hip. Treatment continued as normal for next 2 fractions.
  Patient had received one fraction of 130 – 170 Gy. Severe radiation necrosis of hip.
  Patient hospitalised and died in hospital in November, 1985.
- Lawsuit settled out of court.

AECL notified all users that:

they should confirm turntable position (ie whether x-ray or electron mode was selected) before each beam by "looking at display".

3. Yakima Valley Memorial Hospital, Washington, U.S. Incident:

December 1985, patient being treated with photons developed a **striped erythema** on her hip.

- By time of investigation, block-tray erythema had been discarded as explanation.
-
- Reported to AECL but they replied "**could not have been caused by a Therac-25 malfunction**".
- Hospital staff were not aware of any other incidents in other departments and accepted AECL reassurances.

Following skin grafts, patient survived until late 1990s, with minor disability

- The investigation was closed and the case settled out of court.
- At this time the previous incidents were not well known in other radiotherapy departments.

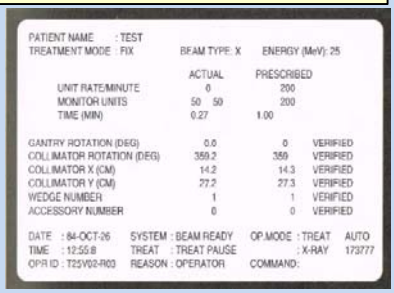
It was not accepted by AECL that an equipment malfunction had caused this incident

4. East Texas Cancer Centre, Tyler, Texas U.S. [Installed 1983]
Incident: March 1986, patient being treated with 22 MeV electrons after removal of tumour from back.

Details of incident
Very experienced operator known for fast typing and editing at console.
Entered "**X**" rather than "**e**"
quickly realised error, used cursor up to delete "X" and typed "e".
[common error]

"Enter" several times to complete verification.
Linac moved to READY STATE,
operator pressed B = "BEAM ON"
linac moved to RADIATION ON state.

After a few seconds, machine faulted to a **TREATMENT PAUSE** and console displayed "**MALFUNCTION 54**".



Manual stated Malfunction 54 = dose too high, too low or zero!!! Display showed 6 MU of 202 MU.

Patient reported that when beam first went on he felt an "electric shock or as if someone had poured hot coffee on his wound" .
The machine made an unusual noise and the beam stopped.
He climbed off table to leave the room.
At that point operator tried again and he felt another shock.
He ran to the treatment room door and hammered on it to escape !!!
How could this happen ?

On that day the treatment room CCTV was disabled and the audio monitor had been broken for several days.

ACTION

- Patient had received a single dose of 165 – 250 Gy in less than 1 second **(over area of < 1 cm).**
  He died 5 months after accident from complications of radiation overexposure..
- Linac dosimetry checked and put into service again on Monday 7 April 1986.
- Incident settled out of court.

But 5 days later on Friday 11 April, 1986 .....

Incident 5. Same department at ETCC Tyler, Texas.

Incident: same operator was treating a man with a facial skin tumour with 10 MeV electrons.

Exactly the same sequence of events occurred with exactly the same consequences.

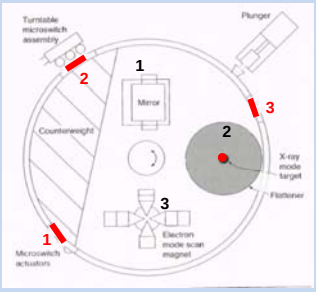
MALFUNCTION 54

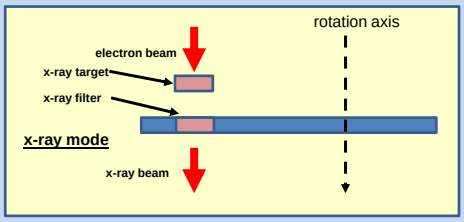
Operator heard patient scream and rushed into the room.
Patient died 3 weeks later from radiation damage to brain stem.

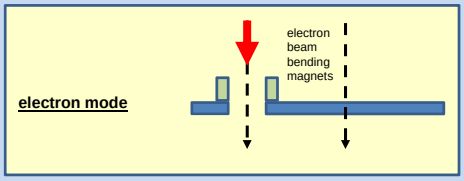
Hospital physicist – **Fritz Hager** – working with the operator was at last able to systematically reproduce malfunction !!

He discovered that to reproduce the fault, the operator had to repeat the exact keystrokes at the same speed.

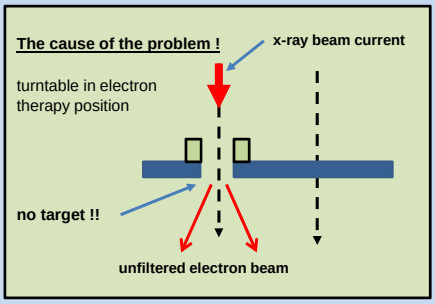
Under these conditions a dose of 250Gy at beam centre was **reproduced every time**.







The cause of the problem !



AECL sent users sent a CORRECTIVE ACTION.

This action was to REMOVE THE KEY CAP OF THE "UP CURSOR (R) KEY and use insulating tape to keep the key contacts in the open switch position. An engineer could be contacted if they required help with this procedure.

So the cause of these incidents has been identified and the " satisfactory" fix implemented.

We can close the episode and look for the lessons to be learned .

January, 1987 at Yakima Valley Memorial Hospital, Washington, U.S.

Their second Therac-25 incident occurred !! PANIC !!

6. Yakima Valley Memorial Hospital, Washington, U.S.

Incident: January, 1987 The second patient of the day was about to be treated.
Before the therapeutic beam (79 cGy), double exposure verification films taken (4 cGy treatment portal; 3 cGy wider). .

Sequence of Events:

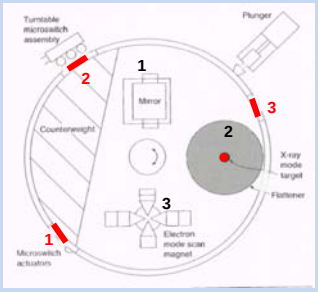
Machine faulted with FLATNESS FAULT displayed and the 7 cGy verification dose displayed.

Patient shouted and operator entered room.
Patient complained of "burning pain in chest".
Later in day the erythema pattern of the photon blocking tray began to show.

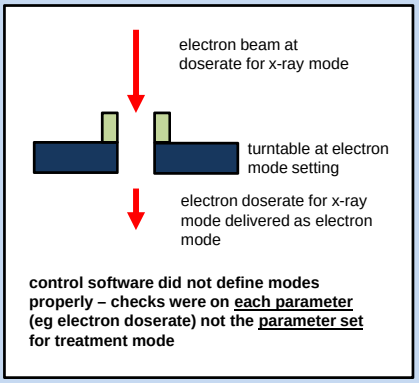
The patient died from complications related to a radiation overdose in April, 2011.

Subsequent clinical investigation estimated that patient received 2 doses of 50 Gy.

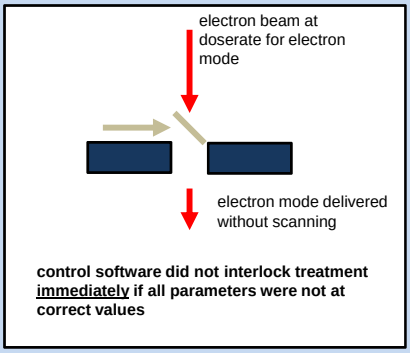
After a week or so it was admitted there was a fault in the software code which permitted an electron beam therapy to be treated with the turntable in the light field position (ie. no x-ray filter and no electron scanning coils).
This was a fault unrelated to the previously identified fault.



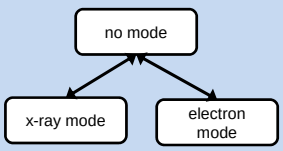
Summary of causes of Therac incidents

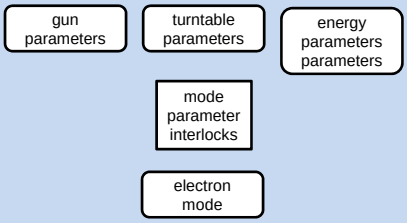


control software did not define modes properly – checks were on <u>each parameter</u> (eg electron doserate) not the <u>parameter set</u> for treatment mode



control software did not interlock treatment <u>immediately</u> if all parameters were not at correct values





The THERAC series of incidents: CONSEQUENCES

- Major response by manufacturers regarding design and testing of both software and hardware systems
- communications between manufacturers and departments was greatly improved
- communication between departments and regulatory authorities began to be improved, particularly relating to reporting and inspection
- communication within the radiotherapy community about malfunctions and related problems – particularly in the radiotherapy physics community – improved and became focussed
- a more co-ordinated and planned approach to **quality control** began to be developed and the professional bodies began to take the lead
- the importance of peripheral safety equipment eg CCTV, audio was recognised

However these responses were largely equipment focussed NOT patient or system focussed i.e. quality control not quality assurance

The Design Changes

- **a clear definition and implementation of SYSTEM STATES such as stand-by; preparatory; ready; and radiation states (and specifically a no-mode state)**
- **critical safety interlocks are implemented in both hardware and software modes**

After several years development the first edition of Guidance Notes for the Medical and Dental Use of Ionising Radiation was published in 1985. This involved co-operation of all the radiotherapy professions and the legislative and enforcement authorities, such as H.S.E. and what was to become the Environment Agency.

Essentially this replaced the earlier RASMP documents.

Two major incidents had consequence for UK radiotherapy.

Exeter Cobalt Radiotherapy Incident, 1988
Due to a repeated error in the dosimetriic calibration of a cobalt teletherapy unit, 205 patients received significant overdoses.

Stoke-on-Trent Radiotherapy treatment planning Incident, 1993
Nearly 1,000 cancer patients received an underdose of up between 10 to 30 per cent below the prescribed dose for a period of up to 10 years,
A computer programming error during treatment planning commissioning was identified as the cause.

The reports on these incidents recommended important improvements in operational radiotherapy.

The three most significant consequences were:

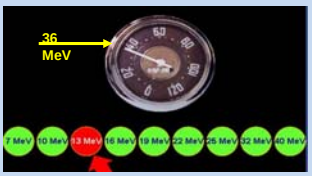
1. the IPEM **inter-departmental dosimetry audit programme**
2. the setting up of the Bleehen committee which led to the setting up the UK national **Quality Assurance in Radiotherapy (QART) programme**
3. Specific guidance from HSE in publication PM77 relating to independent dosimetry calibrations and competency requirements for physicists undertaking these measurements.

A major incident in Zaragoza, Spain occurred in 1990 and it also had consequences for operational radiotherapy internationally.

In December, 1990 in the Zaragoza Clinic a series of incidents occurred following repair of a CGR linear accelerator by a service technician. 27 patients suffered radiation overdoses (200 – 700%) with 20 deaths directly attributed to the incidents.

The Sequence of Events
Wednesday 5 December: the linac failed to produce electron beams. [Not cause of incident.]
A CGR service technician was on-site and after an initial look decided to repair next day (**a public holiday**).
Thursday 6 December: repair undertaken but control panel always indicated 36 MeV (maximum energy) no matter what energy selected and delivered.
Friday 7 December was also a public holiday
Monday 10 December: treatment resumed.
Operator noticed a problem with energy display but assumed:
A) needle stuck and B) selected energy agrees with keyboard entry.

Treatment continued with this problem until Thursday 20 December.



Thursday 20 December:
Electron energy display problem reported to medical physics after 8 days of treatment.

No information passed to hospital engineers about either:
A) original breakdown and B) repair by service technician

[In fact it was 1 month before this information was circulated.]

Friday 21 December

Dosimetry checked and found that electron energy was 36 MeV no matter what energy was selected and displayed.

The causes of the incident
- The maintenance technician from the company was not a linac engineer but a cobalt engineer.
- not skilled in electronics
- accidently shorted a transistor when repairing the reported fault
- did not know how to check the energy of the linac.

The consequence was that:
- symmetry of electron beam was incorrect but interlock tolerance was too high
- monitor chamber only partially irradiated (~ 45 %) leading to 5x dose error
- beam servo system increased gun current to compensate for low monitor dose rate

In effect all beams were 36 MeV no matter what energy was selected.

No handover to radiography or physics staff occurred and in fact physics were not notified that a repair had been undertaken for 10 days.

The lessons from this incident

- Very poor communication of events within department – compounded by holidays, weekends etc
- No **proper handover procedure** or **QC following a service PMI**
- Poor interlock design – perhaps improved if software had monitored independent interlock states and system state
- Poor procedure allowing treatment to take place despite a display incongruity.

Zaragoza – the aftermath

This incident – the worst ever radiotherapy accident attributed to equipment faults - ended with a court case.

- **The court finally attributed 20 deaths and 7 serious injuries to the incident.**
- **The GE service engineer was found guilty of CRIMINAL NEGLIGENCE.**
- **The company was found to have CIVIL LIABILITY for a $3.7 M award to the patients involved in the accident.**

Major incidents such as this and a similar one in Poland (Bialystok Oncology Centre) in 2001 produced substantial reports from IAEA which recommended:

Formal procedures for handover after maintenance, including QC, which must involve the physics department

To perform a review or investigation when unusual displays or behaviour of radiotherapy equipment occurs.

Following 2 significant European Union safety directives the UK introduced 2 radical pieces of legislation:

Ionising Radiations Regulations, 1999

Ionising Radiation (Medical Exposure) Regulations 2000

These were accompanied by a revision of the Guidance Notes for the Use of Ionising Radiation in Medical and Dental Procedures.

The approach to safety in radiotherapy had undergone a paradigm change:

- **patient focussed**
- **based on quality assurance programmes**

and in terms of equipment safety:

- **quality control baselines for the specific equipment not generic equipment types [IRR]**
- **departmental equipment inventory (to include all software revisions) [IRMER]**

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More recent incidents (perhaps not major) have involved data transfer of the radiotherapy prescriptions between different computer systems within the radiotherapy process.

Some common features appear in reports of these incidents.

- as all staff groups become more familiar with computer systems, the distinction between computer workstations for general or home use, and computers in the radiotherapy system is not always observed.
- new paradigms for the quality control and quality assurance of these computer control and imaging-based systems need to be developed

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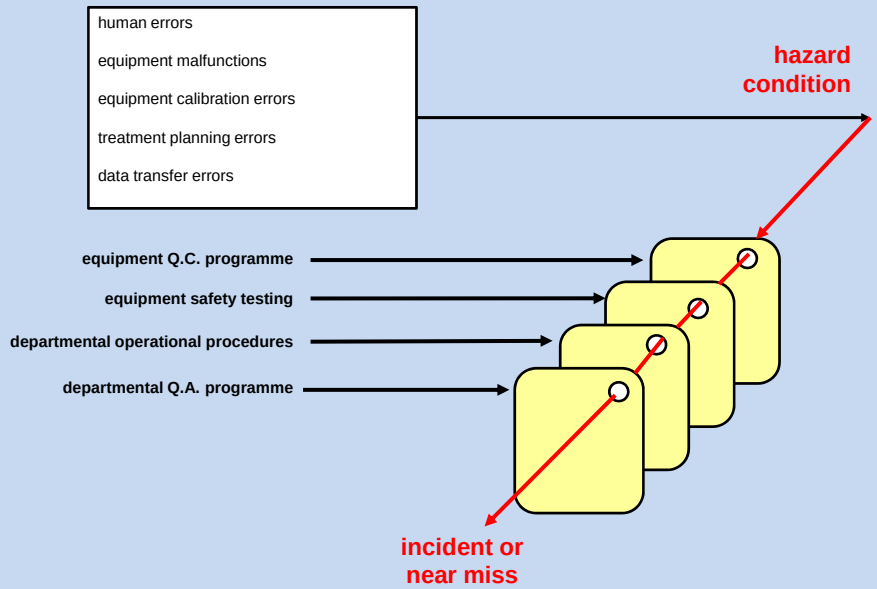

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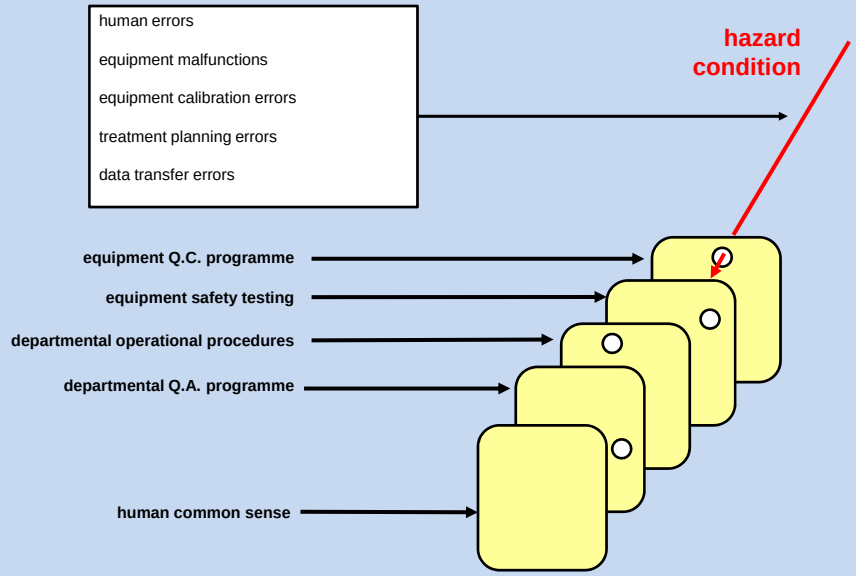

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