

Risks and Accidents in Radiotherapy

Chris Constantinou Ph.D., DABR

November 2018

Cyprus Association of Medical Physics and
Biomedical Engineering

Safety and Quality in Radiotherapy



Lifetime Risk of Cancer Induction

The average (baseline) lifetime risk of death from cancer in the United States is 25 %.

Risk of Cancer Induction from Radiation

a) With **very low dose rate**, the lifetime risk of cancer induction from delivering a dose of 0.1 Sv (10 rem) to the whole body over a long period of time (**chronic exposure**), is estimated to be **0.1 %** or **1 in 1000 chances**.

(UNSCEAR 1977, BEIR report, 1980).

Risk of Cancer Induction from radiation

- b) An acute exposure resulting in a Dose Equivalent of **0.1 Sv (10 Rem)** to all organs of the body, increases that lifetime risk by about **0.8 %**. (or **8 in 1000 chances**)

This is an increase of **766 cases per million**, over and above the naturally occurring **163800 cancers** occurring in the lifetime of **one million**, for other reasons. (BEIR V report, 1990).

Safety and Quality in Radiotherapy

STATISTICS ON RISK FOR INCIDENTS IN RADIOTHERAPY

Propagation of Errors

- As an example, let's assume there are 100 steps in the radiotherapy process
- (many studies identify a higher number of process steps but we'll be conservative)
- Let's further assume that there is a chance of 1 in a 1,000 that an error is made during any process step.
- Based on these assumptions, the probability that the final course of treatment contains an error is:

$$1 - 0.999^{100} = 1 - 0.9 = 10\%$$

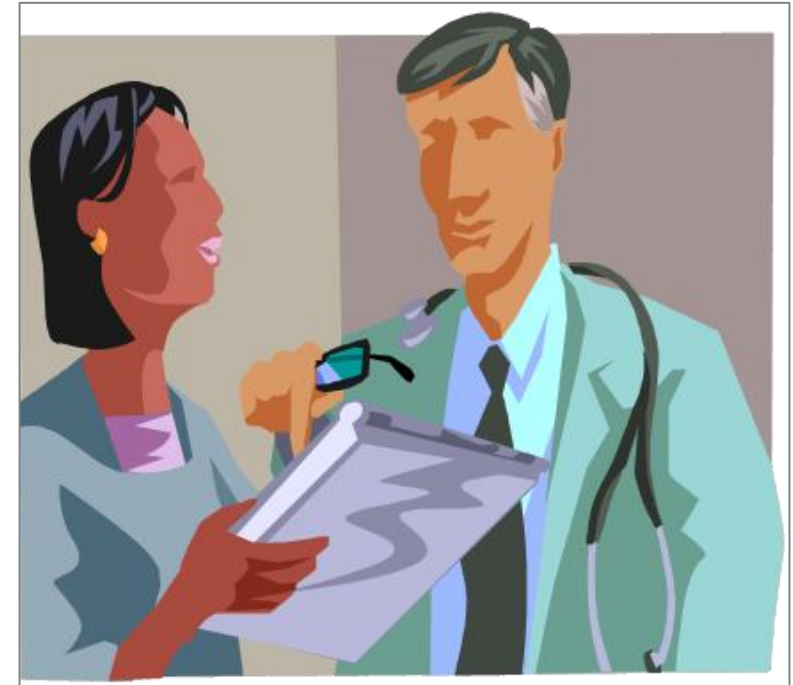
STATISTICS ON RISK FOR INCIDENTS IN RADIO THERAPY

Propagation of Errors

- If the error rate is **10 times higher at 1 in 100** per process step then the probability that the final course of treatment contains an error is:

$$1 - 0.99^{100} = 1 - 0.37 = 63\%$$

This does not state the seriousness of the error



Propagation of errors

Note that we have not mentioned the severity of the error. It is also worth mentioning that **this calculation assumes that errors at different steps are independent of each other, i.e, an error at step N does not affect the probability of an error at any subsequent step.**

Many of the errors that do occur during routine operations may have no impact on the final outcome for the patient.

However, it's surprising how **a relatively low probability of an error at each step,** can make the final probability of an error in the course of treatment **so high.**

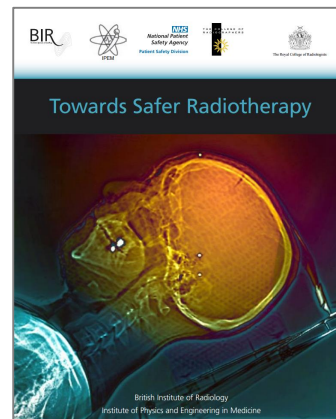
Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOTHERAPY

The UK experience

There are two sources of information on the UK experience with incidents in radiotherapy:

- **Towards Safer Radiotherapy - a consensus document from 5 U.K. organizations²**
- **Statistics compiled by Public Health England³**



Safety and Quality in Radiotherapy

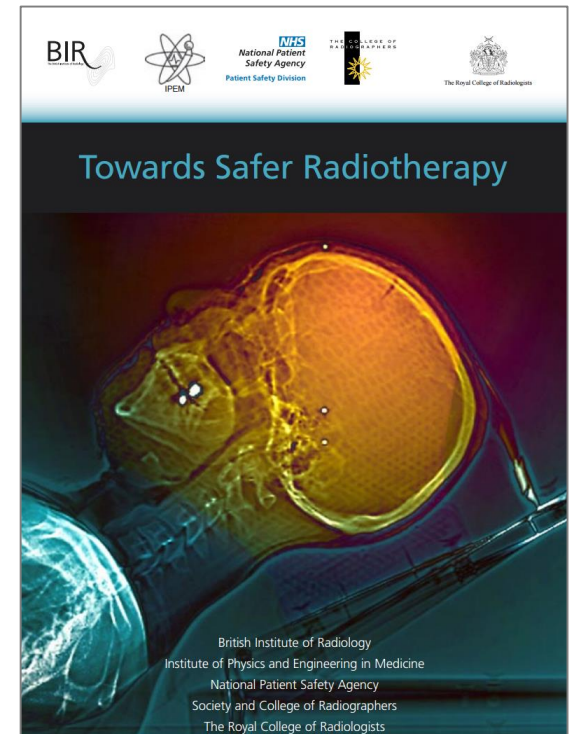
STATISTICS ON INCIDENTS IN RADIO THERAPY

The UK experience

Towards Safer Radiotherapy²

From data collected between May 2000 and August 2006, it was concluded that “around 3 per 100,000 courses of radiotherapy.. were likely to have a clinically significant adverse outcome”.

Radiotherapy is generally safe. During the period May 2000 to August 2006, 181 incidents affecting 338 patients were reported in the UK under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000; an incidence of approximately 40 per 100,000 courses of radiotherapy. Of these, 24 were likely to have a clinically significant adverse outcome, which equates to around 3 per 100,000 courses of radiotherapy.



Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOTHERAPY

The UK experience Towards Safer Radiotherapy²
Radiotherapy is generally safe.

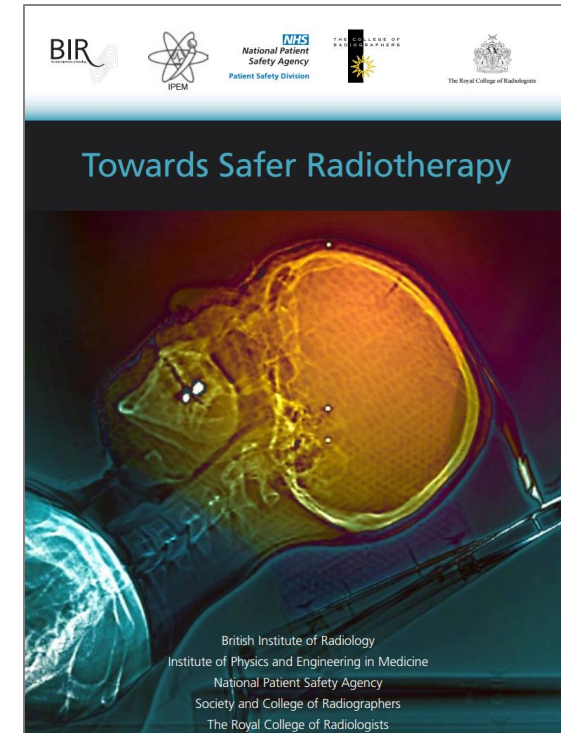
From May 2000 to August 2006,

181 incidents were reported under the Medical exposure Regulations of 2000.

i.e About 40 per 100,000 radiotherapy treatments.

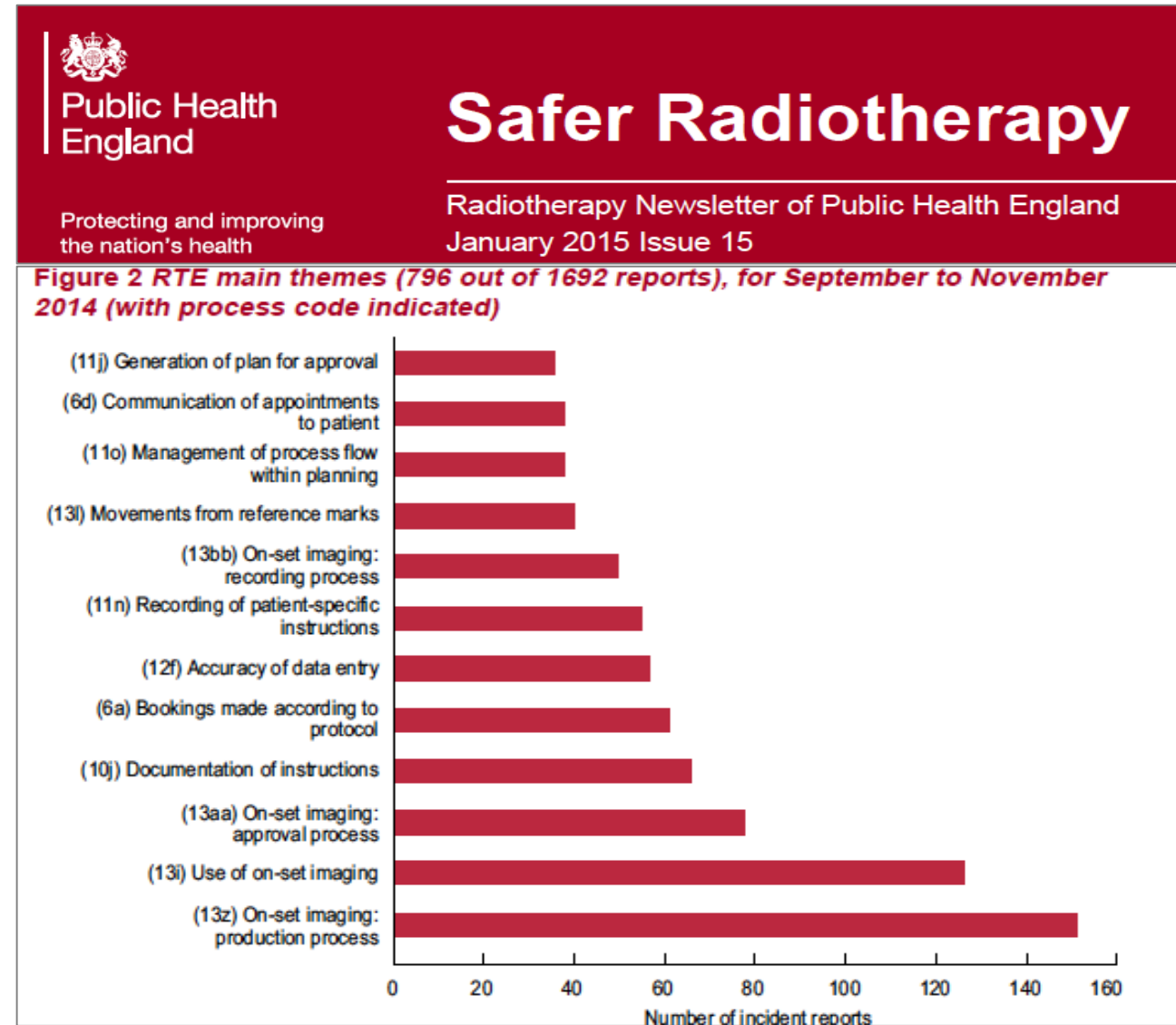
24 were likely to have a clinically significant adverse outcome.

This means that **3 per 100,000 Radiotherapy treatments had a clinically significant adverse outcome.**



Safety and Quality in Radiotherapy

- UK Experience
- FROM SEPTEMBER TO NOVEMBER 2014



UK experience with incidents in radiotherapy:

- a) **Toward safer radiotherapy**, a consensus document from 5 UK organizations
- b) **Statistics compiled by public health England.**

FROM SEPTEMBER TO NOVEMBER 2014

- Range from **40 incidents** related to generation of plan approval
- **80 incidents** in on-set imaging process
- **160 incidents** related to on-set plan approval process



Public Health
England

Protecting and improving
the nation's health

Safer Radiotherapy

Radiotherapy Newsletter of Public Health England
January 2015 Issue 15

The UK experience Public Health England³
Voluntary incident reporting in the U.K.

September 2014 – November 2014

1692 reports

**1.6% were at Level 1, Reportable Radiation Incidents, i.e.
generally clinically significant.**

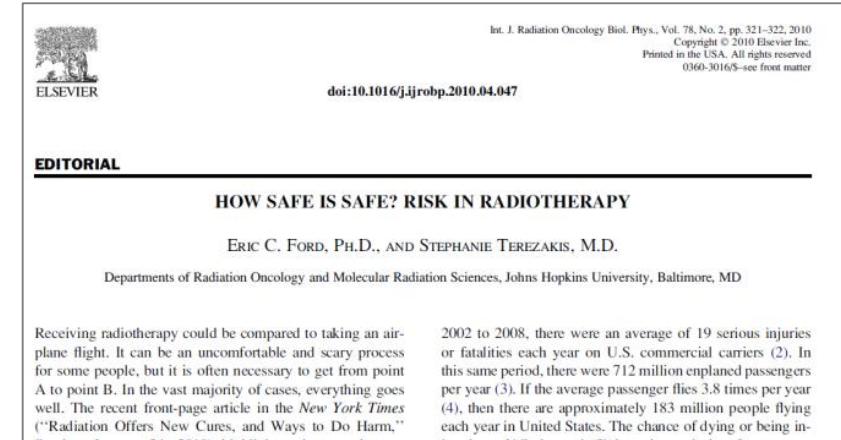
Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOTHERAPY

The New York State experience

A commentary and analysis of the New York data by Ford and Terezakis⁵ presents the following statistics:

- The estimated **rate of misadministrations (in the U.S.) is approximately 1 in 600.**
- **Based on a Canadian studies⁶, “perhaps only 6% of incidents are serious”.**
- **So the “serious” incident rate is approximately 1 in 10,000.**





doi:10.1016/j.ijrobp.2010.04.047

EDITORIAL

HOW SAFE IS SAFE? RISK IN RADIOTHERAPY

ERIC C. FORD, PH.D., AND STEPHANIE TEREZAKIS, M.D.

Departments of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University, Baltimore, MD

Receiving radiotherapy could be compared to taking an airplane flight. It can be an uncomfortable and scary process for some people, but it is often necessary to get from point A to point B. In the vast majority of cases, everything goes well. The recent front-page article in the *New York Times* (“Radiation Offers New Cures, and Ways to Do Harm,”

2002 to 2008, there were an average of 19 serious injuries or fatalities each year on U.S. commercial carriers (2). In this same period, there were 712 million enplaned passengers per year (3). If the average passenger flies 3.8 times per year (4), then there are approximately 183 million people flying each year in United States. The chance of dying or being in-

Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOTHERAPY

So, what do we know about Safety in Radiotherapy?

a) Towards Safer Radiotherapy estimates “around **3 per 100,000** courses of radiotherapy... were likely to have a **clinically significant adverse outcome**”.

b) The **New York State data**, as analyzed by Ford and Terezakis⁴ suggest a “serious” incident rate of about **1 per 10,000 patients**.

These are both relatively small numbers.

Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIO THERAPY

So, what do we know about Safety in Radiotherapy?

These are both relatively small numbers (3 -10/100,000).

So does that mean radiotherapy is safe?

Safe compared to what?

Commercial airlines are widely regarded as a high reliability industry. Most of us have no concern when stepping onto a commercial flight.

The chance of death on a commercial flight worldwide is approximately 5/10,000,000.



Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOOTHERAPY

So, what do we know about Safety in Radiotherapy?

Data on safety in radiotherapy is sparse and of largely unknown accuracy.

Airline fatalities are not ideal comparators for serious injuries caused by radiotherapy incidents.

A reasonable conclusion is that the risk of serious harm from radiotherapy is considerably higher, (perhaps 100 times) than the accompanying a flight on a commercial airlines.

There is clearly room for us to do a lot better.

STATISTICS ON INCIDENTS IN RADIOTHERAPY

REFERENCES AND ADDITIONAL RESOURCES

1. Radiotherapy Risk Profile.
http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf
2. Towards Safer Radiotherapy. <https://www.rcr.ac.uk/towards-safer-radiotherapy>
3. Safer Radiotherapy: error data analysis. <https://www.gov.uk/government/publications/safer-radiotherapy-error-data-analysis-report>
4. New York Patient Occurrence and Tracking System.
<https://www.health.ny.gov/facilities/hospital/nyports/>
5. Ford EC and Terezakis S. How safe is safe? risk in radiotherapy. *Int J Radiat Oncol Biol Phys* 78 (2010) 321-322.
6. Huang G, Medlam G, Lee J, et al. Error in the delivery of radiation therapy: results of a quality assurance review. *Int J Radiat Oncol Biol Phys* 61 (2005) 1590-1595.
7. Safety Report, International Civil Aviation Organization (2014).
http://www.icao.int/safety/Documents/ICAO_2014%20Safety%20Report_final_02042014_web.pdf

Safety and Quality in Radiotherapy

STATISTICS ON INCIDENTS IN RADIOTHERAPY

REFERENCES AND ADDITIONAL RESOURCES

6. Hendee WR and Herman MG. Improving patient safety in radiation oncology. *Prac Radiat Oncol.* 1 (2011) 16-21.
7. Root Cause Analysis Tools.
http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf
8. Target Safely. <https://www.astro.org/Clinical-Practice/Patient-Safety/Target-Safely/Index.aspx>
9. Huq MS, Fraass BA, Dunscombe PB, et al. A method for evaluating quality assurance needs in radiation therapy. *International Journal of Radiation Oncology, Biology, Physics*, 71, S2-S12. 2008.
10. Dunscombe P. Recommendations for safer radiotherapy: what's the message? *Frontiers in Oncology* 2 (doi: 10.3389/fonc.2012, 00129).

Safety and Quality in Radiotherapy

REFERENCES AND ADDITIONAL RESOURCES

1. **Safety Reports Series No. 17.** http://www-pub.iaea.org/books/IAEABooks/Selected_Book_in_the_series/Safety-Reports-Series/73/17
2. **Towards Safer Radiotherapy.** <https://www.rcr.ac.uk/towards-safer-radiotherapy>
3. **ICRP 112.** <http://www.icrp.org/publication.asp?id=ICRP%20Publication%20112>
4. **Safety is No Accident.**
https://www.astro.org/uploadedFiles/Main_Site/Clinical_Practice/Patient_Safety/Blue_Book/SafetyisnoAccident.pdf

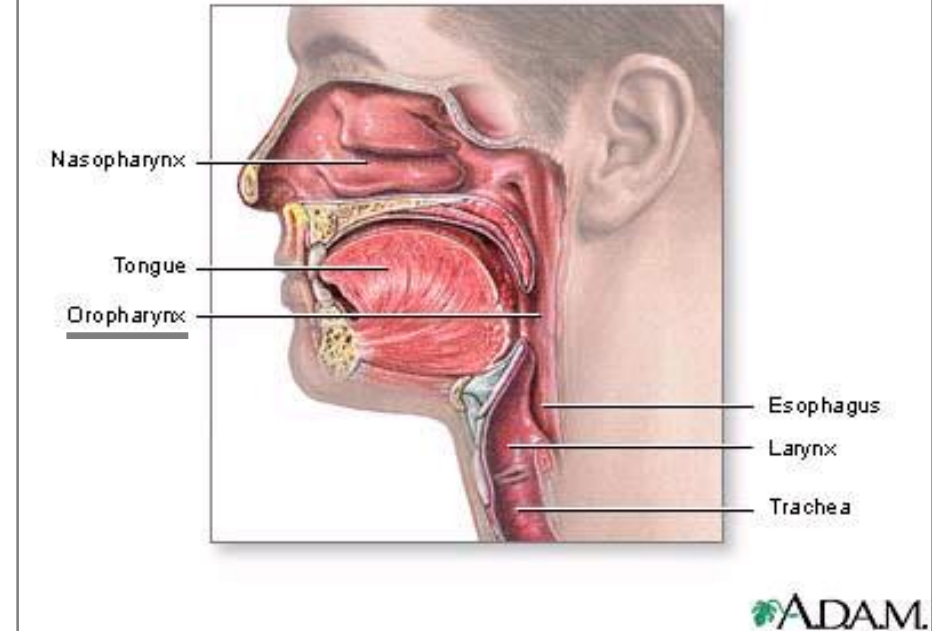
IAEA E-learning Program

Safety and Quality in Radiotherapy



Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT BACKGROUND



March 2005, somewhere in the state of New York, USA

A patient is due to be treated with IMRT for head and neck cancer (oropharynx).

Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 4 – 7, 2005 An IMRT plan is prepared: “1 Oropharyn”. A verification plan is created in the TPS and measurements by Portal Dosimetry (with an EPID*) confirms correctness.



***Electronic Portal Imaging Device (Picture: P.Munro)**

Safety and Quality in Radiotherapy

- Between March 4th and 7th, an intensity modulated radiation therapy (IMRT) treatment plan is prepared and named “1 Oropharynx”. A verification plan is created and the verification plan was used to confirm that the machine parameters are capable of producing the approved dose distribution in the patient at treatment.
- Measurements are done by Portal Dosimetry with an electronic portal imaging device (EPID). In this case, the electronic portal imaging device is irradiated and used as a dosimeter. The measured dose distribution is subsequently compared with the dose distribution calculated under verification irradiation conditions. This confirms the correctness.

Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

March 14, 2005

- Re-optimization work on “1B Oropharynx” starts on workstation 2 (WS2).
- Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved to the database.
- Final calculations are started, where MLC motion control points for IMRT are generated. Normal completion.

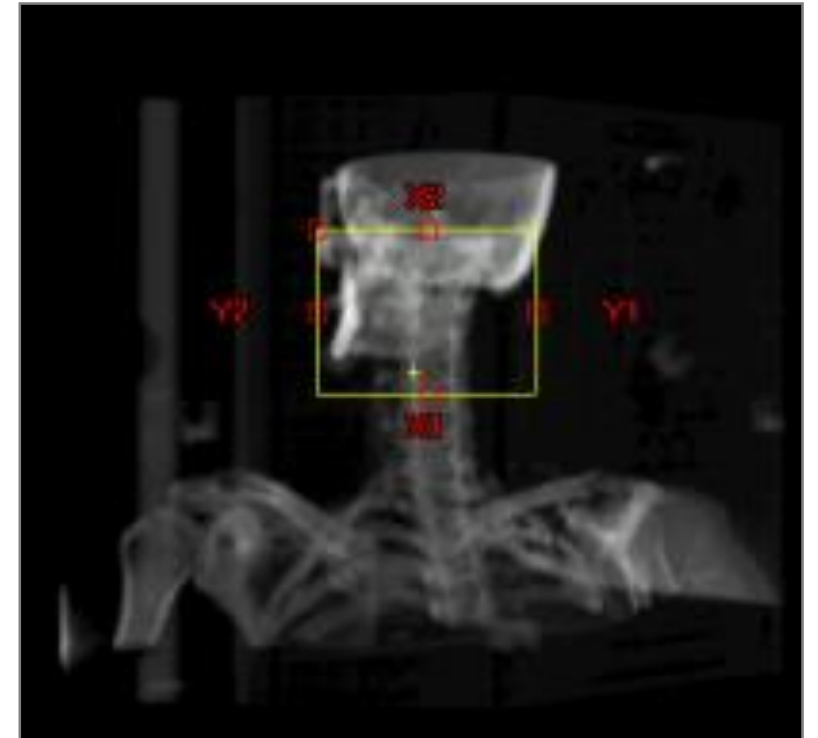


Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

March 14, 2005, 11 a.m.

- “Save all” is started. All new and modified data should be saved to the DB.
- In this process, data are sent to a holding area on the server, and not saved permanently until ALL data elements have been received.
- In this case, data to be saved included:
(1) actual fluence data, (2) the digitally reconstructed radiographs (DRR) and (3) the MLC control points.



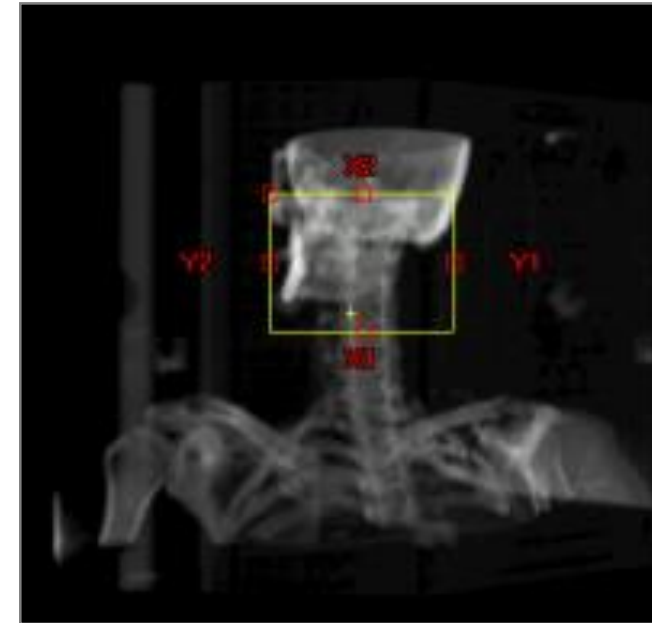
Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

March 14, 2005, 11 a.m.

The actual fluence data is saved normally.

- **Next in line is digitally reconstructed radiograph (DRR). The “Save all” process continues with this, but the “Save” process is not completed.**
- **Saving of MLC control point data would be after the DRRs have been saved.**
- **However, as the previous step, saving the DRRs, did not complete, the system does not save the MLC control points.**



Safety and Quality in Radiotherapy

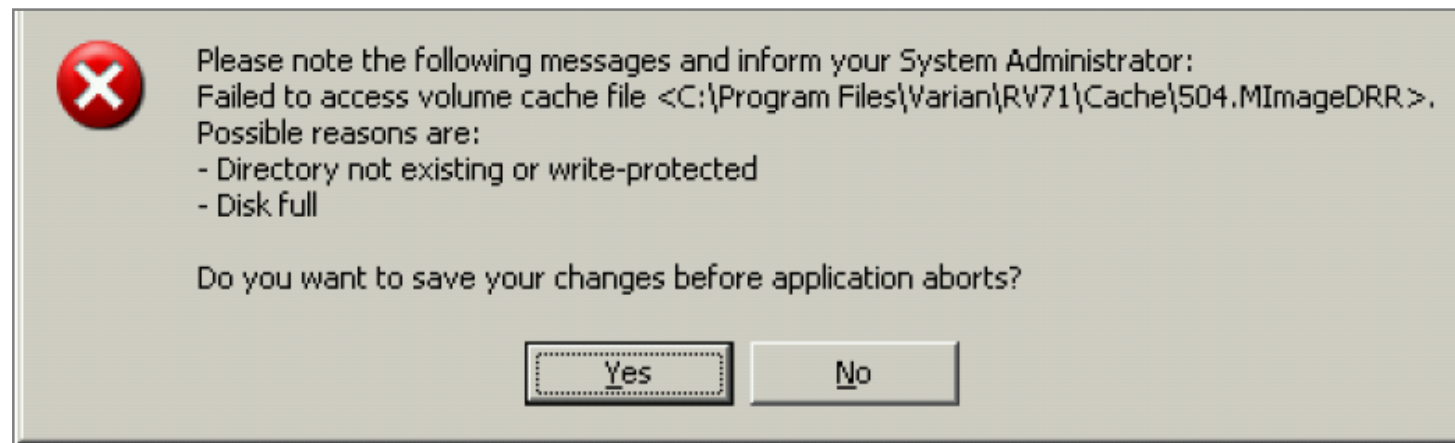
THE NEW YORK STATE INCIDENT

March 14, 2005, 11 a.m.

An error message is displayed.

The user presses “Yes”, which begins a second, separate, save transaction.

MLC control point data are moved to the holding area.



Safety and Quality in Radiotherapy

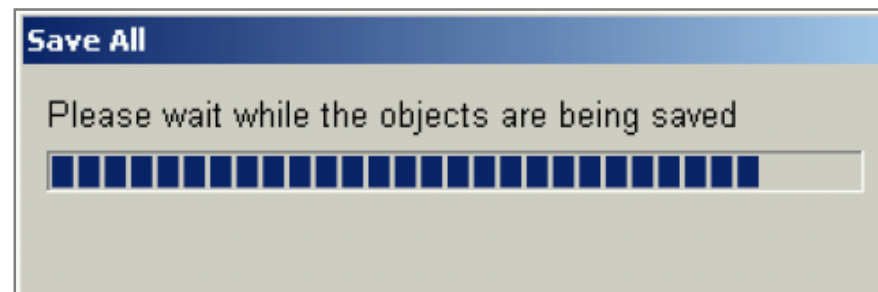
MODULE 2: MAJOR INCIDENTS IN RADIO THERAPY

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 11 a.m.

- **The DRR is, however, still locked into the faulty first attempt to save.**
- **This means the second save won't be able to complete.**
- **The software would have appeared to be frozen.**



Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 11 a.m.

- **The user then terminated the TPS software manually, probably with Ctrl-Alt-Del or Windows Task Manager**
- **At manual termination, the DB performs a “roll-back” to return the data in the holding area to its last known valid state.**
- **The treatment plan now contains (1) actual fluence data; (2) not the full DRR; and (3) no MLC control point data.**

CTRL - ALT - DEL

Safety and Quality in Radiotherapy

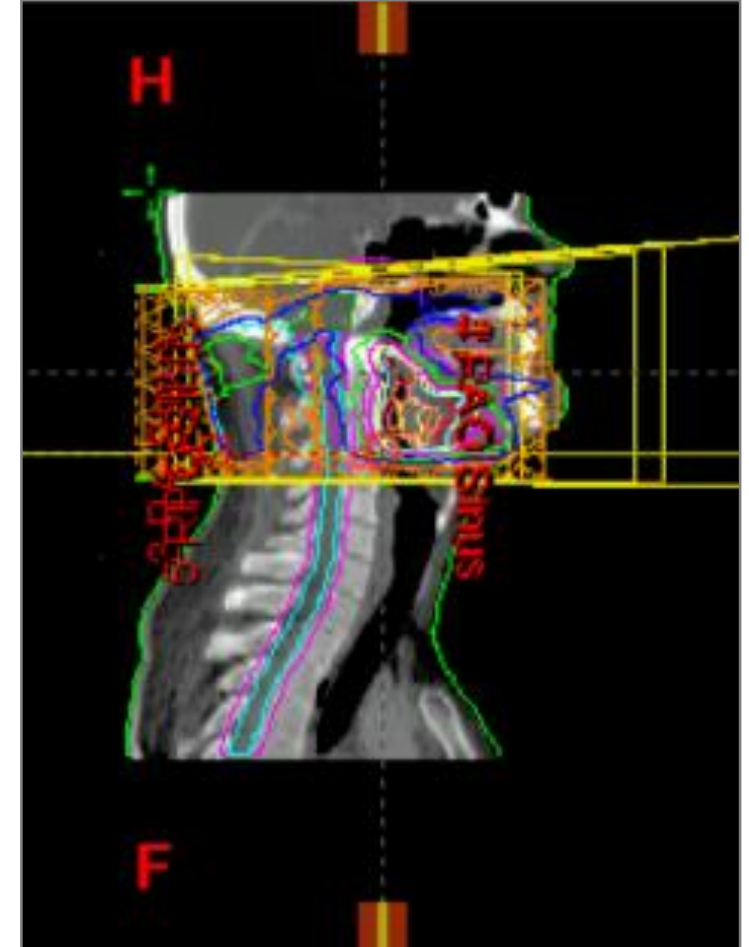
THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 11 a.m.

Within 12 s, another workstation, WS1, is used to open the patients plan. The planner would have seen this:

Valid fluences are already saved. The calculation of the dose distribution is now done by the planner and saved. MLC control point data are not required for calculation of dose distribution.



The sagittal view with field and dose distribution

Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 11 a.m.

No control point data are included in the plan. The plan should look like the one on the right



Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 11 a.m.

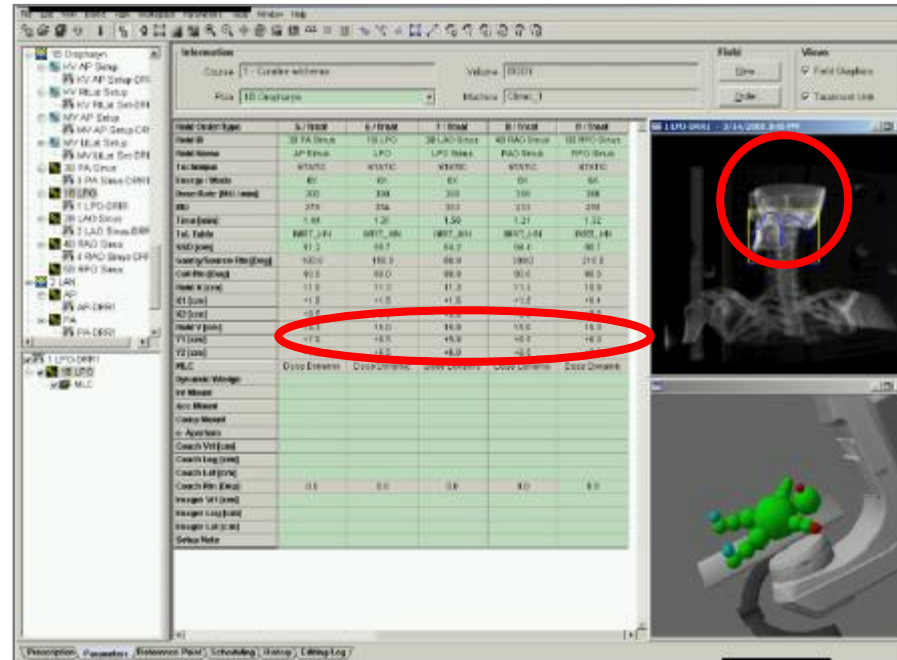
- **No verification plan is generated or used for checking purposes, prior to treatment (it should have been done according to clinic's QA programme)**
- **The plan is subsequently prepared for treatment (treatment scheduling, image scheduling, etc.) – after several computer crashes.**
- **The plan is also approved by a physician**
- **According to QA programme, a second physicist should then have reviewed the plan, including an overview of the irradiated area outline, and the MLC shape used.**

Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

Should have been seen on verification:



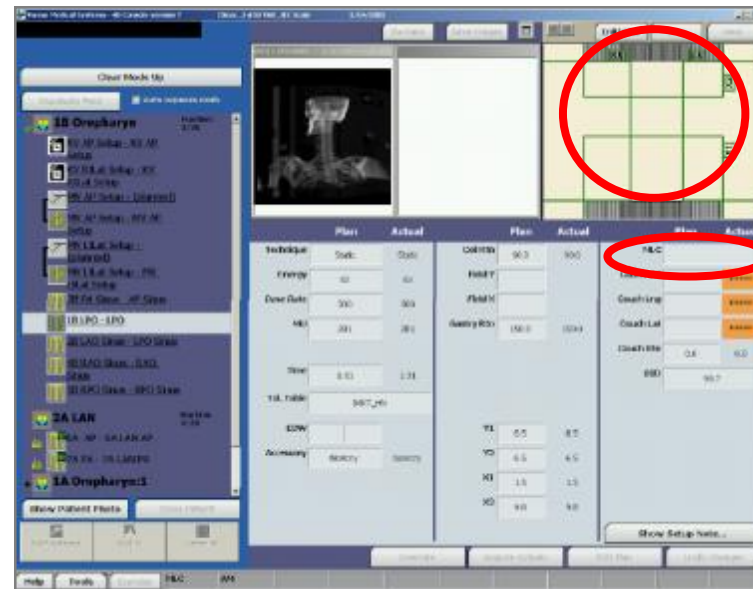
Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT

WHAT HAPPENED?

March 14, 2005, 1 p.m.

The patient is treated. The console screen would have indicated that MLC is not being used during treatment:



Safety and Quality in Radiotherapy

THE NEW YORK STATE INCIDENT DISCOVERY OF ACCIDENT

March 15-16, 2005

- The patient is treated without the MLC for three fractions
- On March 16, a verification plan is created and run on the treatment machine. The operator notices the absence of the MLC.
- A second verification plan is created and run with the same result.
- The patient plan is loaded and run, with the same result.

Impact of accident:

The patient received 13 Gy per fraction for three fractions, i.e. 39 Gy in 3 fractions. The Patient subsequently died from his injuries.

Safety and Quality in Radiotherapy

The New York State incident : **SUMMARY**

1. Oropharynx patient was planned with IMRT.
2. 1st four fractions were delivered correctly.
3. Original plan was copied and modified appropriately.
4. During the “Save” operation, the computer crashed.
5. The fluence distribution, but not the complete DRR and no MLC control points were saved.
6. The absence of the MLC icon and confirmation of MLC activation were not noticed at the treatment console.
7. QA of the modified plan was not performed until three fractions had been delivered.

The patient received 13 Gy per fraction for three fractions, i.e. **39 Gy in 3 fractions.**, and died from his injuries

Accident in EPINAL, France

- **Use of Dynamic (soft) Wedges for treatment**
- **Actual plan was made with physical (hard) wedges**

Safety and Quality in Radiotherapy

THE EPINAL INCIDENT

BACKGROUND

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.**
- **In a country of few Medical Physicists (MP), this facility had a single MP who was also on call in another clinic.**



Safety and Quality in Radiotherapy

SUMMARY

- 1. The clinic decided to implement the use of dynamic (soft) wedges.**
- 2. Treatment planners were given very limited training on planning with dynamic wedges.**
- 3. The treatment planning system manual was in a non-native language.**
- 4. The only medical physicist on staff was also on call for another clinic.**
- 5. Monitor units were calculated for plans developed using (mistakenly) hard (physical) wedges.**
- 6. Treatments were delivered with dynamic wedges.**
- 7. As the monitor units for a hard wedged beam are typically considerably higher than those for a dynamically wedged beam for the same dose, the patients involved received excessive doses.**

At least 23 patients received an overdose (20% or more than the intended dose).

Safety and Quality in Radiotherapy

THE EPINAL INCIDENT

FOLLOWING THE INCIDENT

- 7 patients were informed during the last quarter of 2005.
- 16 other patients were (wrongly) considered not to be affected. Of these ...
 - 3 were informed by a doctor other than their radiotherapist
 - 1 learnt from a third party person
 - 1 learnt from the press
 - 1 learnt by overhearing a doctor speaking to a colleague
 - 4 were informed by management 2 days before press release
 - 1 died before being informed



Safety and Quality in Radiotherapy

THE EPINAL INCIDENT

CONSEQUENCES FOR INVOLVED STAFF

- Besides the misadministrations themselves, failure to disclose was considered a serious offence.
- 2 oncologists were sentenced in January 2013 to 4 years imprisonment and a 20,000 EUR fine each.
- The physicist was sentenced to 3 years imprisonment and a 10,000 EUR fine.
- As of April 2015, all sentences were under appeal.



Recordable events and Misadministration

Radiation Therapy and Therapeutic Nuclear Medicine

Recordable Events

Nuclear Medicine	Administered dosage differs from prescribed by 10% or more
External Beam Radiotherapy	Weekly calculated delivered dose 15% > weekly prescribed dose
Brachytherapy	Calculated delivered dose differs from prescribed dose by more than 10%

Misadministration

(External Beam Therapy)

External beam therapy where total delivered dose differs from total prescribed dose by more than 20%

Misadministration

(Brachytherapy)

- **Brachytherapy to wrong patient**
- **Brachytherapy to wrong site**
- **Brachytherapy with leaking sealed source**

Misadministration (Brachytherapy)

- **Brachytherapy with temporary implant for which one or more sources have not been removed after completion of treatment**
- **Brachytherapy for which the calculated administered dose differs from the prescribed dose by more than 20%**

Misadministration (Therapeutic Nuclear Medicine)

- **Therapeutic Radiopharmaceutical given to the wrong patient**
- **Administration of wrong radiopharmaceutical**
- **Wrong route of administration**
- **Administered therapeutic dose of radiopharmaceutical differing by more than 20% compared from the prescribed**

Misadministration in Diagnostic Radiology and Nuclear Medicine

- **Study performed on wrong patient**
- **Wrong route of administration**
- **Administration of wrong radionuclide and the delivered dose is more than 0.05 Sv whole body or more than 0.5 Sv to individual organ**

Reported Radiation Burn: Case 1



Thank you

