Major accidents…

…in radiotherapy related to treatment planning

Overview

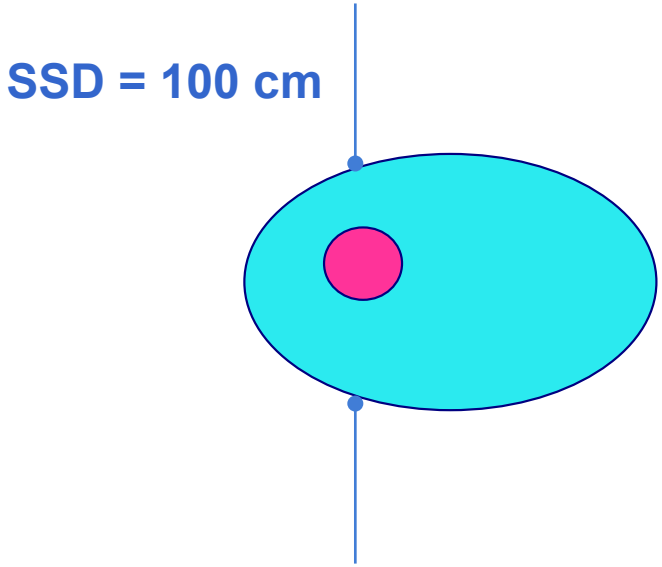
- 2 historic examples of major accidents related to treatment planning
- 3 newer examples of major accidents related to treatment planning
- “Lessons to learn” from all examples

1st historic example:

Erroneous use of TPS (UK - 1982)

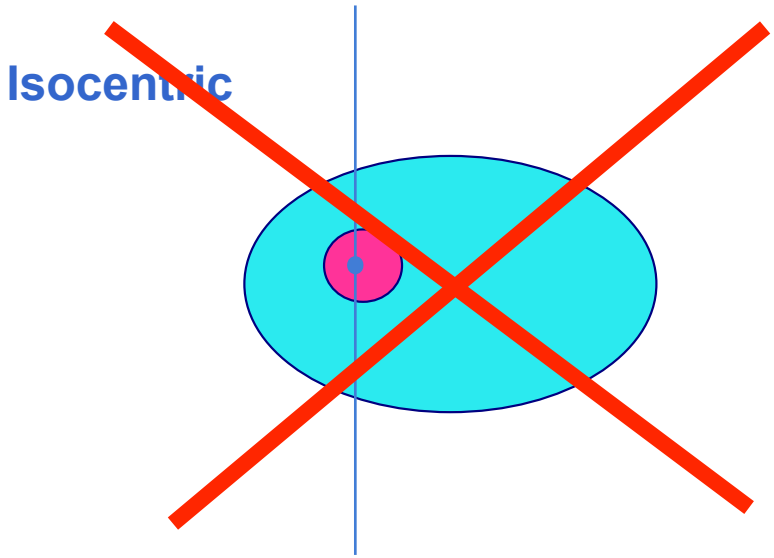
Background

- Until 1982, a hospital relied on manual calculations for the correct dose to be delivered to the tumour
- Treatments were generally performed at standard SSD (100 cm)



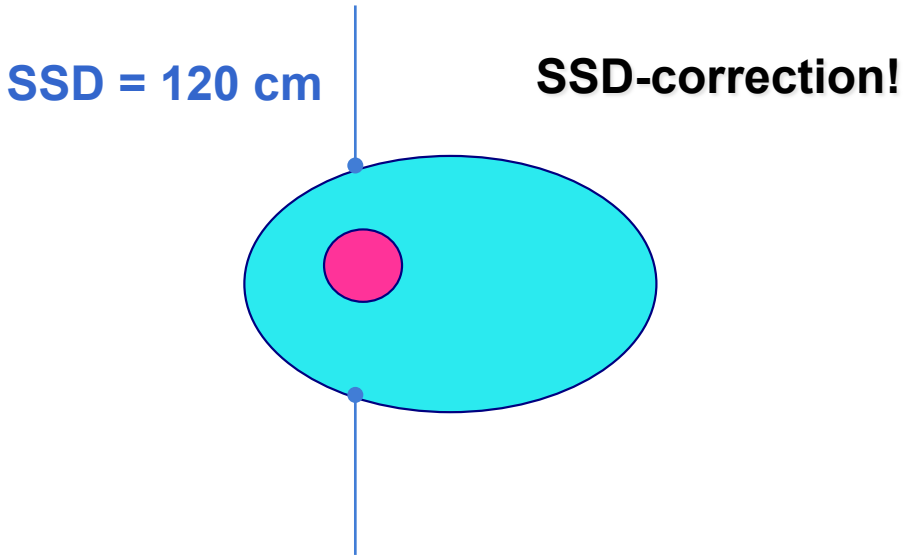
Background

- Isocentric treatments were rarely given in the hospital, because calculations were cumbersome



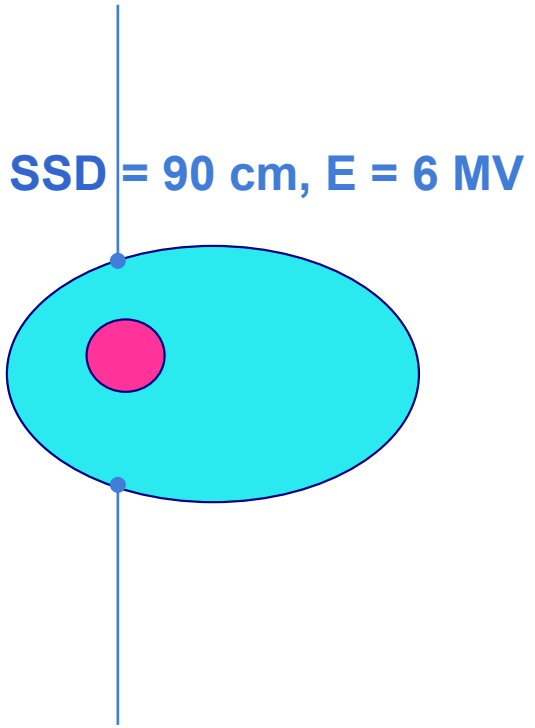
Background

- Some non-standard SSD treatments were performed. SSD-correction was then applied.



Calculation procedure

- A non-written procedure was in effect for treatments at non-standard SSD (including the few isocentric treatments). RTs calculated a correction factor based on the actual SSD used.



Example:

$((100+d_{max}) / (90+d_{max}))^2$
$(101.5 / 91.5)^2 = 1.23$

(Indicating that the dose rate at the shorter distance is 23% greater than at 100 cm SSD)

TPS installation 1982

- A computerized treatment planning system was acquired in 1981, and after some preliminary testing brought into clinical use in autumn of 1982

- Partly because TPS simplified the calculation procedures, the hospital began treating with isocentric techniques more frequently

First isocentric plan from TPS

- When the first isocentric TPS plan was ready and presented to the planning RTs, the following happened:
  - It was assumed by the RTs that correction factors for non-standard SSD should be applied
  - Hospital physicists approved this procedure

First isocentric plan from TPS

- It was not recognized that the TPS already correctly applied an inverse-square correction for isocentric treatments!

Subsequent isocentric plans

- The RTs continued to apply the distance correction factor to all subsequent calculations
- Consequently, distance correction factor was applied twice for all patients treated isocentrically, or at non-standard SSD
- This error caused patients to receive doses lower than prescribed

Discovery of error

- In 1991 a new computer planning system was installed and a discrepancy was discovered between the new plans and those from the previous system

- Further investigation revealed that the original TPS already contained within it the correction for calculations at non-standard SSD.
  - Systematically reapplying the correction factor resulted in underdosage

Investigation of error

- A formal investigation was initiated
- The incorrect procedures were in place until 1991, or for approximately nine years
- During the 9-year period, 6% of patients treated in the department were treated with isocentric technique; for many of these patients it formed only part of their treatment

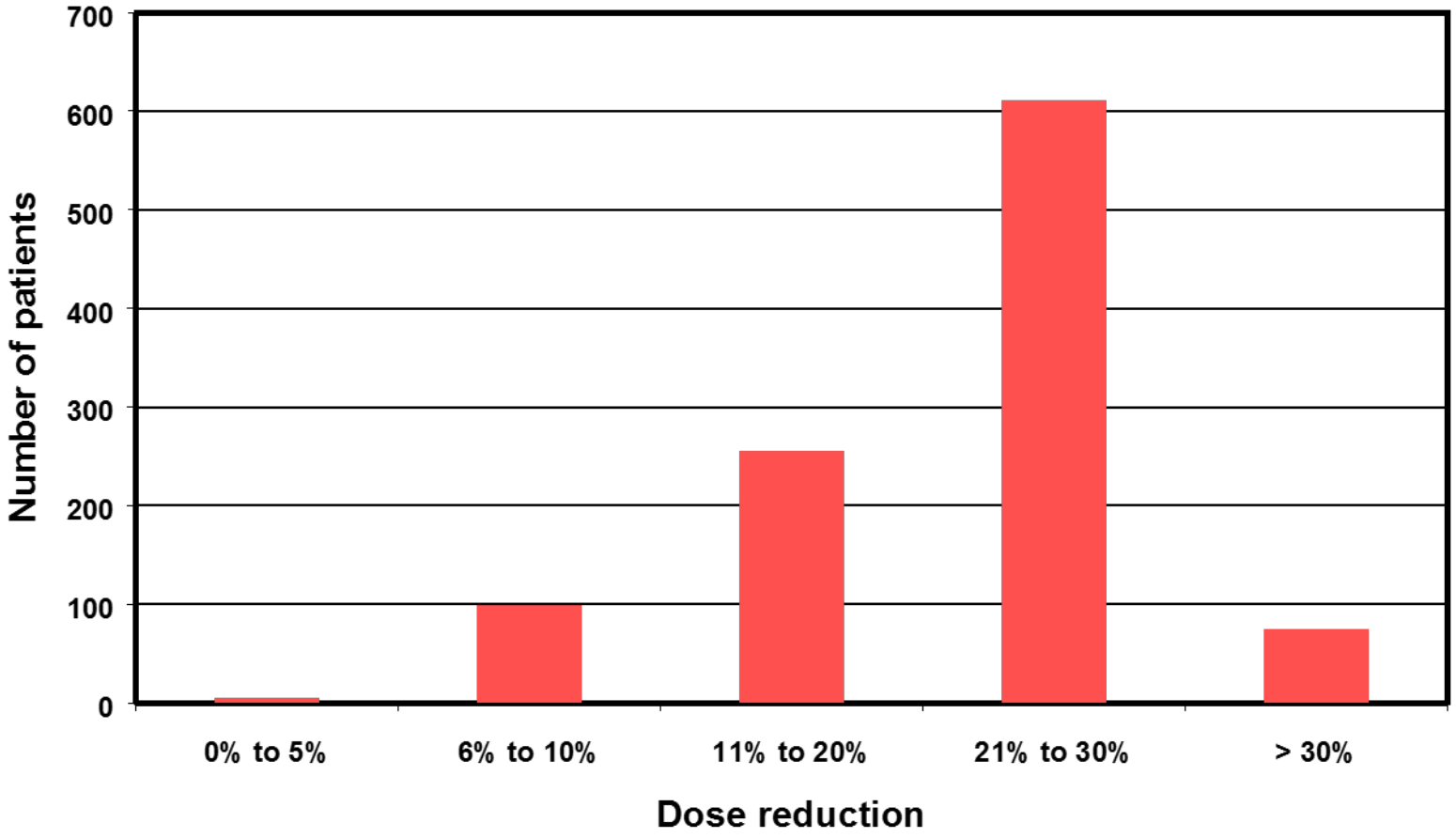
Evaluation of error

- All patients receiving isocentric treatment (performed on two linear accelerators) between Autumn 1982 and December 1991 were identified

- Evaluation by Ash and Bates showed that of 1045 patients whose calculations were affected by the incorrect procedures, 492 developed local recurrences that could be attributed to the error

- Underdose varied between 5% and 35%

Dose reduction distribution for patients



Lessons to learn

- Ensure that staff are properly trained in the operation of the equipment
- Ensure that staff understand the operating procedures
- Include in the Quality Assurance Programme:
  - Procedures to perform complete commissioning of treatment planning equipment before first use
  - Procedures for independent checking of patient treatment time calculations

Reference

- Ash D, Bates T. Report on the clinical effects of inadvertent radiation underdosage in 1045 patients. Clin Oncol 6: 214-225 (1994)

2nd historic example:

Error in TPS data entry
(Panama - 2000)

Background

- Year 2000, the radiation therapy department of ION was divided between two different hospitals and a total of 1100 patients received radiotherapy.
  - Justo Arosemena hospital
    (External beam therapy)
  - Gorgas hospital
    (Brachytherapy and hospitalization of in-patients)

Background

- Factors influencing workload in Justo Arosemena hospital:
  - 70 to 80 patients treated per day on single cobalt unit
  - Many of these patients treated during the evening with only a single therapist present
  - Team divided between two sites
  - Multiple fields (SSD set-up technique) with beam modifying devices (blocks and wedges) utilised

Treatment planning

- The treatment planning system (TPS) at ION:
  - Multidata RTD/2
  - Version 2.11
  - System installed in 1993. Beam data for Co-60 entered and verified at this stage.
  - This is a 2D TPS. It allows shielding blocks to be entered and taken into account when calculating treatment time and dose distribution.

Treatment planning

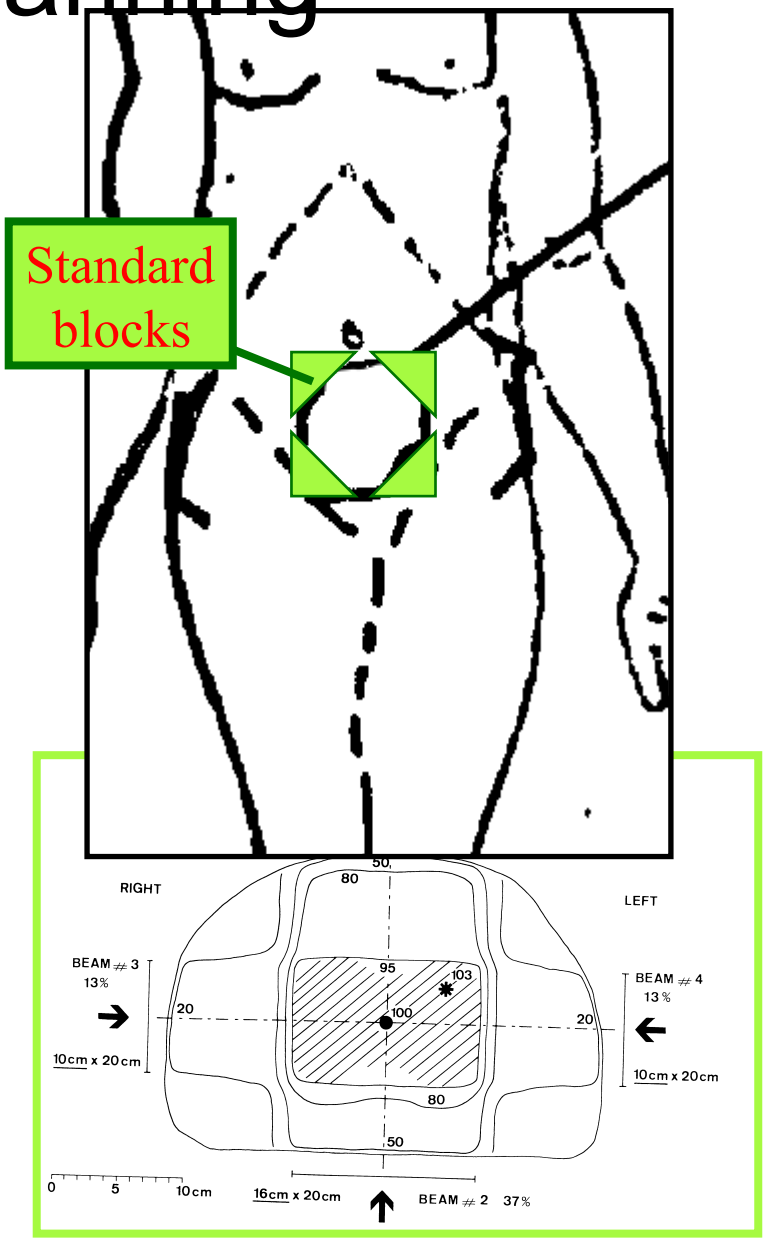
- Two of the modules in the Multidata TPS:
  - "Dose chart calculator" for calculation of treatment time to a given point
  - "External beam" for calculation of treatment time to a given point *AND* calculation of isodoses

Treatment planning

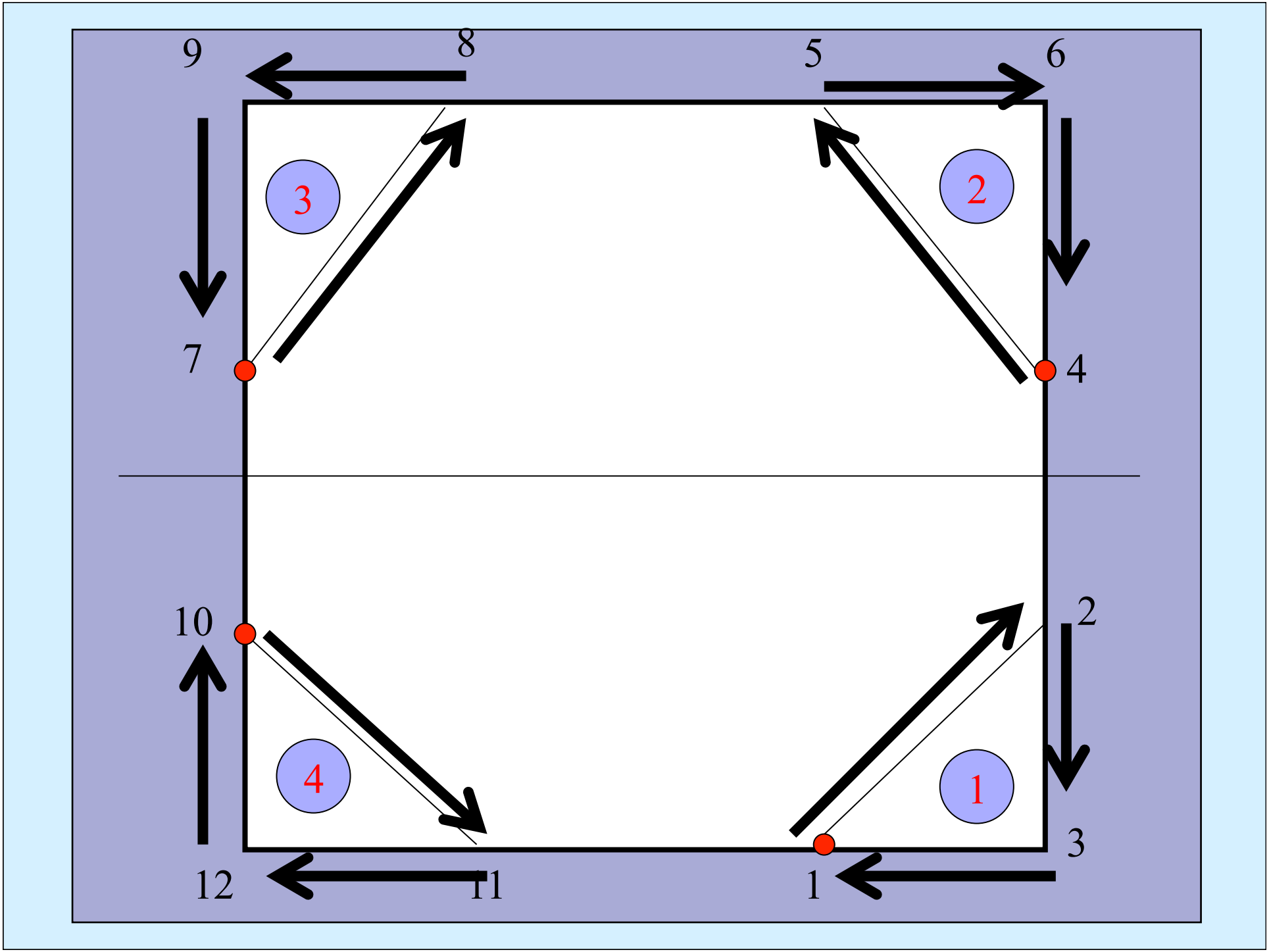
- Restriction of the treatment planning system:
  - Maximum 4 blocks can be digitized for a field in the “External beam” module.
  - In the “Dose chart calculator” module, there no such restriction.

Treatment planning

- Treatments in the pelvic region were performed using “the box technique”.
- Up to four blocks per field were often used for these fields.



Entering four shielding blocks correctly


9
8
5
6
3
2
7
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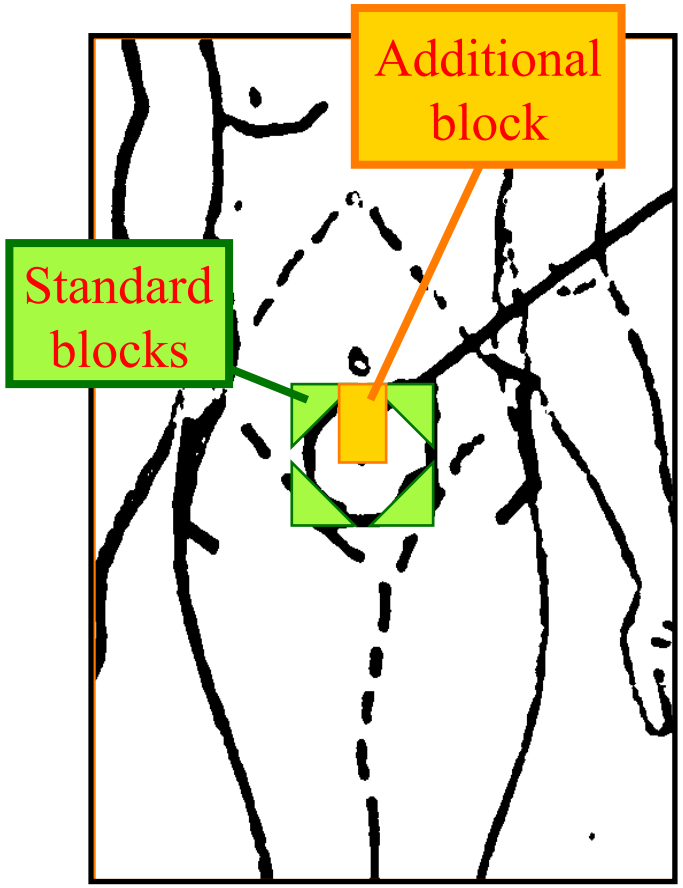
2
4
1
3
12
11
1

Treatment planning

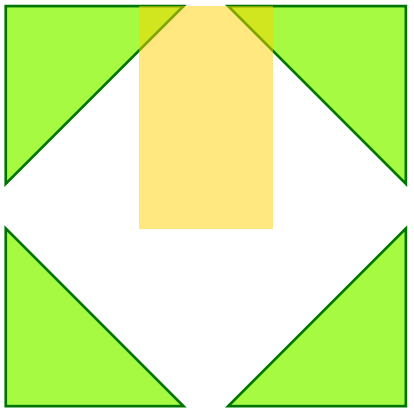
- In April 2000 one of the oncologists required one additional block for some treatments in the pelvic region
- Since no isodoses were requested for these cases, the “Dose chart calculator” module was used. This allows for more than four blocks.



- Treatment time was correctly calculated.

Treatment planning

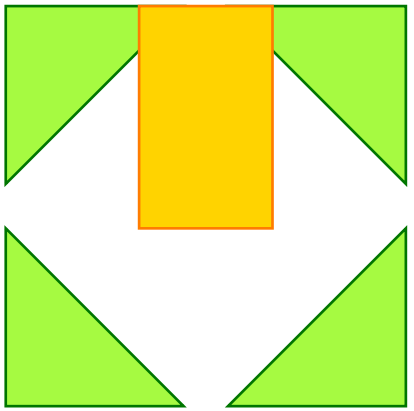
- One of the oncologists started to request isodoses for these patients with five blocks.
- The “External beam” module had to be used for this. Because of the four block limitation, initially four or less blocks were digitized.



- Treatment time was slightly incorrect due to this. The effect was understood.

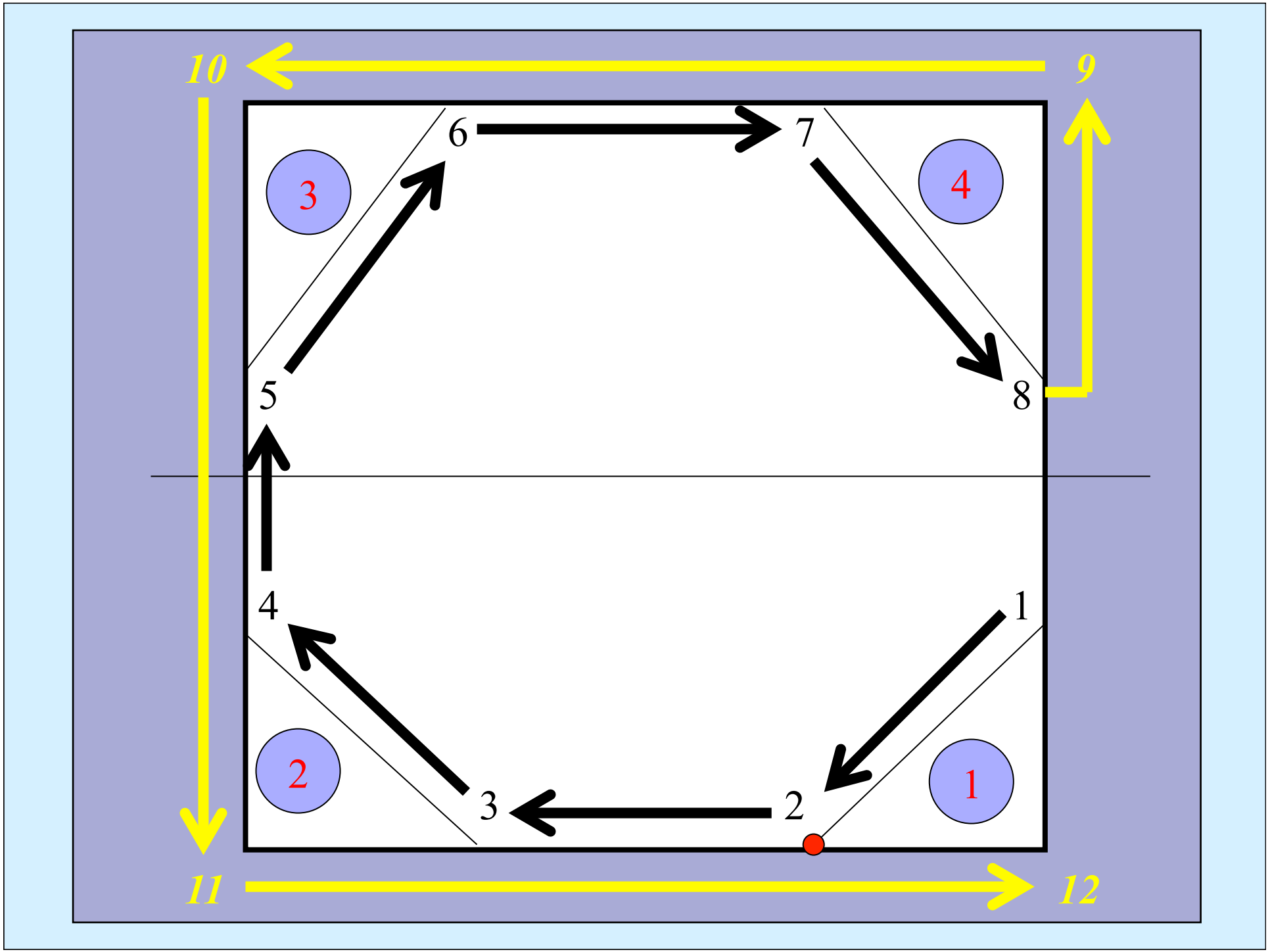
Treatment planning

- Staff came up with an approach to enter multiple blocks simultaneously.
- This approach was used for fields with four or more blocks. Even though the method was incorrect, the TPS was essentially able to handle this method.



- Treatment time was essentially correctly calculated.

Entering several blocks as one - “homemade” method 1


10
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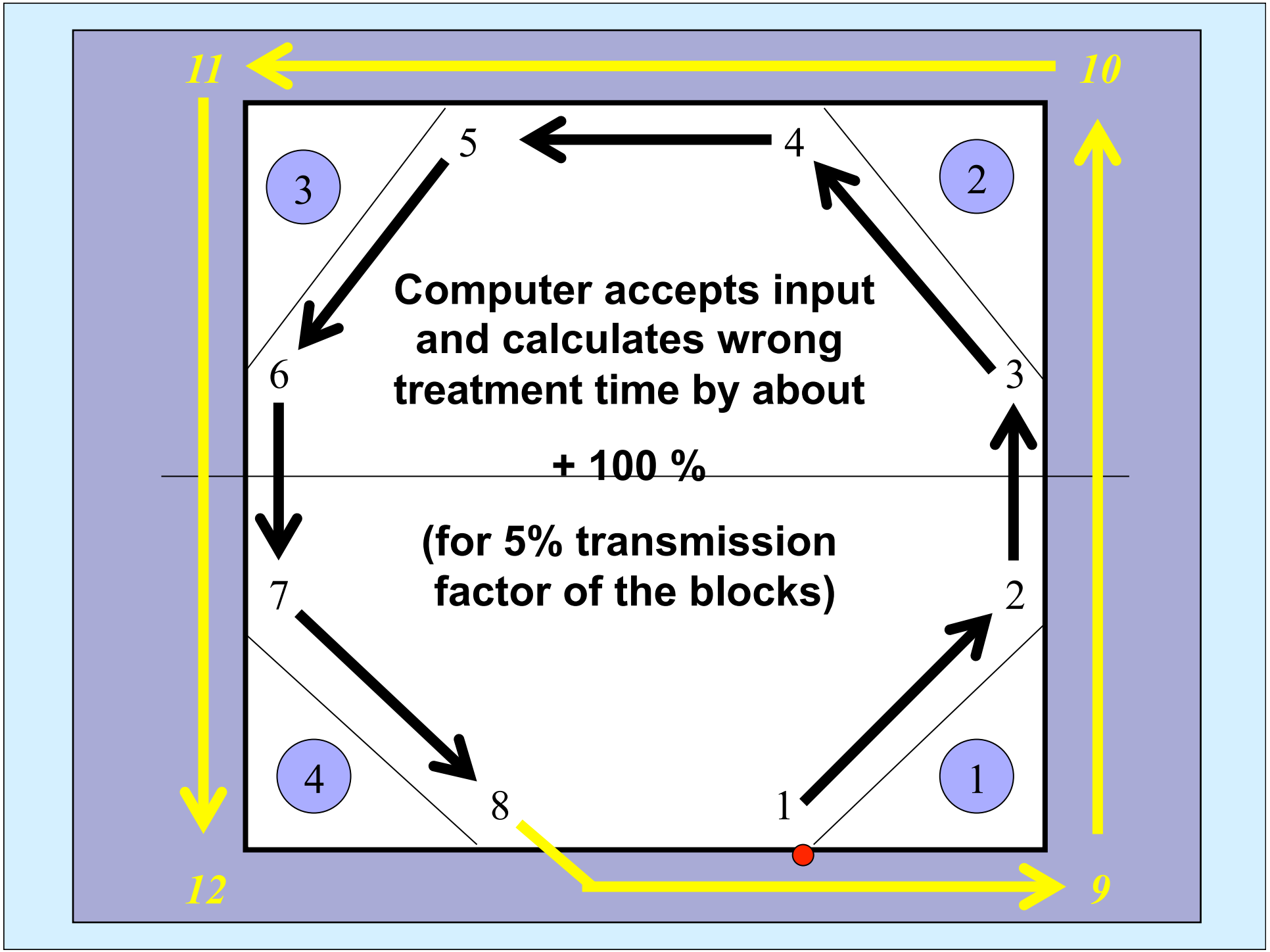
12

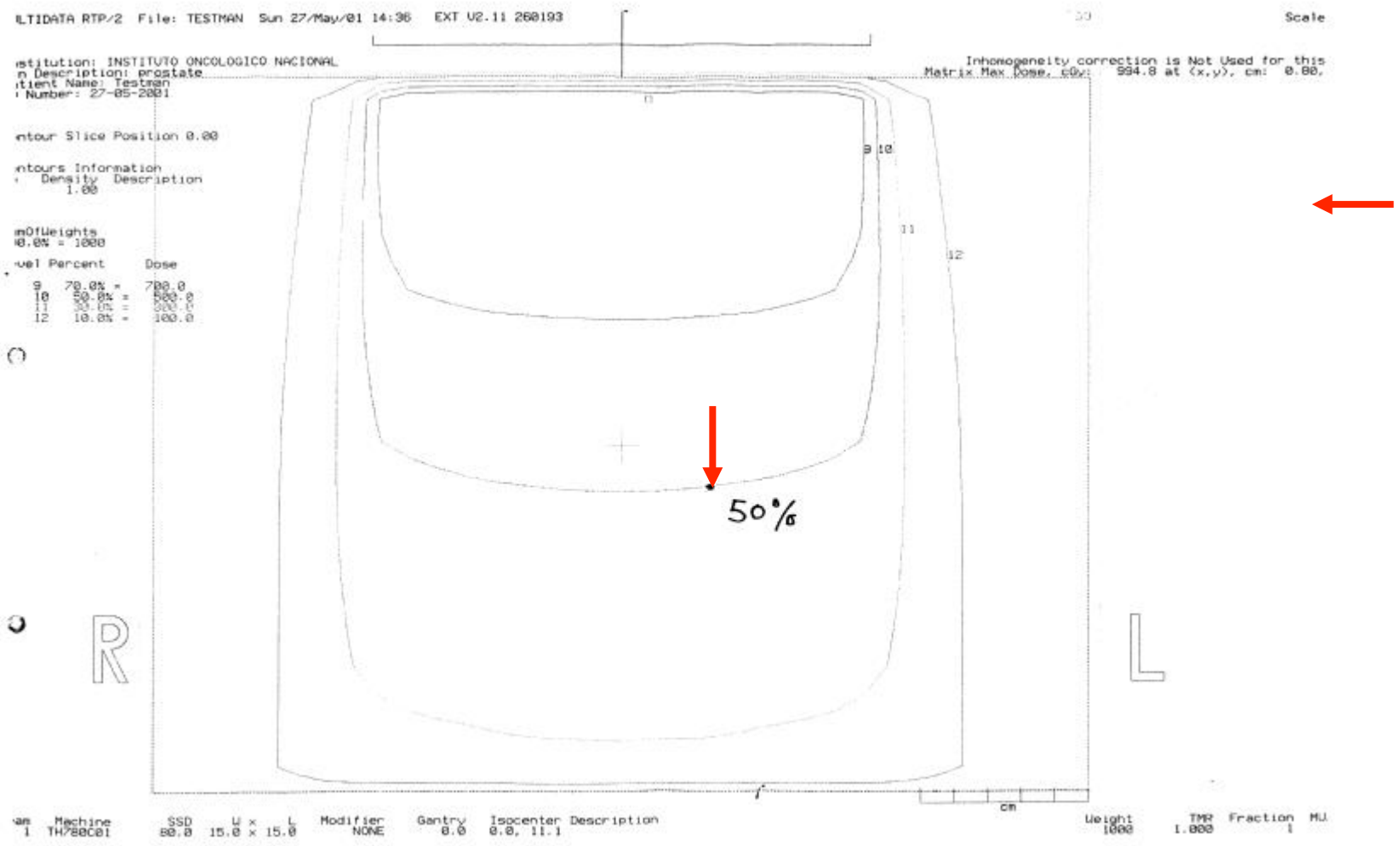
Variation to new approach

- This worked well, but, as the procedure was not written…
- …another physicist entered the data in a similar but slightly different way.
- This variation causes wrong isodoses and the wrong treatment time.

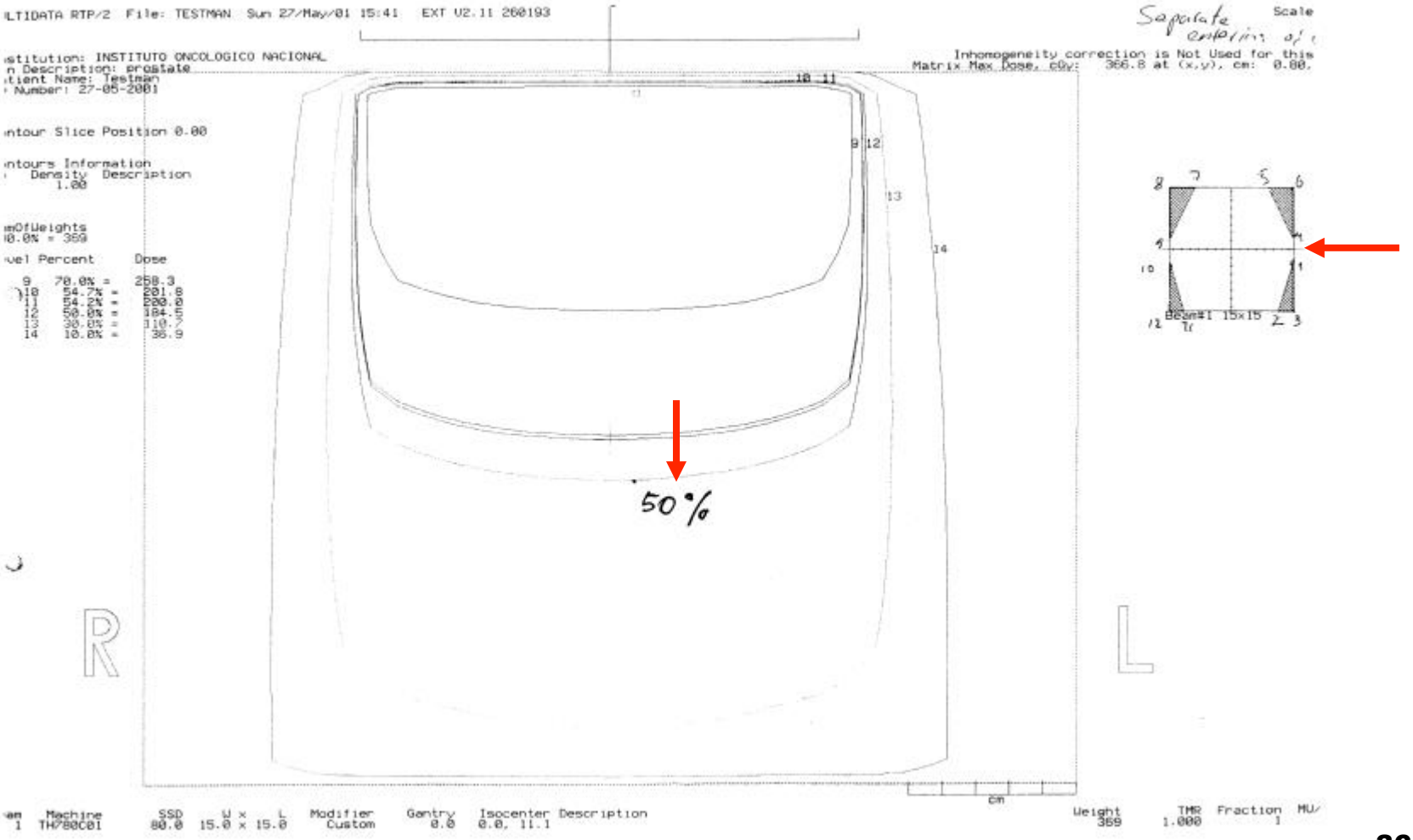
Entering several blocks as one - “homemade” method 2


11
10
5
4
3
2
Computer accepts input
and calculates wrong
treatment time by about
6
3
+ 100 %
(for 5% transmission
factor of the blocks)
7
2
4
8
1
1
12
9

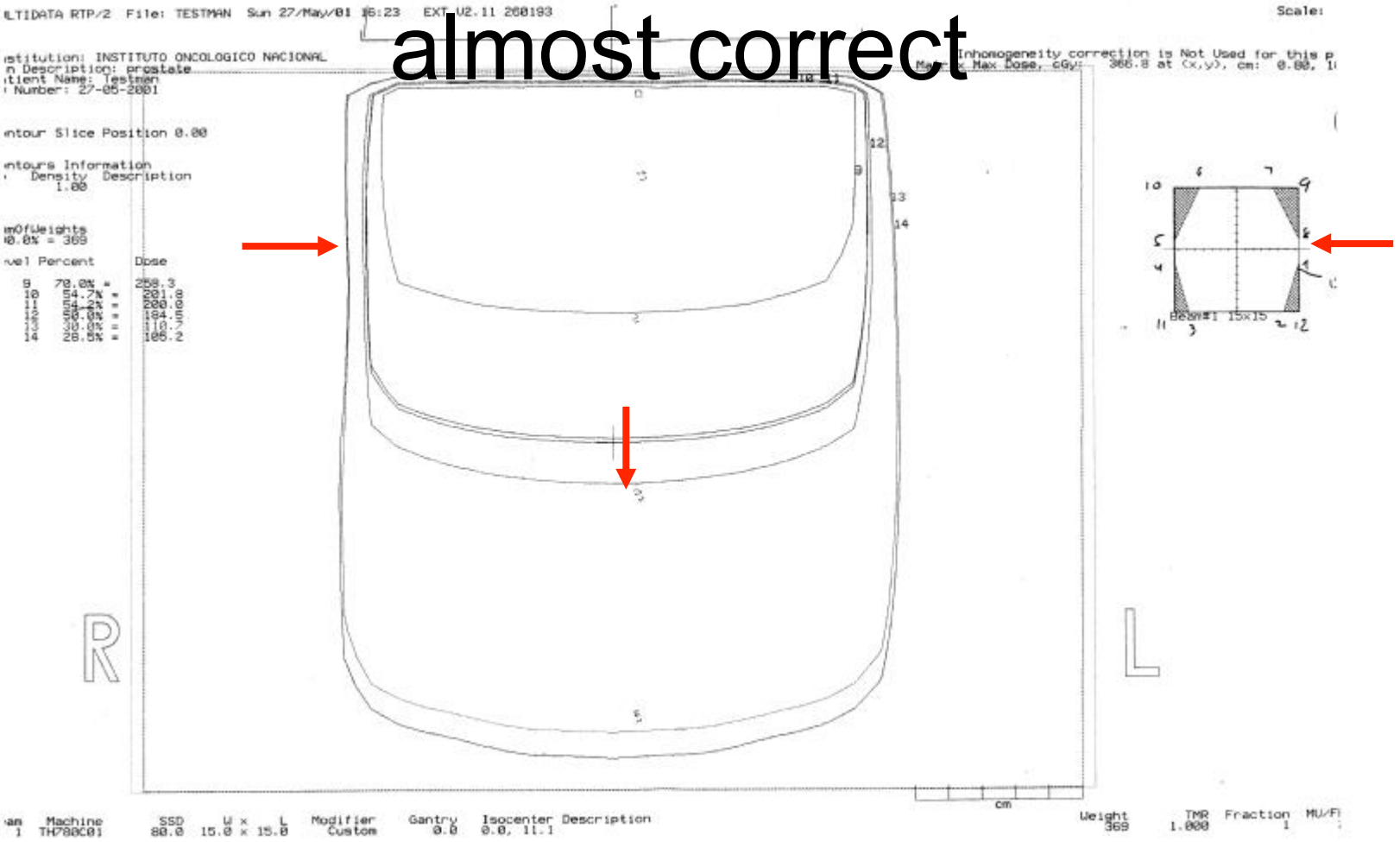
Open field, no icon shown



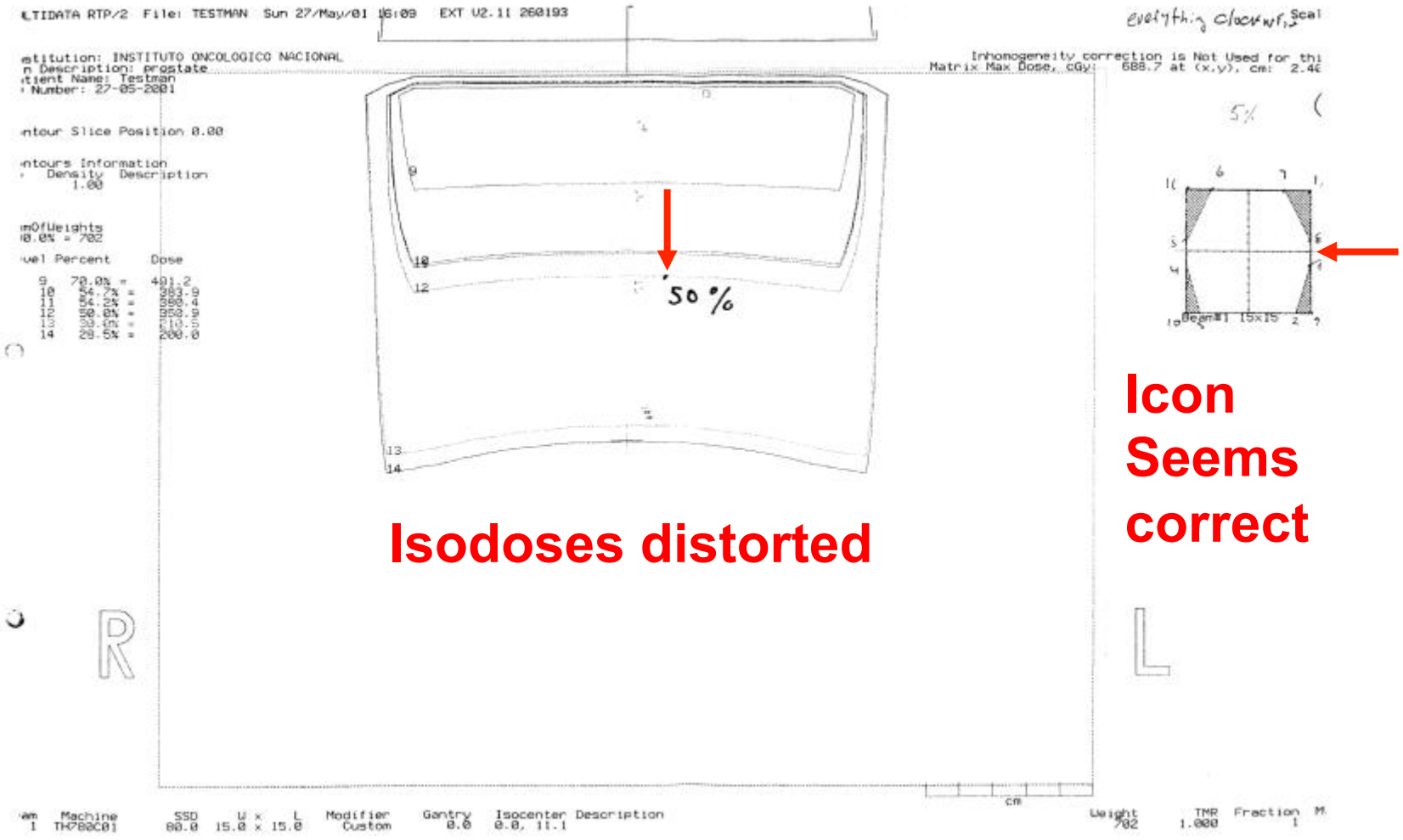
Four blocks, correct entry, an icon is shown with the blocks



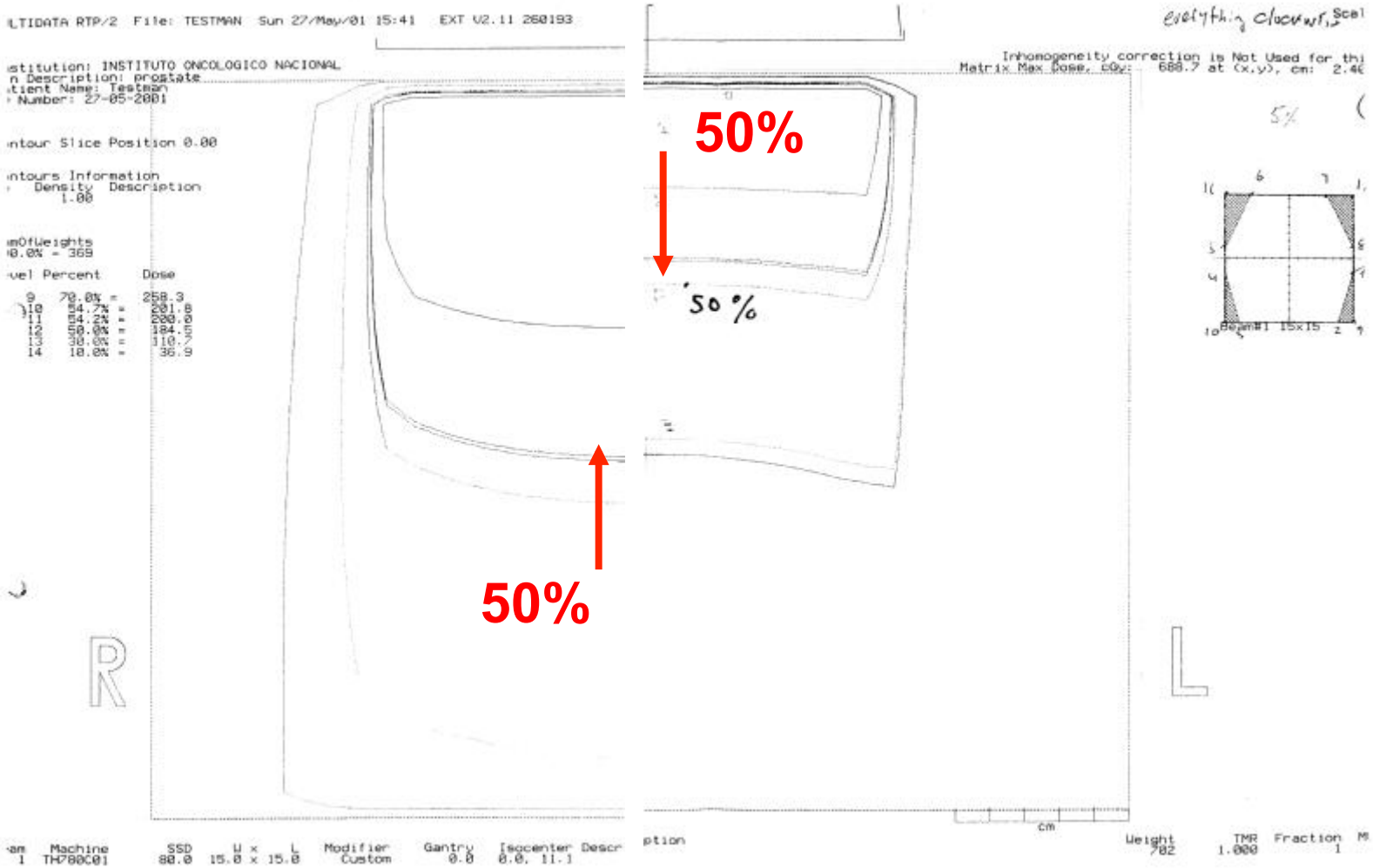
Blocked field: blocks entered as one block, first variation, isodose almost correct



Isodose for single field, Incorrect block entry; second variation



Comparison of isodoses

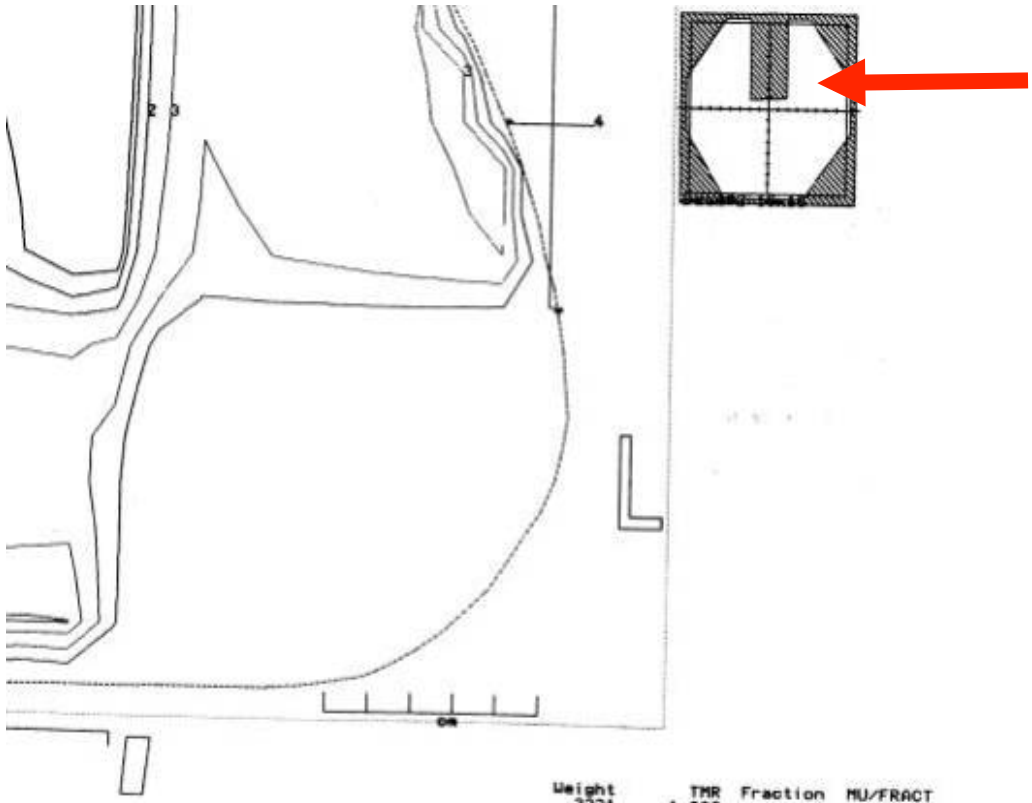


Coordinates for each block entered separately

Coordinates entered as a single block (second var.)

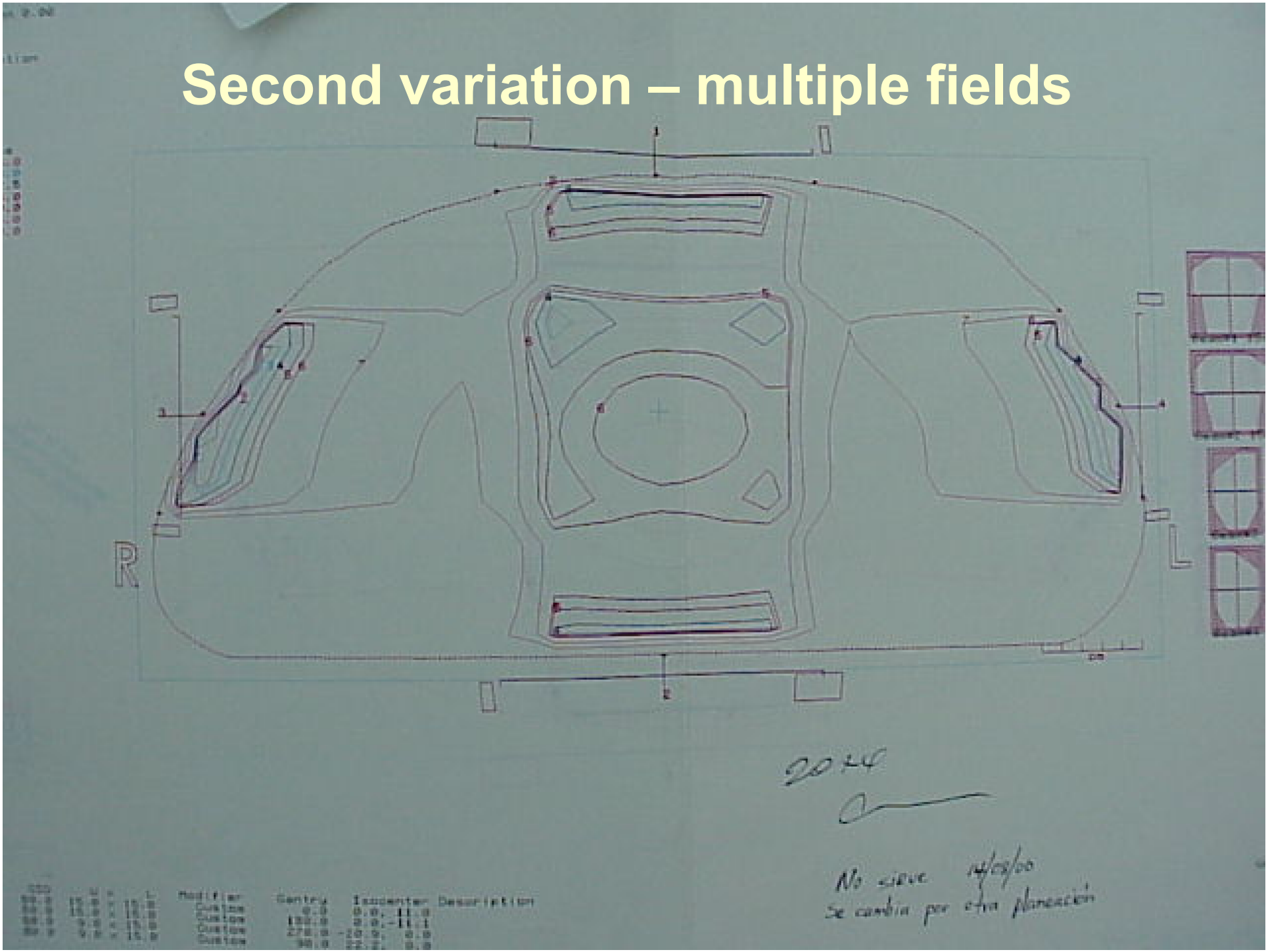
Second variation – multiple fields

- The distortion is not so obvious for a four field treatment.

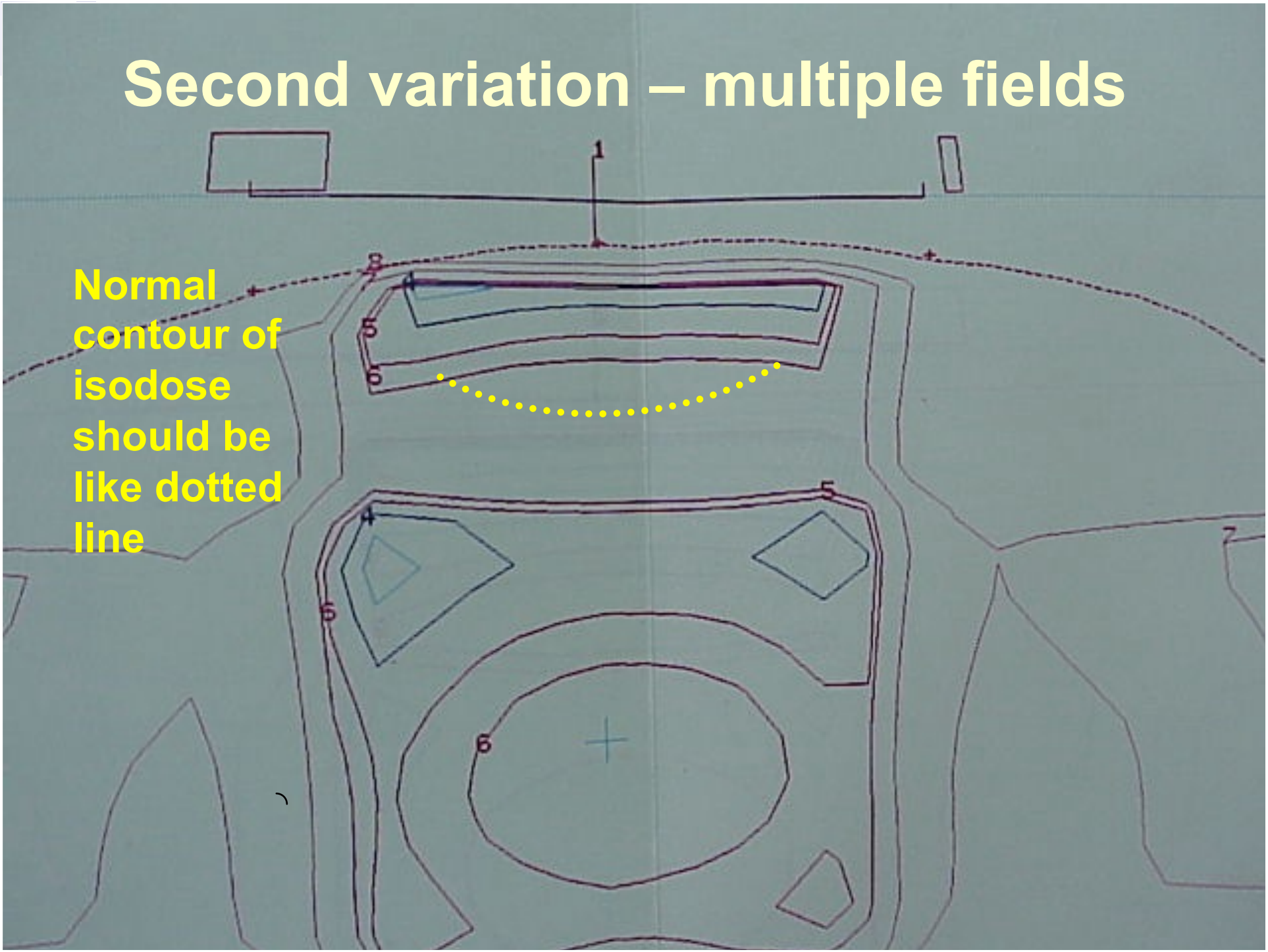


- **The icon does not indicate that the TPS is incorrectly used**
- **Calculated treatment time approximately TWICE AS LONG AS INTENDED**

Second variation – multiple fields

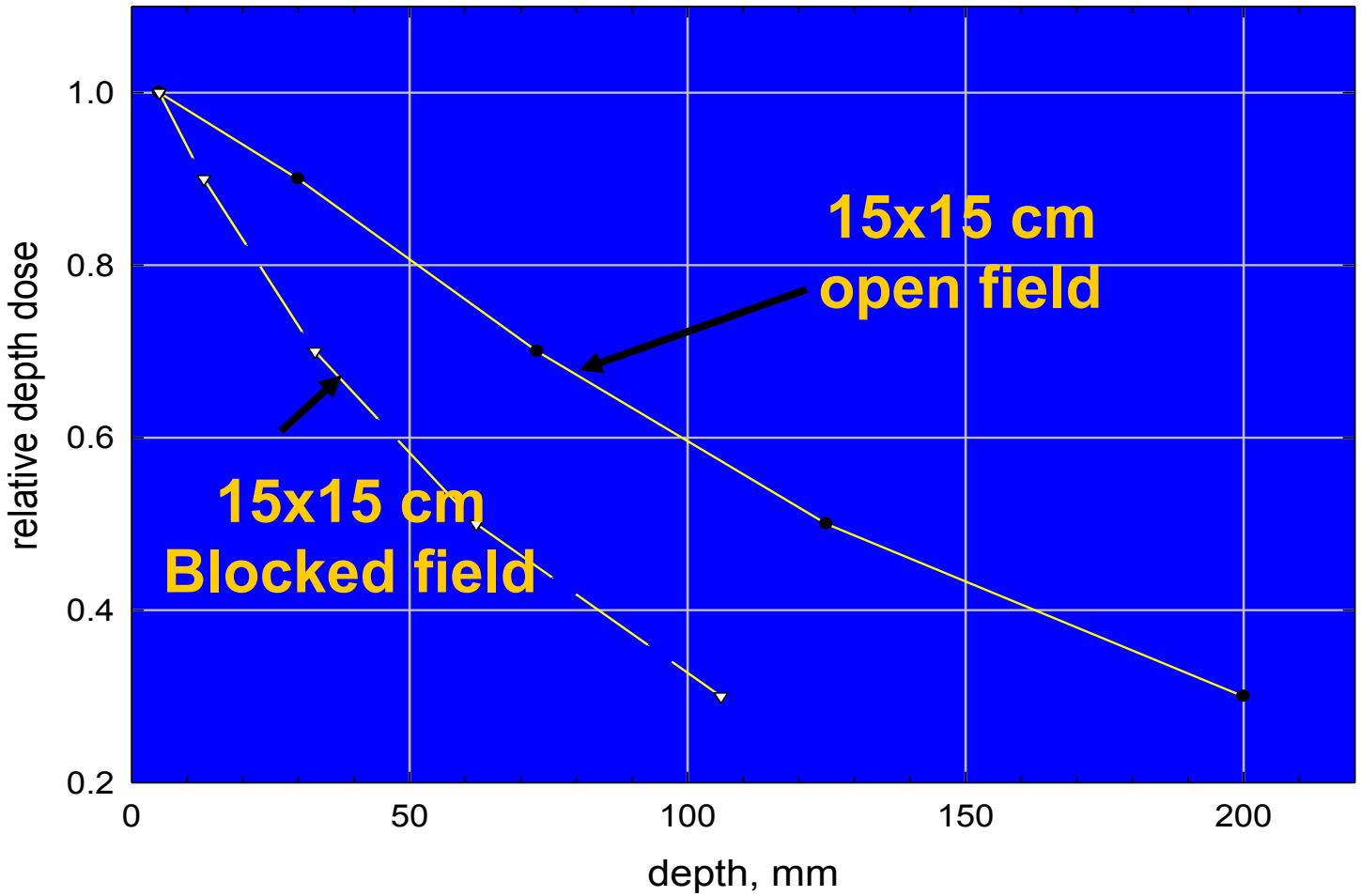


Second variation – multiple fields



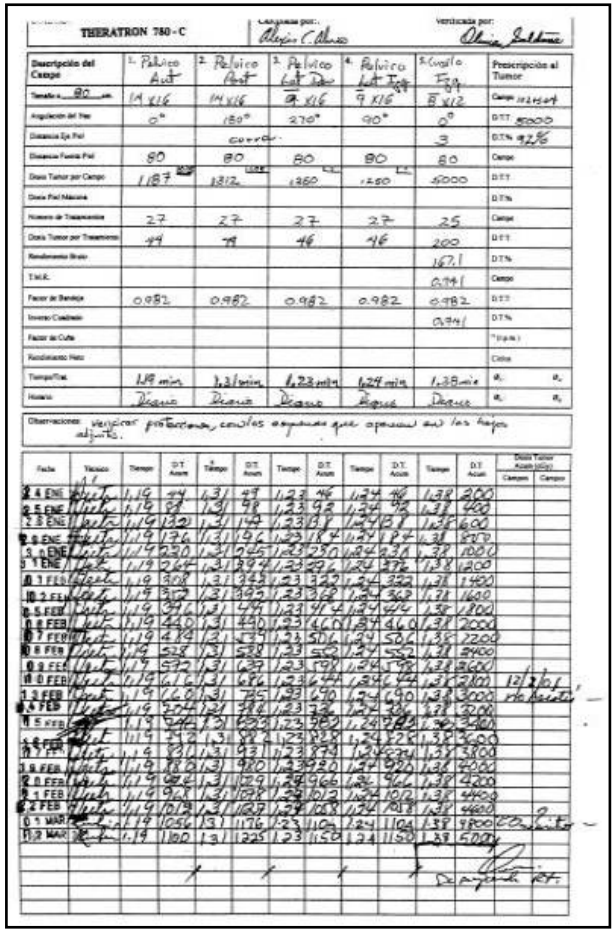
Depth dose falls faster than real, in the case of wrong data entry

TPS calculated central axis depth dose distributions



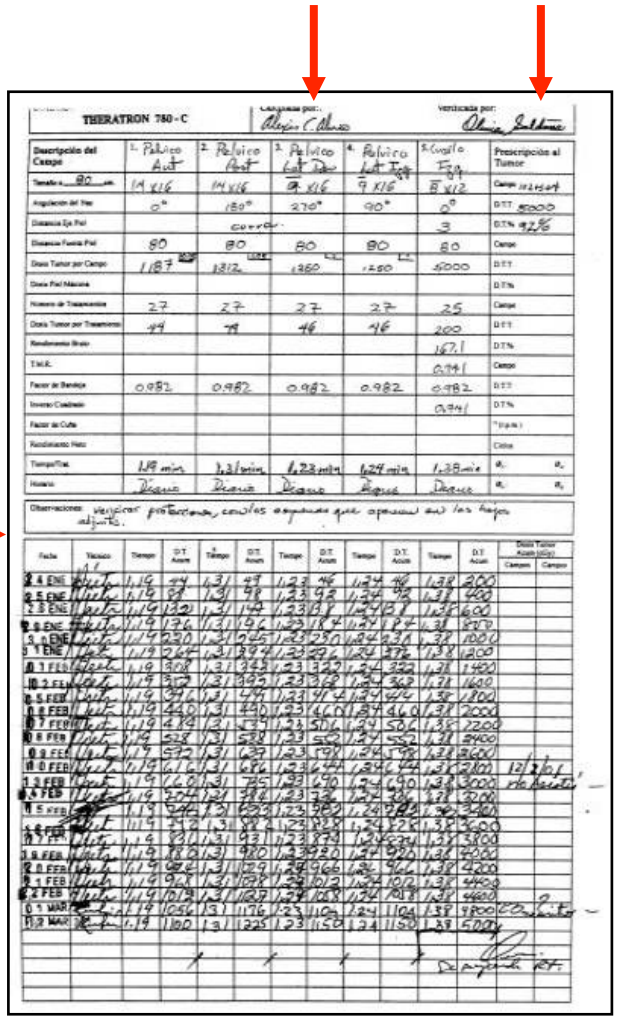
Calculated treatment time

- The calculated treatment time was approximately twice the intended
- Example: Treatment time on similar patients had been 0.6 min (one field). Now it had become more than 1.2 min (one field).



Discovery of the problem

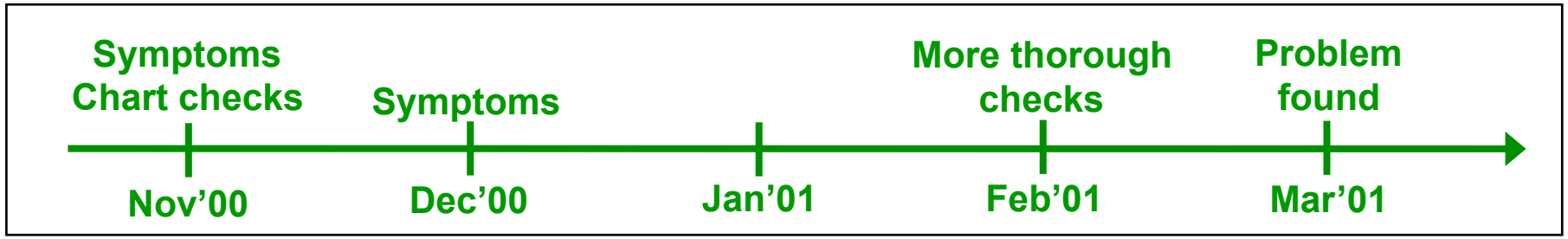
- In November 2000, radiation oncologists were observing unusually prolonged diarrhoea in some patients.
- On request, physicists reviewed charts (double checked). TPS output was not questioned. No anomaly was found.



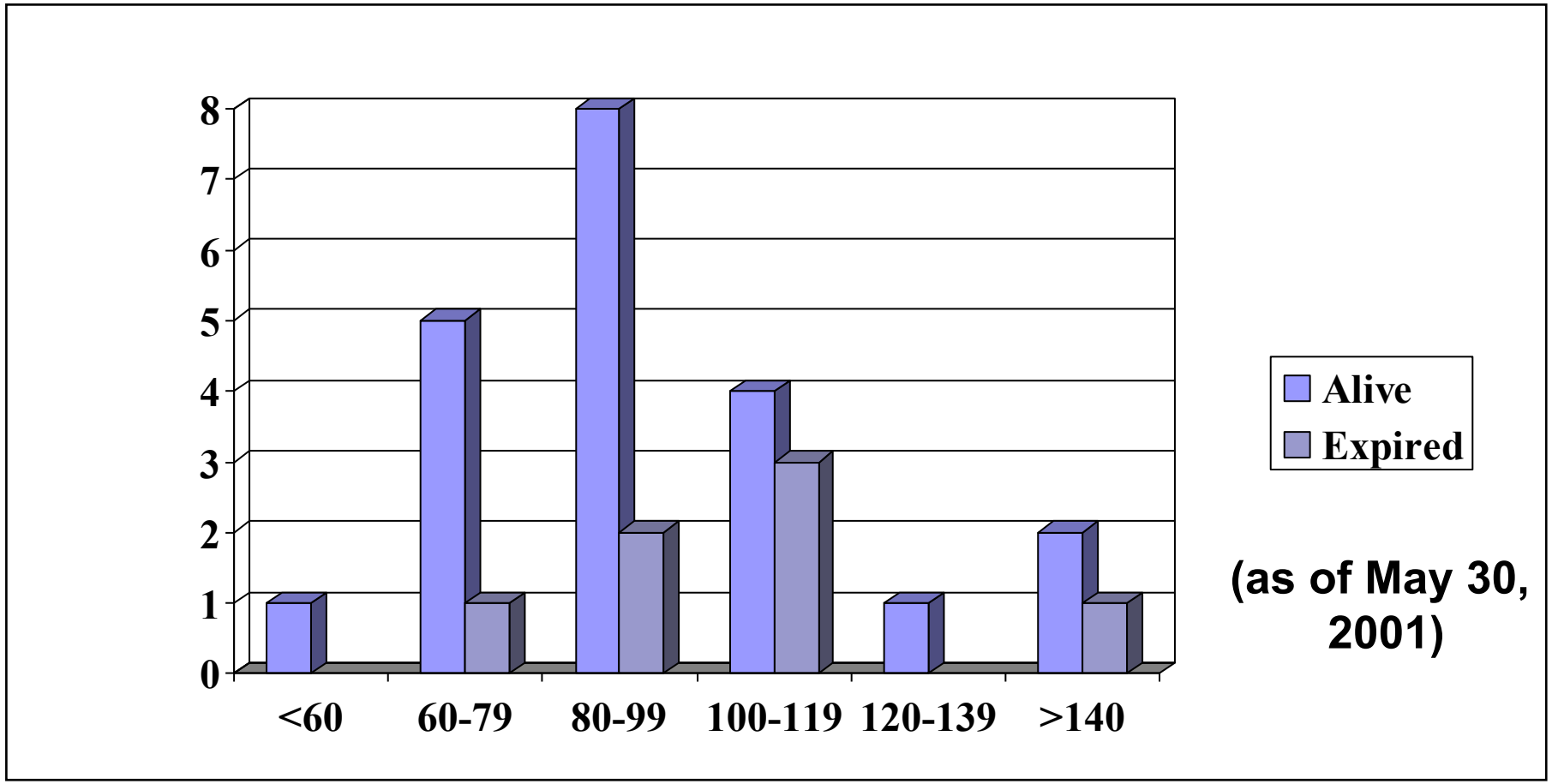
Discovery of the problem

- In Dec 2000, similar symptoms were observed. In Feb 2001, physicists initiated a more thorough search for the cause.

- In March 2001, physicists identified a problem with computer calculations. Treatment was suspended.



Number of patients and their dose (equivalent to 2 Gy/fraction)




Skin changes even though multiple fields used

Effects on patients

Effects at the moment of the evaluation mission (May 30, 2001)

- 8 deaths of 28 patients
- 5 of these deaths radiation related
- 2 unknown (not enough data)
- 1 due to metastatic cancer
- 20 surviving patients of the affected

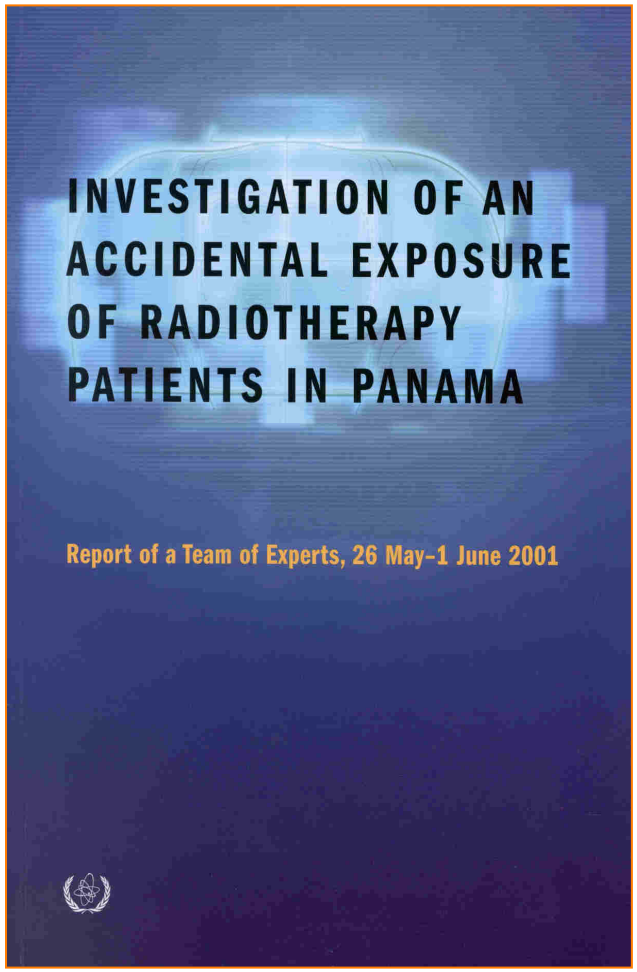
Lessons to learn

- Lessons for manufacturers
  - Avoid ambiguity in the instructions
  - Thorough testing of software, also for non-intended use
  - Guide users with warnings on the screen for incorrect data entry
- Lessons for radiotherapy departments
  - TPS is a safety critical piece of equipment
  - Quality control should include TPS, procedures should be written and changes in procedures should be validated before being put into use
  - Computer calculation should be verified (manual checks for one point) + Awareness of staff for unusual treatment parameters should be stimulated and trained!

Reference

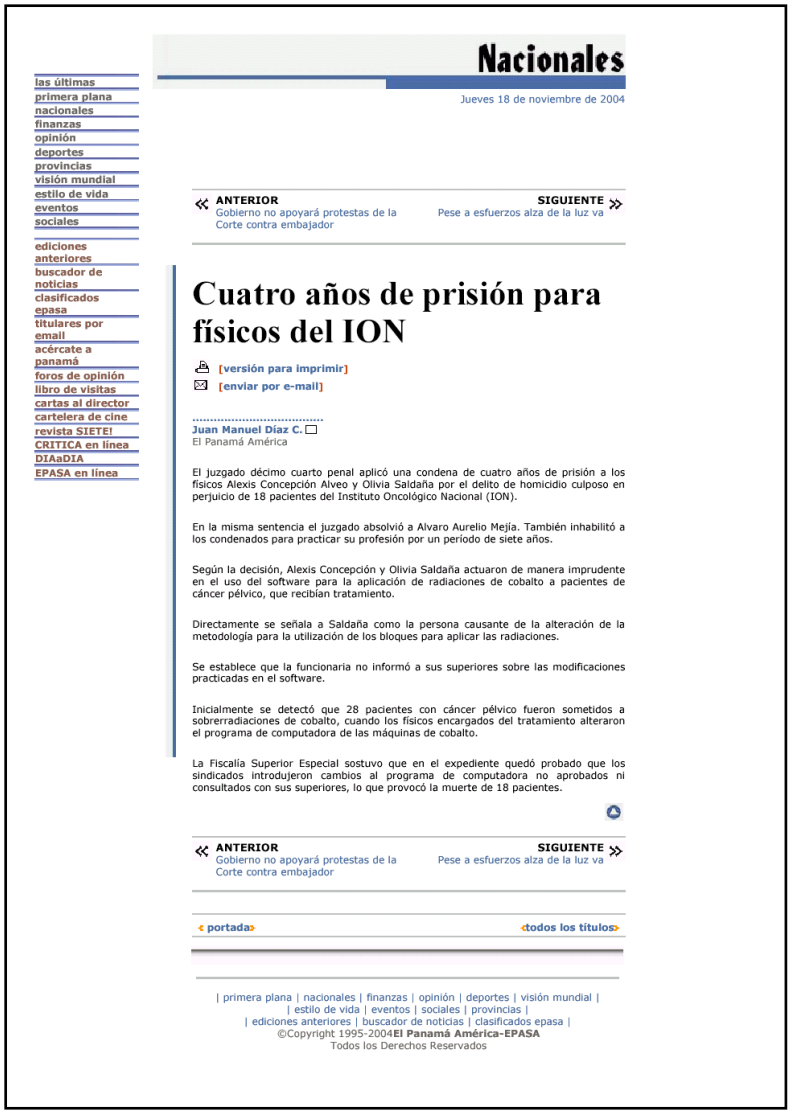
- IAEA: Investigation of an accidental exposure of radiotherapy patients in Panama (2001)

rpop.iaea.org



Postscript

- Towards the end of 2004, two physicists involved in this event were sentenced to four years in prison respectively, as well as a period of seven years when they were not allowed to practice in the profession.



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Nacionales

Jueves 18 de noviembre de 2004

« ANTERIOR
Gobierno no apoyará protestas de la Corte contra embajador

SIGUIENTE »
Pese a esfuerzos alza de la luz va

Cuatro años de prisión para físicos del ION

[versión para imprimir]
[enviar por e-mail]

Juan Manuel Díaz C.
El Panamá América

El juzgado décimo cuarto penal aplicó una condena de cuatro años de prisión a los físicos Alexis Concepción Alveo y Olivia Saldaña por el delito de homicidio culposo en perjuicio de 18 pacientes del Instituto Oncológico Nacional (ION).

En la misma sentencia el juzgado absolvió a Alvaro Aurelio Mejía. También inhabilitó a los condenados para practicar su profesión por un período de siete años.

Según la decisión, Alexis Concepción y Olivia Saldaña actuaron de manera imprudente en el uso del software para la aplicación de radiaciones de cobalto a pacientes de cáncer pélvico, que recibían tratamiento.

Directamente se señala a Saldaña como la persona causante de la alteración de la metodología para la utilización de los bloques para aplicar las radiaciones.

Se establece que la funcionaria no informó a sus superiores sobre las modificaciones practicadas en el software.

Inicialmente se detectó que 28 pacientes con cáncer pélvico fueron sometidos a sobrerradiaciones de cobalto, cuando los físicos encargados del tratamiento alteraron el programa de computadora de las máquinas de cobalto.

La Fiscalía Superior Especial sostuvo que en el expediente quedó probado que los sindicados introdujeron cambios al programa de computadora no aprobados ni consultados con sus superiores, lo que provocó la muerte de 18 pacientes.

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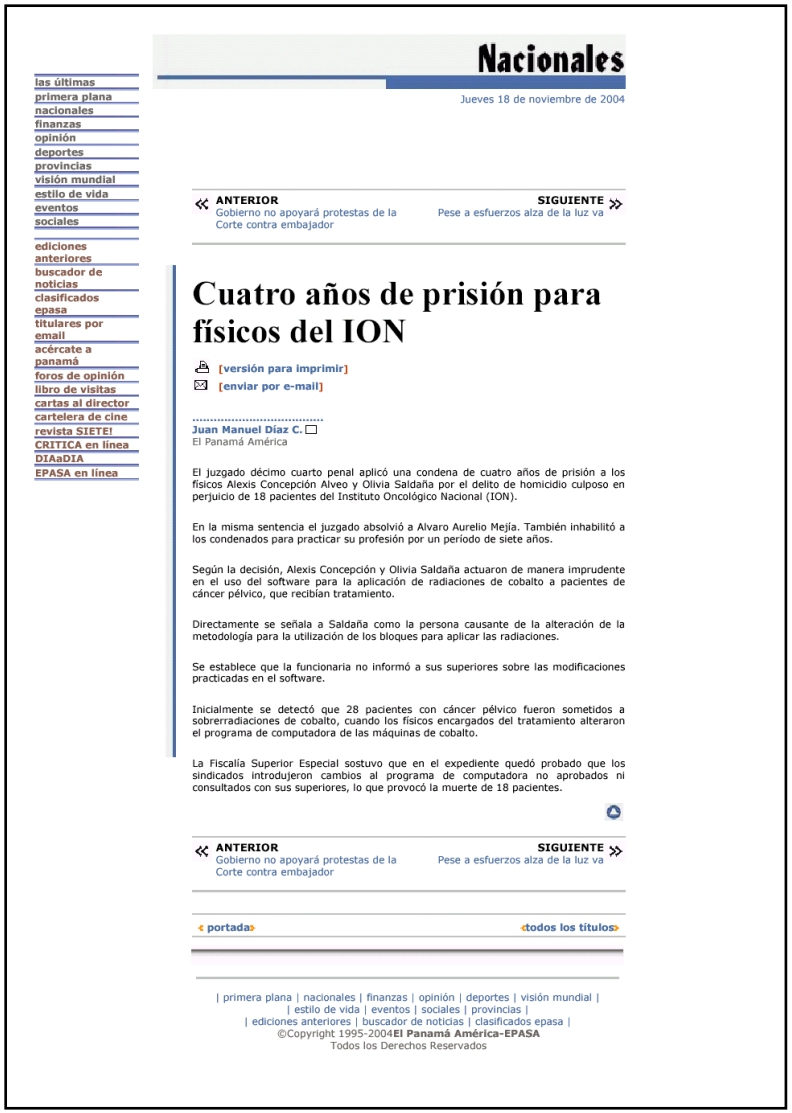
« portada » « todos los títulos »

Postscript

- According to the court, they did not inform their superiors regarding the modifications in practice in relation to the use of the treatment planning software.



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1st new example:

Incorrect manual parameter transfer (UK - 2006)

Background

- January 2006 at the Beatson Oncology Centre (BOC) in Glasgow, Scotland
  - At the time: Radiotherapy physics staffing levels in Scotland less than 60% of the recommended level
  - “Glasgow has problems with recruiting physicists, as shown by their high number of vacancies.”

The Beatson Oncology Centre in Glasgow

Background

- Treatment planning at BOC:
  - 14.5 whole time equivalent (WTE) staff were available for between 4500 and 5000 new treatment plans per year.
  - When staffing levels were compared with guidelines from IPEM, it was seen that 18 WTE staff would be the recommended level.

Background

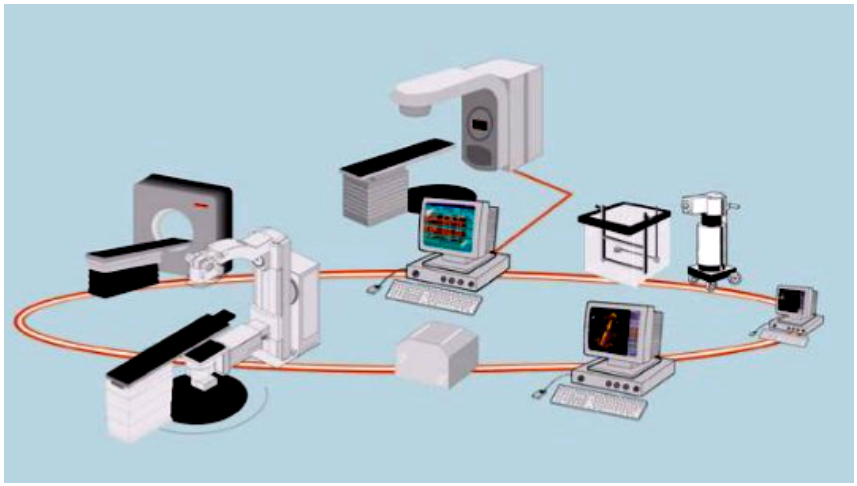
- Treatment planning at BOC:
  - Planning staff members and planning procedures were both categorized
  - A to C denotes senior to junior staff
  - A to E denotes simple to complex plans
  - The main duties per staff category is outlined in column 4

Staff planning category	Number of staff members in each category	WTE* allocation to treatment planning for Dec 2005	Categories of plans
A1	5	3.2	*D* and *E* (as checker)
A2	2	1	*C*, *D* and *E* as planner and checker
A3	4	2.3	*C* and *D* as planner and checker
B	5	3.3	*B*, *C* and *D* as planner *A*, *B* and *C* checker
C	7	4.7	*A*, *B* and *C* as planner
Totals	23	14.5	

Table from: "Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposures) Regulations 2000"

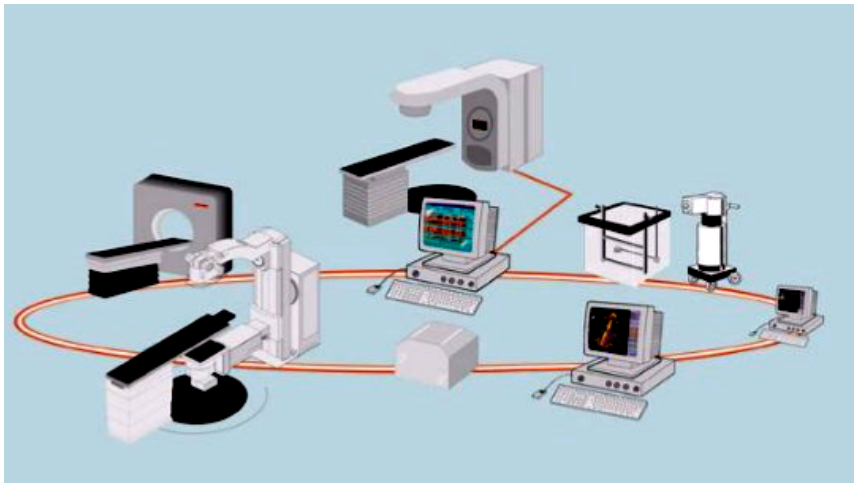
Background

- Treatment planning at BOC:
  - Practice prior to 2005 had been to let the treatment planning system (TPS) calculate the Monitor Units (MU) for 1 Gy followed by manual multiplication with the intended dose per fraction for the correct MU-setting to use.



Background

- Treatment planning at BOC:
  - In May 2005, the Record and Verify (RV) system was upgraded to be a more integrated platform.
  - The centre decided to input the dose per fraction already in the TPS, for most but not all treatment techniques.



What happened?

- 5th January 2006, Lisa Norris, 15 years old, started her whole CNS treatment at BOC
- The treatment plan was divided into head-fields and lower and upper spine-fields
- This is considered to be a complex treatment plan, performed about six times per year at the BOC.

Lisa Norris

What happened?

- The bulk of the planning was done by “Planner X” in Dec’05, a junior planner
- “Planner X” had not yet been registered internally to be competent to plan whole CNS, or to train on these
- “Planner X” got initial instructions and the opportunity to be supervised when creating the plan

What happened?

- Whole CNS plans still went by the “old system”, where TPS calculates MU for 1 Gy with subsequent upscaling for dose per fx
- A “medulla planning form” was used, which is passed to treatment radiographers for final MU calculations

Annex 2: A blank copy of the first page of Medulla Planning FM.14.014 as used for Lisa Norris’s treatment plan

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

MEDULLA PLANNING FORM **FM.14.014**
TWO SPINE FIELDS

Name:	**Site:**
B.O.C. No:	**Unit:**
Radiotherapist:	**Date:**
Physics:	

Setup	Head fields isocentric; asymmetric jaws; customised shielding trays. Physics to move junction after every ..... fractions (see over).			
Site	**Head (a)**		**Upper Spine (b)**	**Lower Spine (c)**
Description	Right Lateral	Left Lateral	Posterior	Post / Sup
Field Size (approx for first ..... fractions				
Jaw Settings	x_1 y_1 x_2 y_2	x_1 y_1 x_2 y_2		
F.S.D.	ISOCENTRIC		100 cm	100 cm
Gantry Angle	90°	270°	0°	.....° (i.e. ..... ° to sup)
Collimators	.....° (i.e. ....° Sup End Post)	.....° (i.e. .....° Sup End Post)	90°	90°
Floor Rotation	0°	0°	270°	270°
Beam Modifier	Shielding block tray code =	Shielding block tray code =	Wax compensator (a). tray code 17	Wax compensator (b). tray code 17

Beam Weight (%)	100% (a)	100% (a)	100% (b)	100% (c)
Output (MU/100cGy)				
Dose Information	T.A.D. mid brain = 100% Normalisation = ... %		spinal cord: .....% max subcut: .....%	spinal cord: .....% max subcut: .....%

File Name: FM14014	**Page Number: 1 of: 1**	**Date: 11.8.98**
Issue Number: 1	**Authorised By:**	**Issued By:**

Output (MU/100cGy)

What happened?

- HOWEVER – "Planner X" let the TPS calculate the MU for the full dose per fx – not for 1 Gy as intended
- Since the dose per fx to the head was 1.67 Gy, the MU's entered in the form were 67% too high for each of the head-fields

Annex 2: A blank copy of the first page of Medulla Planning FM.14.014 as used for Lisa Norris's treatment plan

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

MEDULLA PLANNING FORM **FM.14.014**
TWO SPINE FIELDS

Name:	**Site:**
B.O.C. No:	**Unit:**
Radiotherapist:	**Date:**
Physics:	

Setup	Head fields isocentric; asymmetric jaws; customised shielding trays. Physics to move junction after every ..... fractions (see over).			
Site	**Head (a)**		**Upper Spine (b)**	**Lower Spine (c)**
Description	Right Lateral	Left Lateral	Posterior	Post / Sup
Field Size (approx for first ..... fractions				
Jaw Settings	x_1 y_1 x_2 y_2	x_1 y_1 x_2 y_2		
F.S.D.	ISOCENTRIC		100 cm	100 cm
Gantry Angle	90°	270°	0°	.....° (i.e. .....° to sup)
Collimators	.....° (i.e. ....° Sup End Post)	.....° (i.e. .....° Sup End Post)	90°	90°
Floor Rotation	0°	0°	270°	270°
Beam Modifier	Shielding block tray code =	Shielding block tray code =	Wax compensator (a). tray code 17	Wax compensator (b). tray code 17

Beam Weight (%)	100% (a)	100% (a)	100% (b)	100% (c)
Output (MU/100cGy)				
Dose Information	T.A.D. mid brain = 100% Normalisation = ... %		spinal cord: .....% max subcut: .....%	spinal cord: .....% max subcut: .....%

File Name: FM14014	**Page Number: 1 of: 1**	**Date: 11.8.98**
Issue Number: 1	**Authorised By:**	**Issued By:**

Output (MU/100cGy)

What happened?

- This error was not found by the more senior planners who checked the plan
- The radiographer on the unit thus multiplied with the dose per fx a second time
- 2.92 Gy per fx to the head

Annex 2: A blank copy of the first page of Medulla Planning FM.14.014 as used for Lisa Norris's treatment plan

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

MEDULLA PLANNING FORM **FM.14.014**
TWO SPINE FIELDS

Name:	**Site:**
B.O.C. No:	**Unit:**
Radiotherapist:	**Date:**
Physics:	

Setup	Head fields isocentric; asymmetric jaws; customised shielding trays. Physics to move junction after every ..... fractions (see over).			
Site	**Head (a)**		**Upper Spine (b)**	**Lower Spine (c)**
Description	Right Lateral	Left Lateral	Posterior	Post / Sup
Field Size (approx for first ..... fractions				
Jaw Settings	x_1 y_1 x_2 y_2	x_1 y_1 x_2 y_2		
F.S.D.	ISOCENTRIC		100 cm	100 cm
Gantry Angle	90°	270°	0°	.....° (i.e. .....° to sup)
Collimators	.....° (i.e. ....° Sup End Post)	.....° (i.e. .....° Sup End Post)	90°	90°
Floor Rotation	0°	0°	270°	270°
Beam Modifier	Shielding block tray code =	Shielding block tray code =	Wax compensator (a). tray code 17	Wax compensator (b). tray code 17

Beam Weight (%)	100% (a)	100% (a)	100% (b)	100% (c)
Output (MU/100cGy)				
Dose Information	T.A.D. mid brain = 100% Normalisation = ... %		spinal cord: .....% max subcut: .....%	spinal cord: .....% max subcut: .....%

File Name: FM14014	**Page Number: 1 of: 1**	**Date: 11.8.98**
Issue Number: 1	**Authorised By:**	**Issued By:**

Output (MU/100cGy)

Discovery of accident

- “Planner X” calculated another plan of the same kind and made the same mistake
- This time, the error was discovered by a senior checker (1st of Feb ‘’06)
- The same day, the error in calculations for Lisa Norris was also identified

Impact of accident

- 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

Lessons to learn

- Ensure that all staff
  - Are properly trained in safety critical procedures
  - Are included in training programmes and has supervision as necessary, and that records of training are kept up-to-date
  - Understand their responsibilities
- Include in the Quality Assurance Program
  - Formal procedures for verifying the risks following the introduction of new technologies and procedures
  - Independent MU checking of ALL treatment plans
- Review staffing levels and competencies

References

- Unintended overexposure of patient Lisa Norris during radiotherapy treatment at the Beatson Oncology Centre, Glasgow in January 2006. Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposures) Regulations 2000 (2006)

- Cancer in Scotland: Radiotherapy Activity Planning for Scotland 2011 – 2015. Report of The Radiotherapy Activity Planning Steering Group' The Scottish Executive. Edinburgh. (2006)

- The Glasgow incident – a physicist's reflections. W.P.M. Mayles. Clin Oncol 19:4-7 (2007)

- Radiotherapy near misses, incidents and errors: radiotherapy incident in Glasgow. M.V. Williams. Clin Oncol 19:1-3 (2007)

2nd new example:

Erroneous calculation for soft wedges (France - 2004)

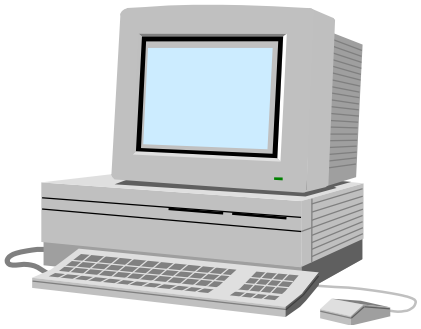
Background

- 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

The Jean Monnet Hospital in Epinal

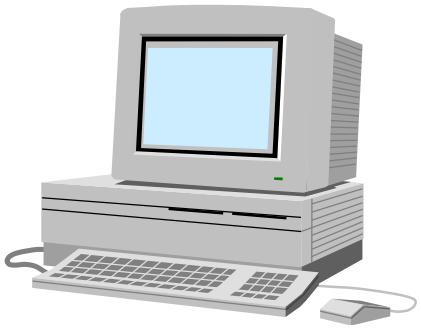
Background

- In preparation for the change in treatment technique, two operators (treatment planners?) were given two brief demo's
  - The operators did not have any operating manual in their native language



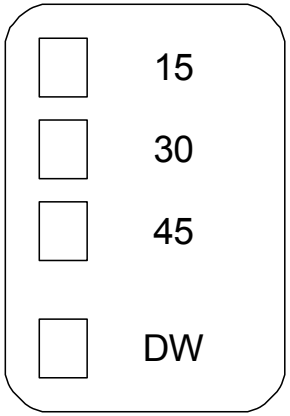
Background

- When the soft wedges were introduced:
  - The independent MU check in use could not be used anymore (unless modified)
  - The diodes used for independent dose check could not be correctly interpreted anymore



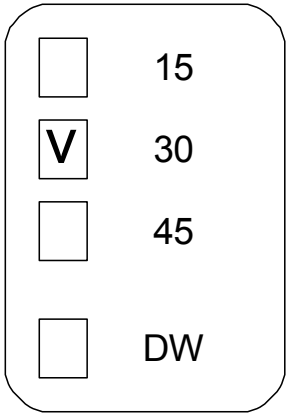
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system



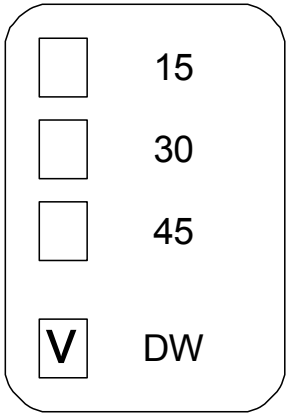
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system
  - Some selected the planning for mechanical wedge when intending dynamic wedge



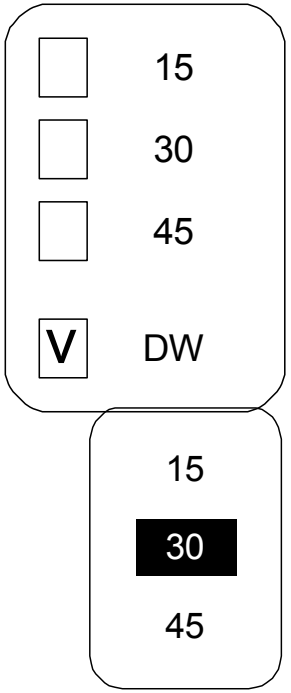
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system
  - Some selected the planning for mechanical wedge when intending dynamic wedge
  - Instead they should have selected Dynamic Wedge…



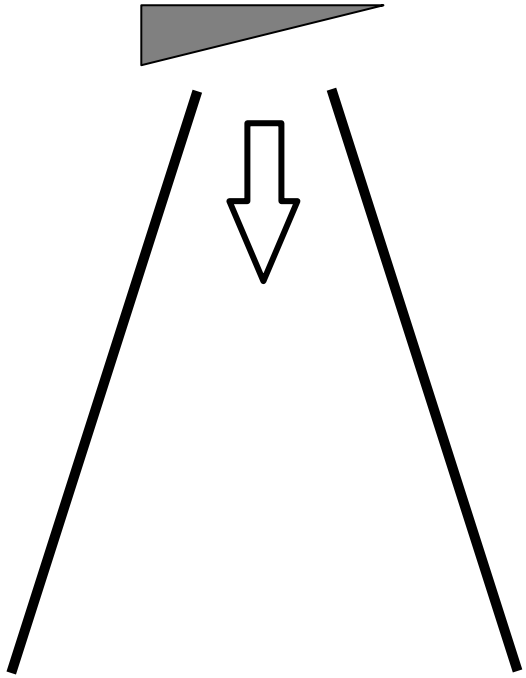
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system
  - Some selected the planning for mechanical wedge when intending dynamic wedge
  - Instead they should have selected Dynamic Wedge…
    - …which would have let the correct planning tool appear



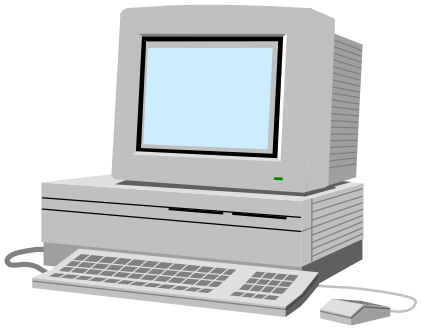
What happened?

- When planning was finished and the isodose distribution approved
  - …the parameters were manually transferred to the treatment unit
  - Manually transferred MU's would have been calculated for mechanical wedges and would be much greater than what is needed for giving the same dose with dynamic wedges



Discovery of accident

- Details not clear, BUT: it might have been when MU check software was replaced and updated to be able to handle independent checking of dynamic wedges.



Impact of accident

- 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)

Information following accident

- 15 Sep 2005, two doctors from the clinic passed on information that went to the Regional Dept. of Health and Social Security (DDASS)
- 5 Oct 2005 a meeting was held at DDASS. Decisions were not documented or uniformly interpreted.
- National authorities in charge were not informed at this stage, but only a full year after the accident (July 2006)

Information following accident

- 7 patients were informed during the last quarter of 2005.
- 16 other patients were (wrongly) considered no to be affected. Of these …
  - … 3 were informed by another doctor 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

Lessons to learn

- Ensure that staff
  - Understand the properties and limitations of the equipment they are using
  - Are properly trained in safety critical procedures
- Include in the Quality Assurance Program
  - Formal procedures for verifying new technologies and procedures before implementation
  - Independent MU checking of ALL treatment plans
  - In vivo dosimetry
- Make sure the clinic has a system in place for
  - Investigation and reporting of accidents
  - Patient management and follow up, including communication to patients
- Instructions should be in a language that is understood

References

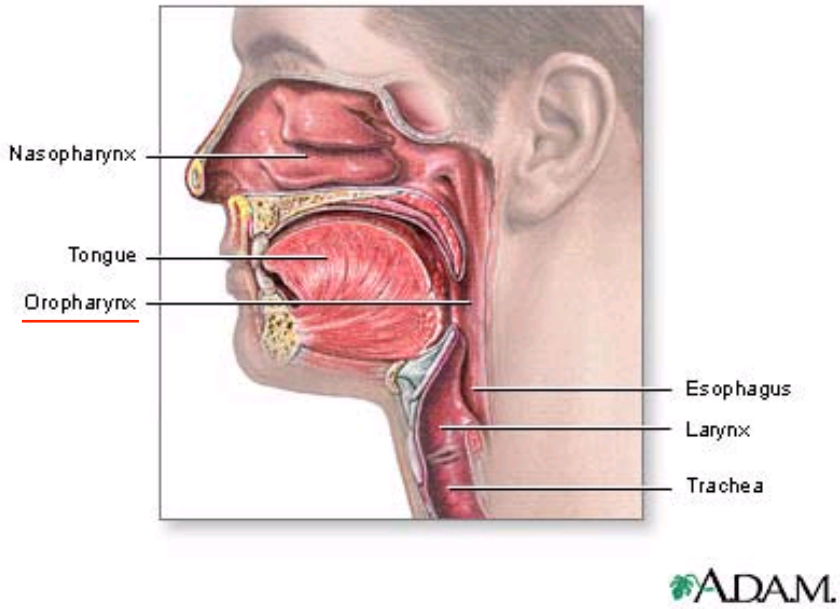
- Summary of ASN report n° 2006 ENSTR 019 - IGAS n° RM 2007-015P on the Epinal radiotherapy accident. G. Wack, F. Lalande, M.D. Seligman (2007)
- Accident de radiothérapie à Épinal. P.J. Compte. Société Française de Physique Médicale (2006)
- Lessons from Epinal. D. Ash. Clin Oncol 19:614-615 (2007)

3rd new example:

Incorrect IMRT Planning
(USA - 2005)

Background

- March 2005, in the state of New York, USA
  - A patient is due to be treated with IMRT for head and neck cancer (oropharynx)



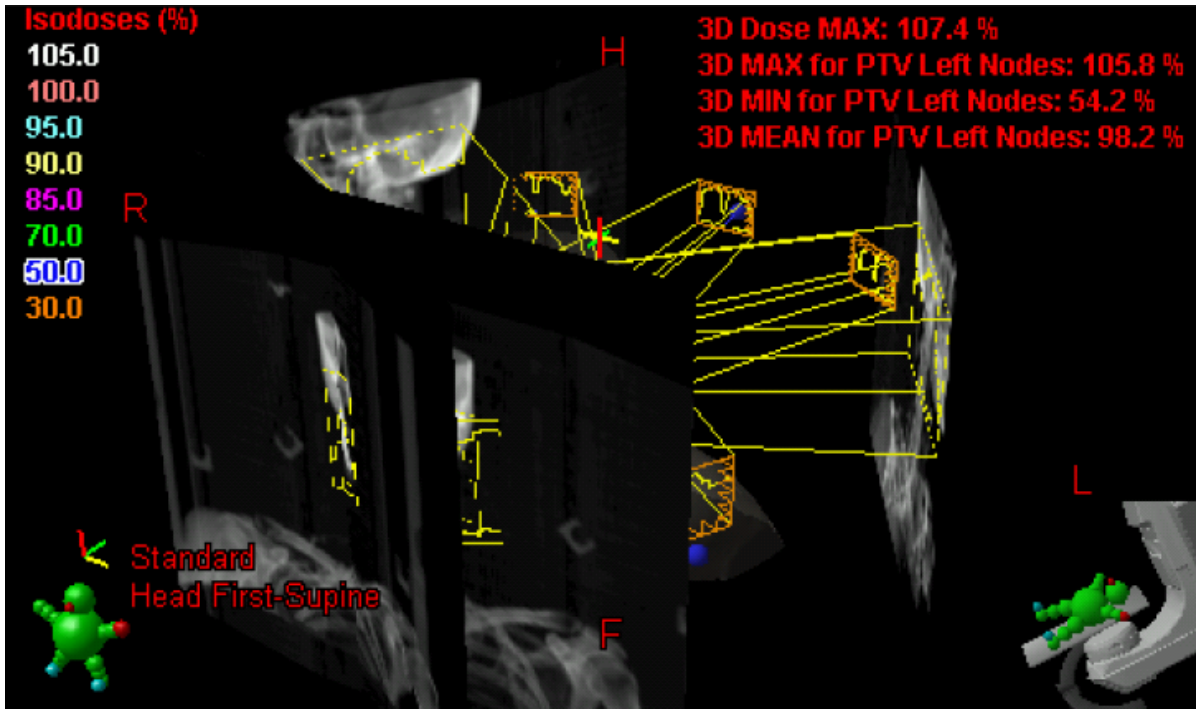
What happened?

- 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 EPID) confirms correctness.

Example of an EPID (Electronic Portal Imaging Device) (Picture: P.Munro)

What happened?

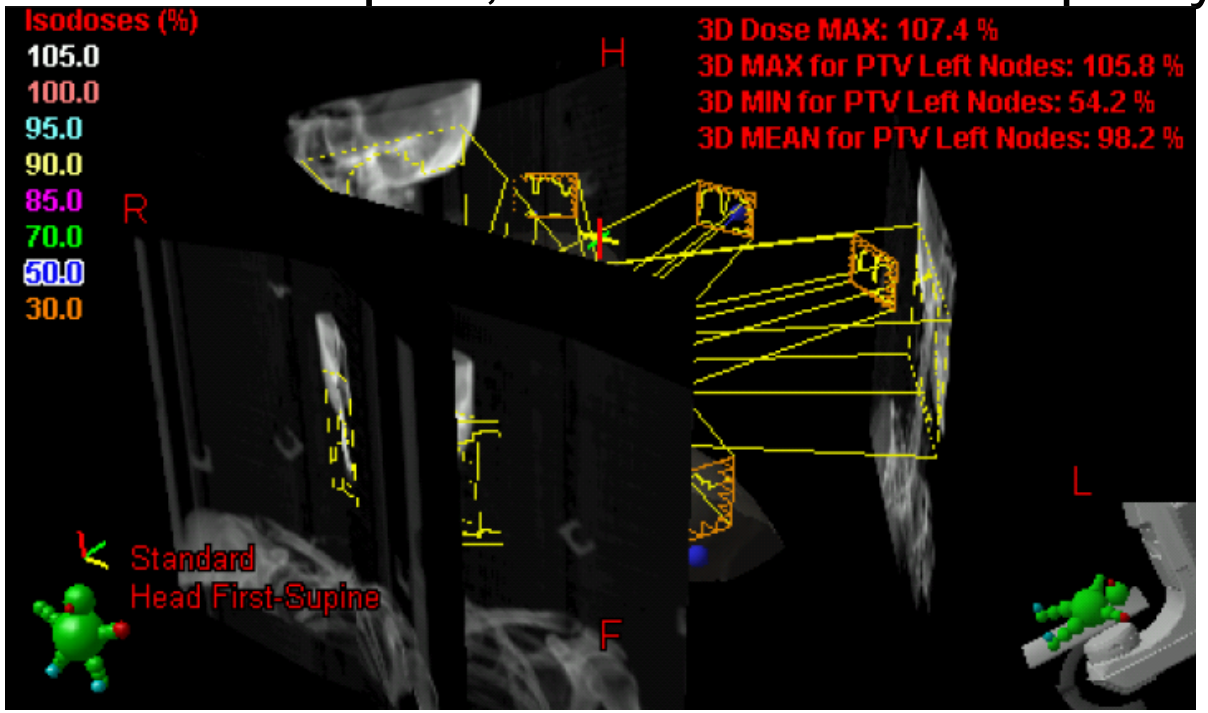
- March 8, 2005
  - The patient begins treatment with the plan “1 Oropharyn”. This treatment is delivered correctly.



“Model view” of treatment plan (Picture: VMS)

What happened?

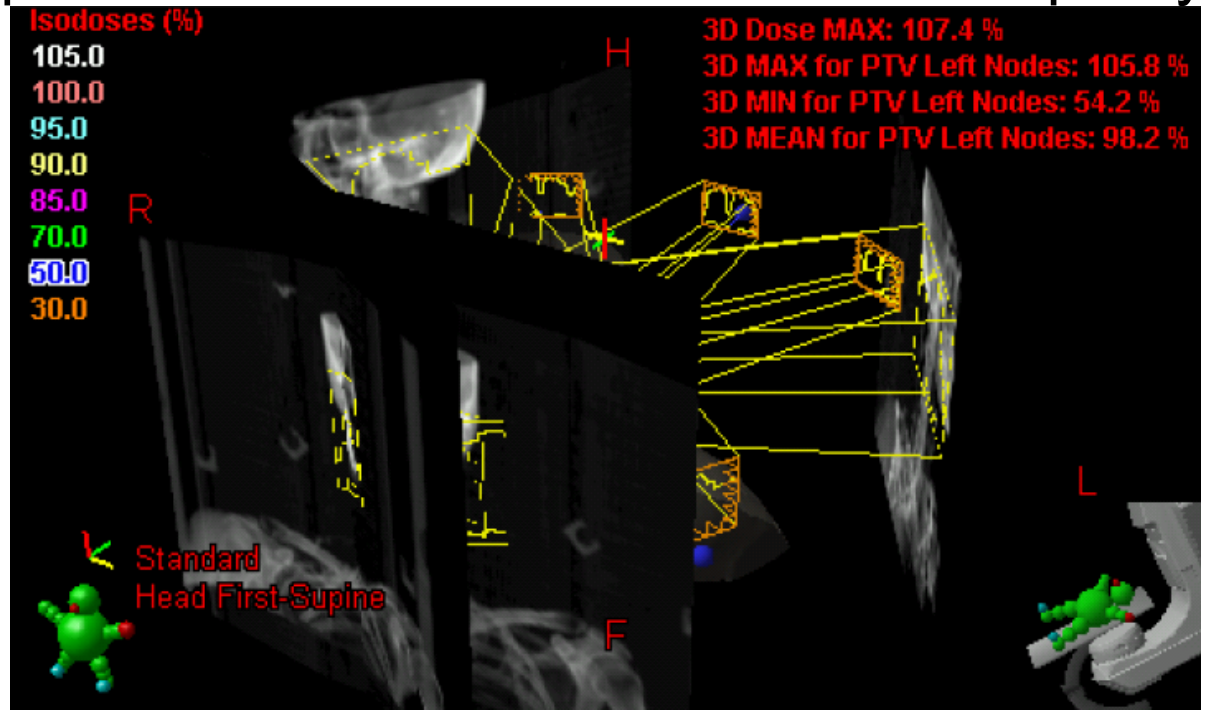
- March 9-11, 2005
  - Fractions #2, 3 and 4 are also delivered correctly. Verification images for the kV imaging system are created and added to the plan, now called “1A Oropharyn”.



“Model view” of treatment plan (Picture: VMS)

What happened?

- March 11, 2005
  - The physician reviews the case and wants a modified dose distribution (reducing dose to teeth) “1A Oropharyn” is copied and saved to the DB as “1B Oropharyn”.

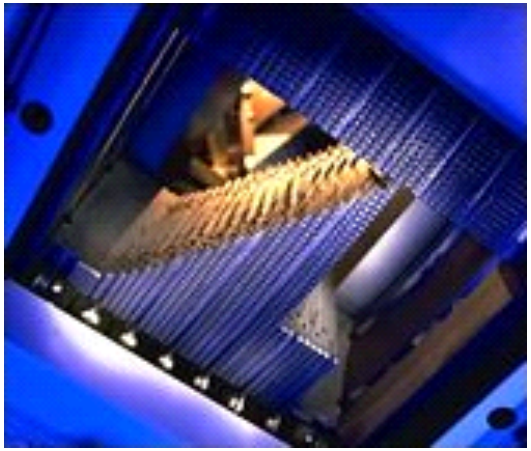


“Model view” of treatment plan (Picture: VMS)

What happened?

- March 14, 2005
  - Re-optimization work on “1B Oropharyn” starts on workstation 2 (WS2).
  - Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved to DB.
  - Final calculations are started, where MLC motion control points for IMRT are generated. Normal completion.

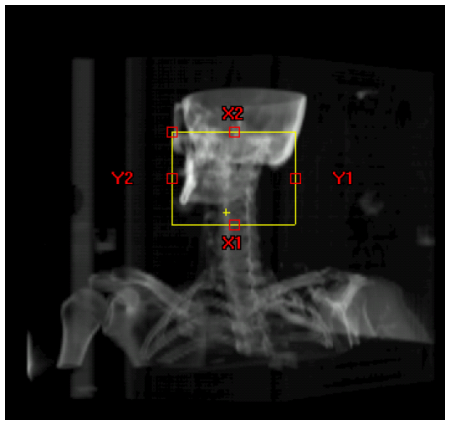
Multi Leaf Collimator (MLC)



What happened?

- 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 is 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) a DRR and (3) the MLC control points

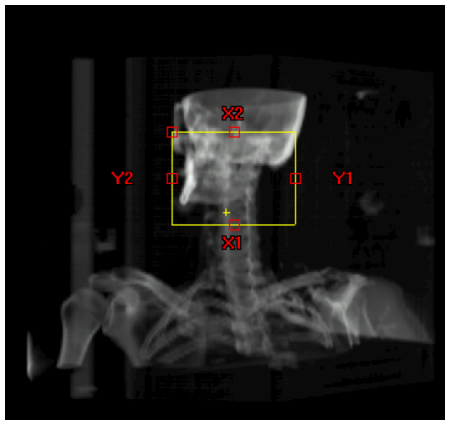
A Digitally Reconstructed Radiograph (DRR) of the patient



What happened?

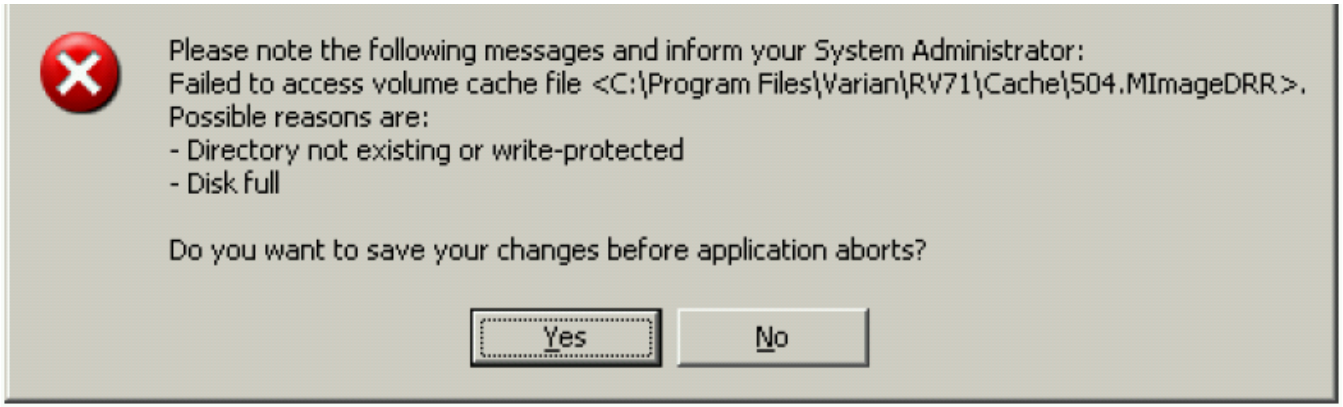
- March 14, 2005, 11 a.m.
- The actual fluence data is saved normally.
  - Next in line is the DRR. The “Save all” process continues with this, but is not completed.
  - Saving of MLC control point data would be after the DRR, but will not start because of the above.

A Digitally Reconstructed Radiograph (DRR) of the patient



What happened?

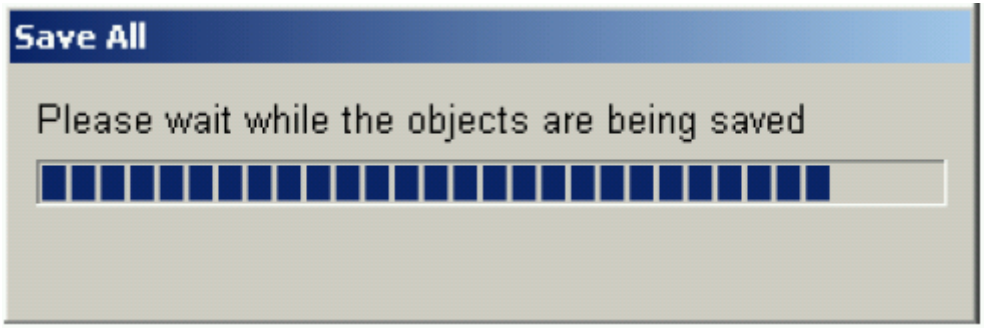
- March 14, 2005, 11 a.m.
  - An error message is displayed.
  - The user presses “Yes”, which begins a second, separate, save transaction.
  - MLC control point data is moved to the holding area.



The transaction error message displayed

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.



The frozen state of the second "Save All" progress indication

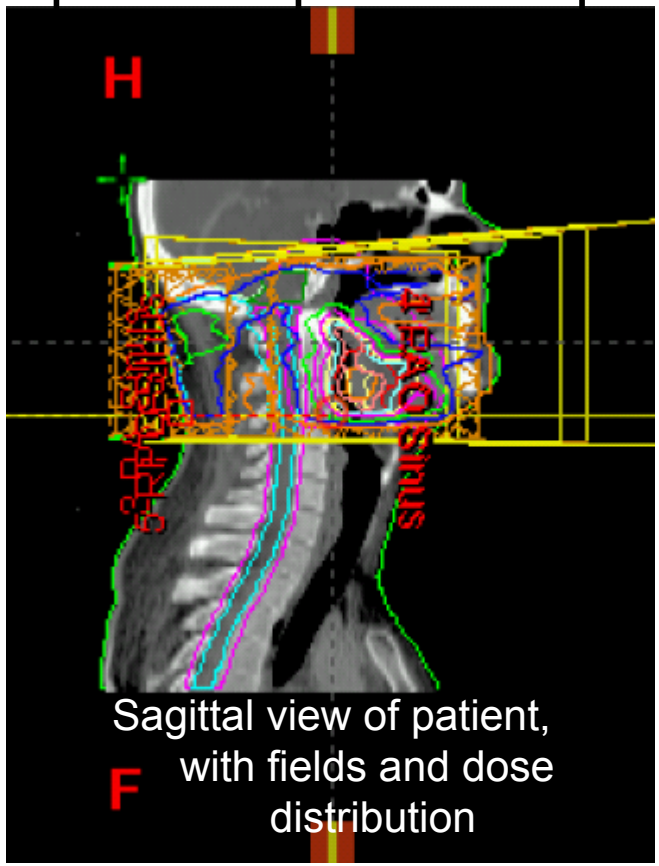
What happened?

- 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; (3) no MLC control point data

Ctrl-Alt-Del

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:

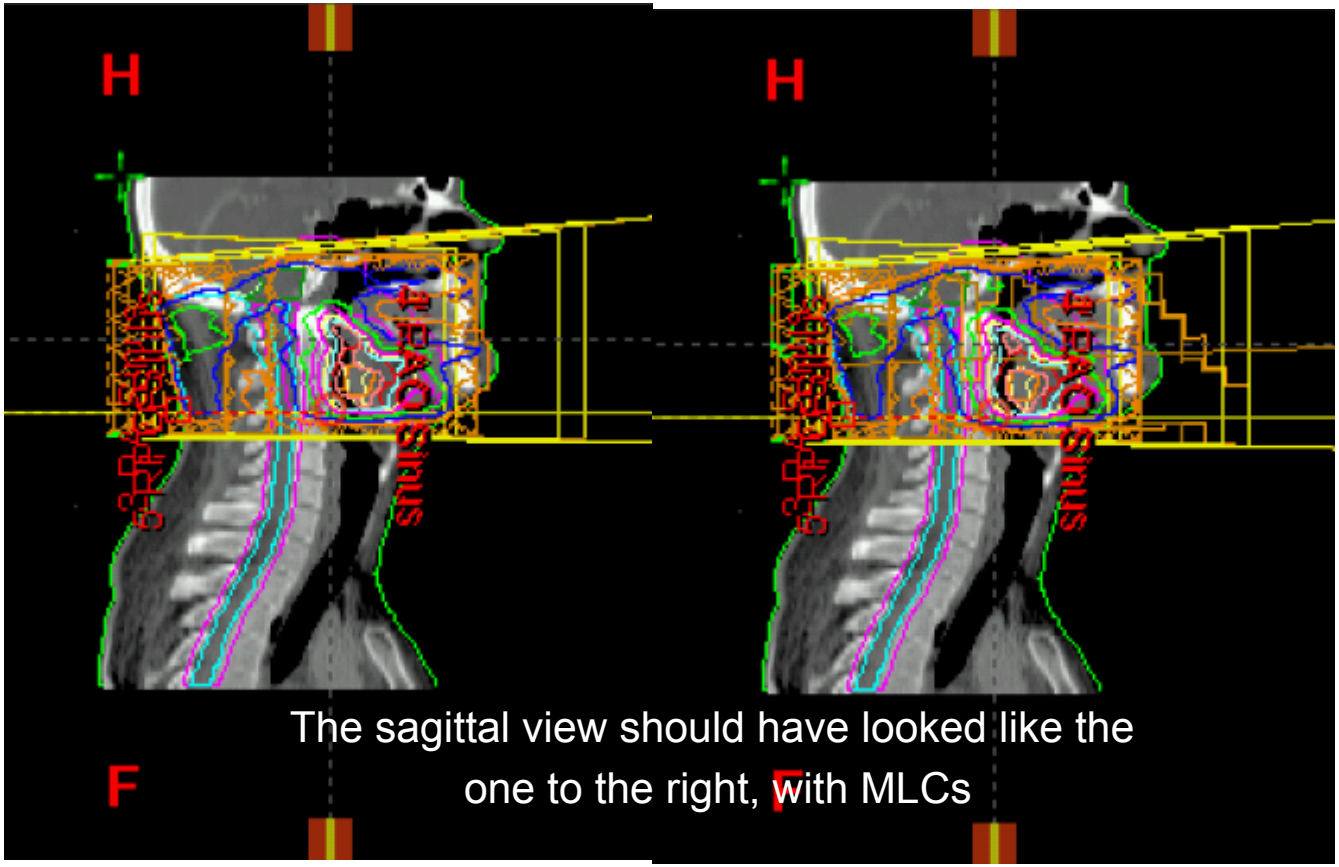


Sagittal view of patient, with fields and dose distribution

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

What happened?

- March 14, 2005, 11.a.m.
  - No control point data is included in the plan.

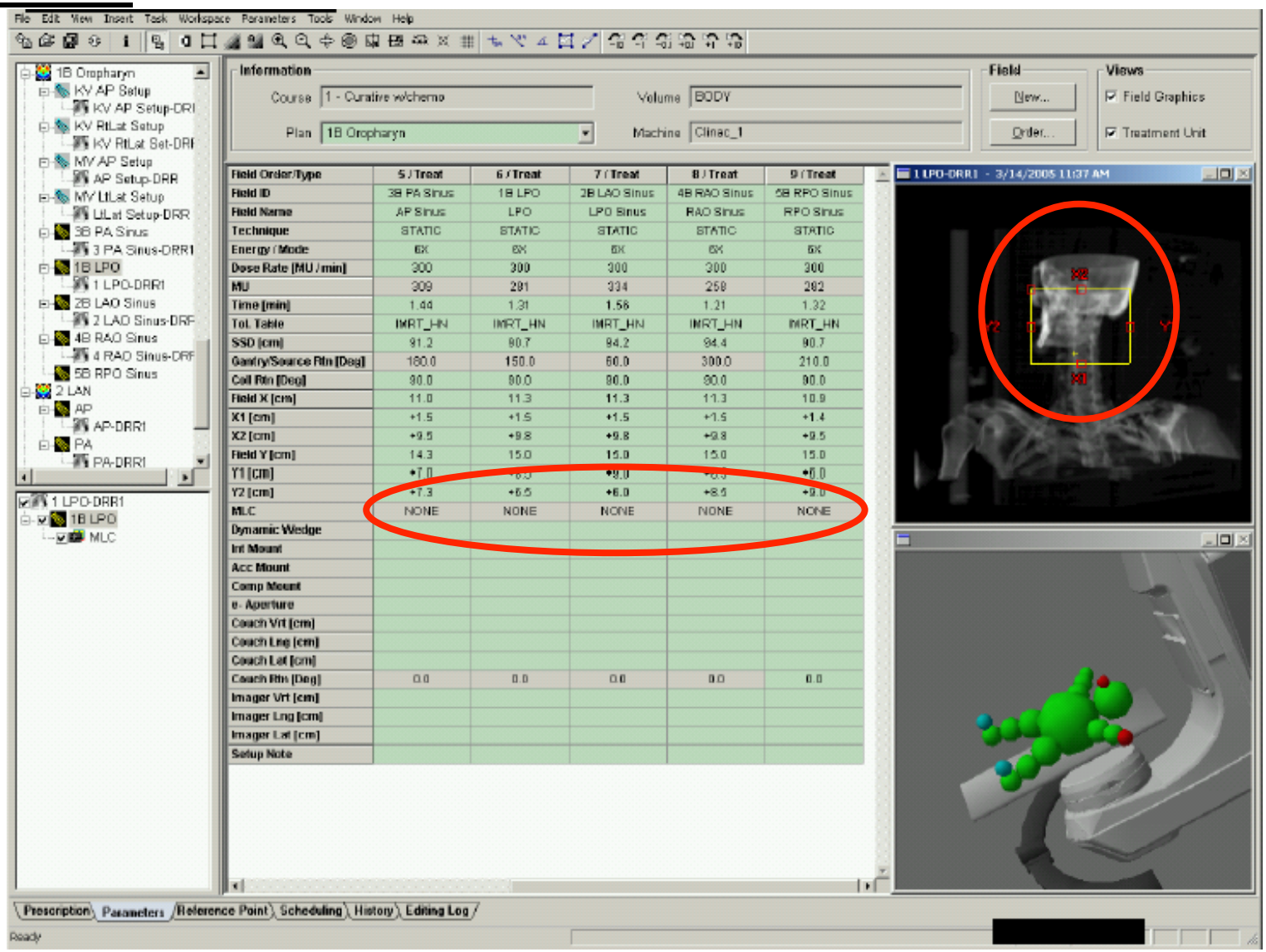


What happened?

- March 14, 2005, 11 a.m.
  - No verification plan is generated or used for checking purposes, prior to treatment (should be done according to clinics QA programme)
  - The plan is subsequently prepared for treatment (treatment scheduling, image scheduling, etc) – after several computer crashes.
  - It 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.

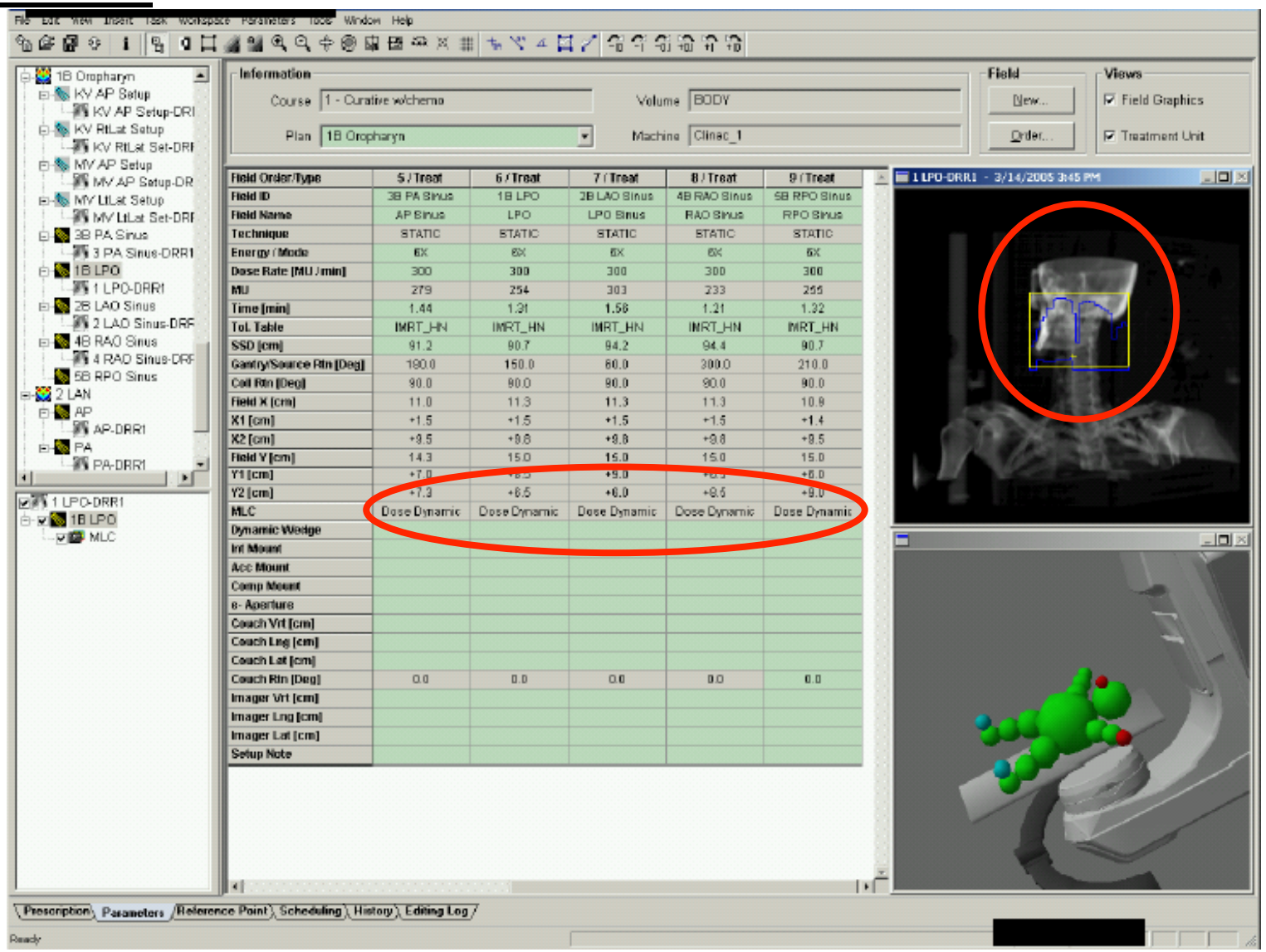
What happened?

- Would have been seen on verification:



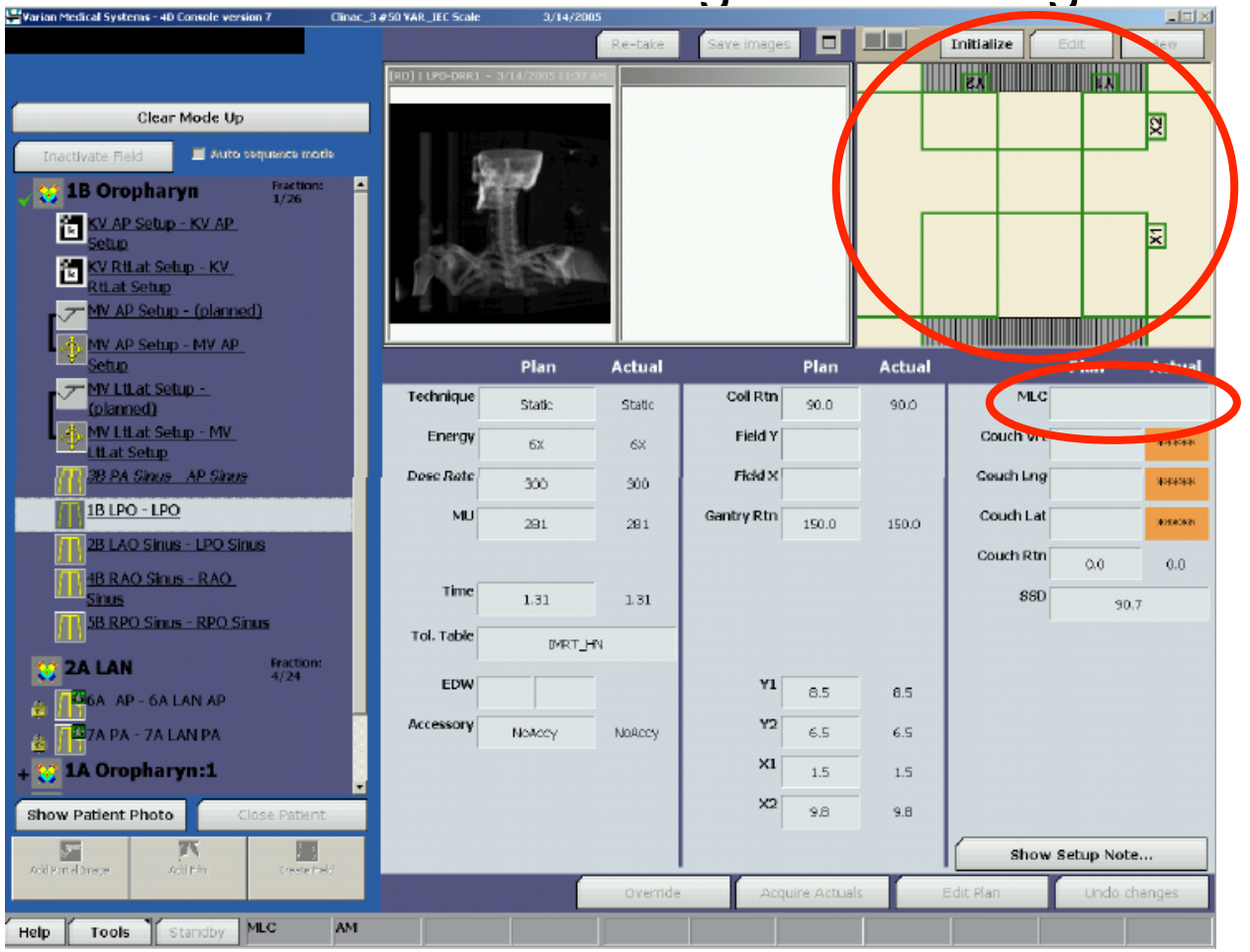
What happened?

- Should have been seen on verification:



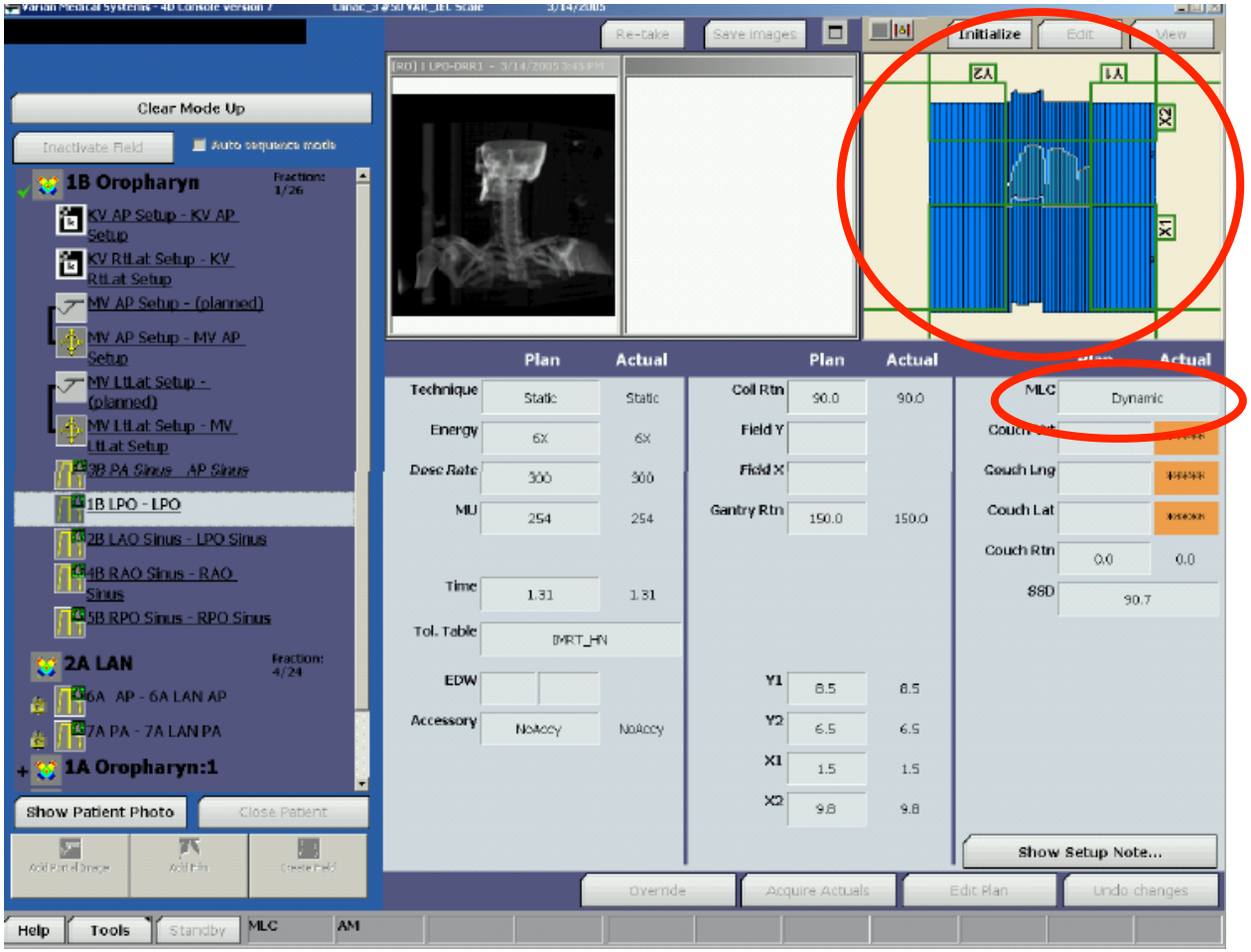
What happened?

- March 14, 2005, 1 p.m.
  - The patient is treated. The console screen would have indicated that MLC is not being used during treatment:



What happened?

- March 14, 2005, 1 p.m.
  - Expected display:



Discovery of accident

- March 15-16, 2005
  - The patient is treated without MLCs for three fractions
  - On March 16, a verification plan is created and run on the treatment machine. The operator notices the absence of MLCs.
  - 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

Lessons to learn

- Do what you should be doing according to your QA program – the error could have been found through verification plan (normal QA procedure at the facility) or independent review
- Be alert when computer crashes or freezes, when the data worked on is safety critical
- Work with awareness at treatment unit, and keep an eye out for unexpected behaviour of machine

References

- [Treatment Facility] Incident Evaluation Summary, CP-2005-049 VMS. 1-12 (2005)
- ORH Information Notice 2005-01. Office of Radiological Health, NYC Department of Health and Mental Hygien (2005)