Lessons Learned from Misadministrations and Accidents in Radiation Therapy: Teletherapy

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Disclosures

- I receive research funding from Elekta, Ltd and the Cancer Prevention Initiative of Texas.

Acknowledgements

- Tim Solberg, PhD – UTSW Radiation Oncology
- Fritz Hager, MS – UTSW Radiation Oncology

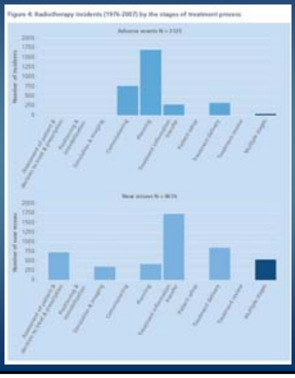
Overview

- Introduction
- Summary of accidents and misadministrations
- Resources and guidance
- Lessons learned
- Conclusions

Purpose/Objectives

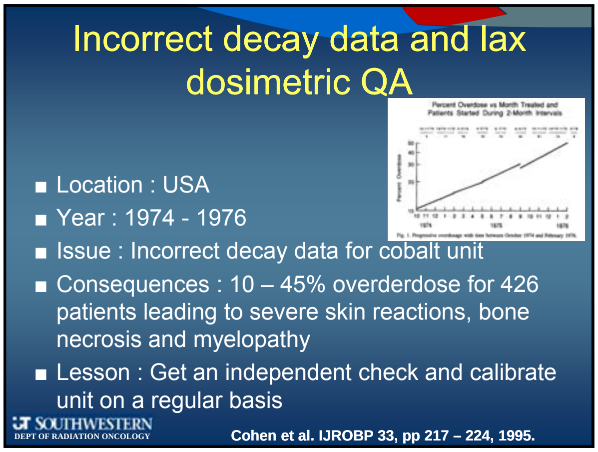
- To learn from previous accidents and misadministrations
- To understand the types of things that can occur
- Not to point fingers or criticize other institutions
- Not to beat on the vendors
- Some of these incidents could have happened to any one of us

What are the sources of errors?



WHO Radiotherapy Risk Profile 2008

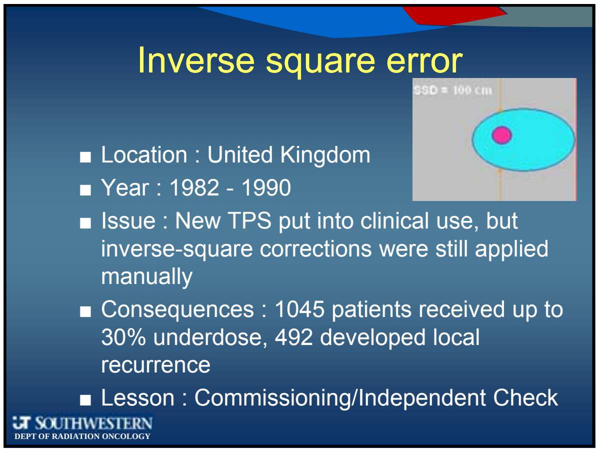
SUMMARY OF ACCIDENTS



Incorrect decay data and lax dosimetric QA

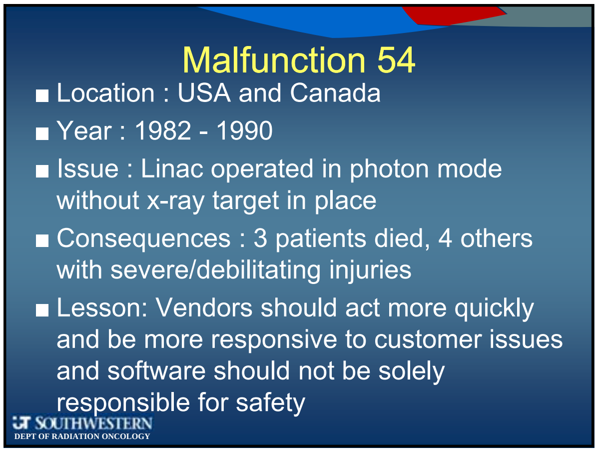
- Location : USA
- Year : 1974 - 1976
- Issue : Incorrect decay data for cobalt unit
- Consequences : 10 – 45% overderdose for 426 patients leading to severe skin reactions, bone necrosis and myelopathy
- Lesson : Get an independent check and calibrate unit on a regular basis

Cohen et al. IJROBP 33, pp 217 – 224, 1995.



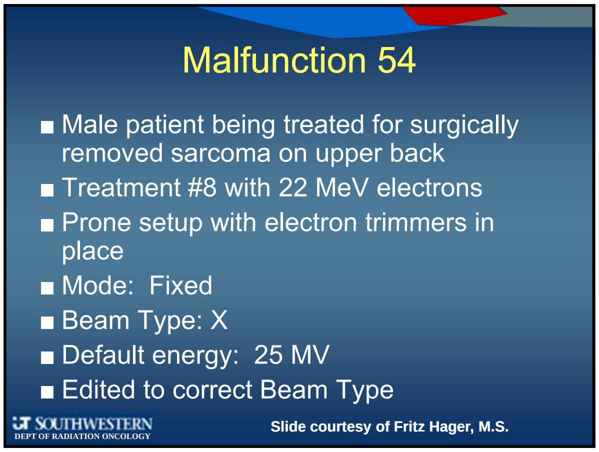
Inverse square error

- Location : United Kingdom
- Year : 1982 - 1990
- Issue : New TPS put into clinical use, but inverse-square corrections were still applied manually
- Consequences : 1045 patients received up to 30% underdose, 492 developed local recurrence
- Lesson : Commissioning/Independent Check



Malfunction 54

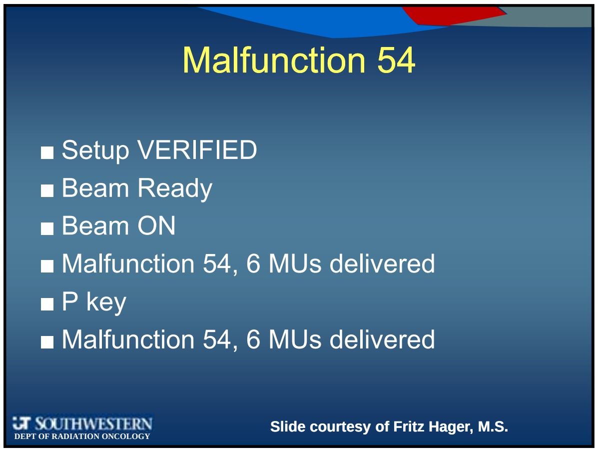
- Location : USA and Canada
- Year : 1982 - 1990
- Issue : Linac operated in photon mode without x-ray target in place
- Consequences : 3 patients died, 4 others with severe/debilitating injuries
- Lesson: Vendors should act more quickly and be more responsive to customer issues and software should not be solely responsible for safety



Malfunction 54

- Male patient being treated for surgically removed sarcoma on upper back
- Treatment #8 with 22 MeV electrons
- Prone setup with electron trimmers in place
- Mode: Fixed
- Beam Type: X
- Default energy: 25 MV
- Edited to correct Beam Type

Slide courtesy of Fritz Hager, M.S.



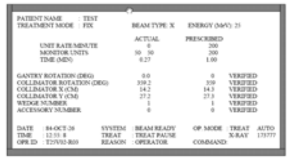
Malfunction 54

- Setup VERIFIED
- Beam Ready
- Beam ON
- Malfunction 54, 6 MUs delivered
- P key
- Malfunction 54, 6 MUs delivered

Slide courtesy of Fritz Hager, M.S.

Malfunction 54 Re-enactment

- Therapist recalls setting Beam Type as X with default to 25 MV
- Used up arrow key to change Beam Type to E and energy to 10 MeV
- Used enter key to go to the bottom of the screen
- Beam Ready
- Beam On
- Malfunction 54



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PATIENT NAME      : TEST
TREATMENT MODE    : FIX              BEAM TYPE: X      ENERGY (MeV): 25

                                     ACTUAL            PRESCRIBED
        UNIT RATE/MINUTE               0                  200
        MONITOR UNITS                 50   50             200
        TIME (MIN)                    0.27                1.00

GANTRY ROTATION (DEG)                 0.0                 0       VERIFIED
COLLIMATOR ROTATION (DEG)           359.2               359       VERIFIED
COLLIMATOR X (CM)                    14.2                14.3     VERIFIED
COLLIMATOR Y (CM)                    27.2                27.3     VERIFIED
WEDGE NUMBER                          1                   1       VERIFIED
ACCESSORY NUMBER                      0                   0       VERIFIED

DATE    : 84-OCT-26     SYSTEM  : BEAM READY     OP. MODE  : TREAT   AUTO
TIME    : 12:55: 8      TREAT   : TREAT PAUSE                X-RAY   173777
OPR ID  : T25V02-R03    REASON  : OPERATOR       COMMAND:
```

UT SOUTHWESTERN
DEPT OF RADIATION ONCOLOGY

Image taken from Leveson, Safeware: System Safety and Computers, Addison_Wesley, 1995. Slide courtesy of Fritz Hager, M.S.

Malfunction 54 Visualized

25 MeV Electrons, 16,000 rads in 100 msec

Photo courtesy of Fritz Hager, M.S.

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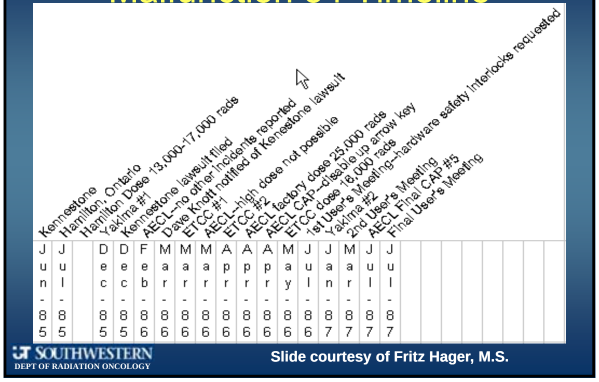
DEPT OF RADIATION ONCOLOGY

Malfunction 54 Timeline



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DEPT OF RADIATION ONCOLOGY

Slide courtesy of Fritz Hager, M.S.

Incorrect Linac Repair

- Location : Spain
- Year : 1990
- Issue : Linac repair led to 36 MeV electron beams, regardless of console input
- Consequences : 15 patients died from overdose
- Lesson : Notify physicist any time linac repairs are performed and do not ignore console warnings

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DEPT OF RADIATION ONCOLOGY

Figure courtesy of IAEA

Decay rate error

Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica

- Location : Costa Rica
- Year : 1996
- Issue : ^{60}Co dose rate calculation error; 0.3 min mistakenly believed to be 30 s, not 18 s
- Consequences : Patients overdosed by ~73%; Side effects include ulceration, bleeding and anemia
- Lesson : Periodic calibration checks of machines, clinical awareness

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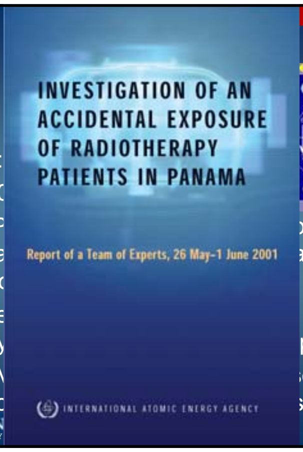
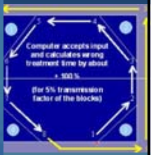
Figure courtesy of IAEA



INVESTIGATION OF AN ACCIDENTAL EXPOSURE OF RADIOTHERAPY PATIENTS IN PANAMA

Report of a Team of Experts, 26 May–1 June 2001

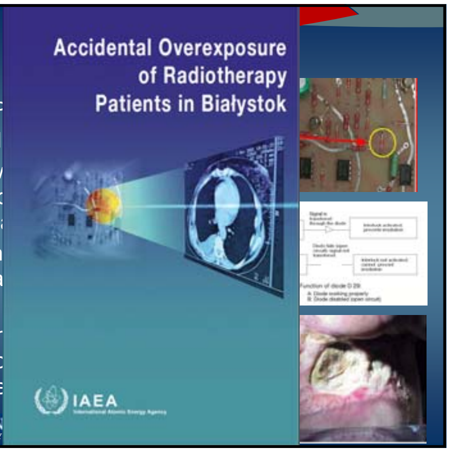
INTERNATIONAL ATOMIC ENERGY AGENCY



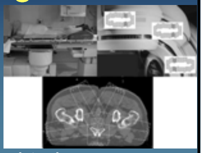
- Location :
- Year : 200
- Issue : TP blocks were entered, a as tried and seemed t
- Conseque calculated incorrectl posure
- Lesson : V econd check of c s

UT SOUTHWESTERN
DEPT OF RADIATION ONCOLOGY

- Location : P
- Year : 2001
- Issue : Pow machine inc dose rate ha
- Consequen increased a overdosed.
- Lesson : Ch repairs befo service/inve



Procedure change



- Location : France
- Year : 2004
- Issue : Clinic moved from physical wedges to dynamic wedges for prostate treatment, but MU continued to be calculated for physical wedges
- Consequences : Overdoses of 20 – 30%; 1 patient died, others with severe complications
- Lesson : Validate procedure changes, independent calculation

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE
S. Derreumaux*, C. Etard, C. Huet, et al.
Institut de Radioprotection et de Su˘ rete´ Nucle´aire, Direction de la Radioprotection de l'Homme, IRSN, BP 17, F-92262 Fontenay-aux-Roses Cedex, France
Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135

Improper Jaw Size During SRS

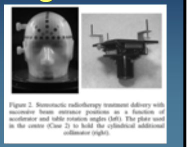


Figure 2. Stereotactic radiotherapy treatment delivery with successive beam entrance positions as a function of accelerator and table rotation angles (left). The plate used in the centre (Case 2) to hold the cylindrical additional collimator (right).

- Location : France
- Year : 2004
- Issue : Physicist told therapist to set a "40x40" for cone SRS treatment; therapist set 40x40 cm^2
- Consequences : Some normal tissue received more dose than the target; developed "fibrosis and oeso-tracheal fistula" requiring surgery; patient died from "brutal haemorrhage" a few days after surgery
- Lesson : Have clear procedures/checklists in place

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Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135

Miscalibration

77 Moffitt patients get excess radiation

Errors in a machine's installation caused the patients to get radiation doses 50 percent more powerful than prescribed.

By MICHAEL VAN SICKLER, Times Staff Writer
Published April 2, 2005

- Location : Florida
- Year : 2004-2005
- Issue : Miscalibration of linac
- Consequences : 77 patients received a 50% overdose
- Lesson : Get independent/second check of the output (RPC)

Procedure change

- Location : Glasgow, Scotland
- Year : 2005
- Issue : Treatment parameters manually transferred incorrectly after R&V upgrade
- Consequences : One patient received ~60% overdose to the whole brain and died
- Lesson : Independent check of calculations/understand procedure changes

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- L c

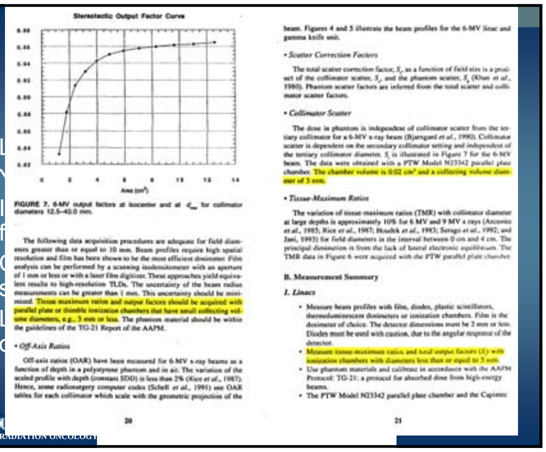

FIGURE 7. 6-MV output factors at isocenter and at d_{max} for collimator diameters 12.5–40.0 mm.

The following data acquisition procedures are adequate for field diameters greater than or equal to 10 mm. Beam profiles require high spatial resolution and film has been shown to be the most efficient dosimeter. Film analysis can be performed by a scanning isodensitometer with an aperture of 1 mm or less or with a laser film digitizer. These approaches yield equivalent results to high-resolution TLDs. The uncertainty of the beam radius measurements can be greater than 1 mm. This uncertainty should be minimized. Tissue maximum ratios and output factors should be acquired with parallel plate or thimble ionization chambers that have small collecting volume diameters, e.g., 3 mm or less. The phantom material should be within the guidelines of the TG-21 Report of the AAPM.

• *Off-Axis Ratios*

Off-axis ratios (OAR) have been measured for 6-MV x-ray beams as a function of depth in a polystyrene phantom and in air. The variation of the scaled profile with depth (constant SDD) is less than 2% (*Rice et al.*, 1987). Hence, some radiosurgery computer codes (Schell *et al.*, 1991) use OAR tables for each collimator which scale with the geometric projection of the

20

beam. Figures 4 and 5 illustrate the beam profiles for the 6-MV linac and gamma knife unit.

• *Scatter Correction Factors*

The total scatter correction factor, $S_{c,p}$ as a function of field size is a product of the collimator scatter, S_c, and the phantom scatter, S_p (Khan *et al.*, 1980). Phantom scatter factors are inferred from the total scatter and collimator scatter factors.

• *Collimator Scatter*

The dose in phantom is independent of collimator scatter from the tertiary collimator for a 6-MV x-ray beam (Bjarngard *et al.*, 1990). Collimator scatter is dependent on the secondary collimator setting and independent of the tertiary collimator diameter. S_c is illustrated in Figure 7 for the 6-MV beam. The data were obtained with a PTW Model N23342 parallel plate chamber. The chamber volume is 0.02 cm^3 and a collecting volume diameter of 3 mm.

• *Tissue-Maximum Ratios*

The variation of tissue-maximum ratios (TMR) with collimator diameter at large depths is approximately 10% for 6 MV and 9 MV x rays (Arcovito *et al.*, 1985; Rice *et al.*, 1987; Houdek *et al.*, 1983; Serago *et al.*, 1992; and Jani, 1993) for field diameters in the interval between 0 cm and 4 cm. The principal diminution is from the lack of lateral electronic equilibrium. The TMR data in Figure 6 were acquired with the PTW parallel plate chamber.

B. Measurement Summary

1. Linacs

- Measure beam profiles with film, diodes, plastic scintillators, thermoluminescent dosimeters or ionization chambers. Film is the dosimeter of choice. The detector dimensions must be 2 mm or less. Diodes must be used with caution, due to the angular response of the detector.
- Measure tissue-maximum ratios and total output factors (S_t) with ionization chambers with diameters less than or equal to 3 mm.
- Use phantom materials and calibrate in accordance with the AAPM Protocol: TG-21: a protocol for absorbed dose from high-energy beams.
- The PTW Model N23342 parallel plate chamber and the Capintec

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Publicity

2/25/2010 Missouri Hospital Reports Errors in Ra…

The New York Times Reprints

INCLUDING BEST ACTOR JEFF BRIDGES

February 24, 2010

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ

Who's responsible?

The New York Times

Radiation Errors Reported in Missouri

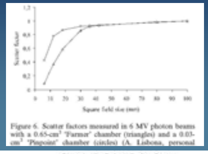


Figure 6. Scatter factors measured in 6 MV photon beams with a 0.65-cm³ 'Farmer' chamber (triangles) and a 0.03-cm³ 'Pinpoint' chamber (circles) (A. Lisbona, personal

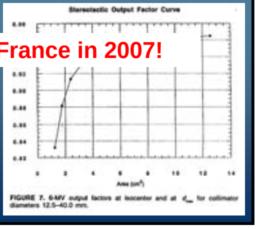


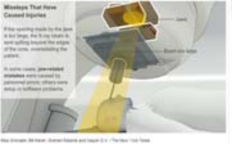
FIGURE 7. 6-MV output factors at isocenter and at d_{max} for collimator diameters 12.5–40.0 mm.

This happened in France in 2007!

Improper Jaw Size During SRS

The New York Times

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing



- Location : United States

This occurred in France in 2004!

- using cones were left open during treatment
- Consequences : Patient "is in a nursing home, nearly comatose…"
- Lesson : Interlocks needed, better communication, standardized procedures

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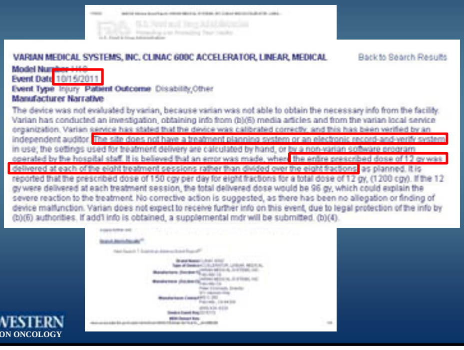
Miscalibration

91 of 223 dead

Final report finds T&T cancer patients suffered severe radiation injuries at Lara Treatment Centre

- Location : Trinidad and Tobago
- Year : 2009 - 2010
- Issue : Linac miscalibrated, skipped annual QA
- Consequences : 223 patients received overdoses ranging from 4 – 20% (13.9%)
- Lesson : IAEA report pending

How many don't we know about?



VARIAN MEDICAL SYSTEMS, INC. CLINAC 600C ACCELERATOR, LINEAR, MEDICAL

Back to Search Results

Model Number 1110

Event Date 10/15/2011

Event Type Injury **Patient Outcome** Disability,Other

Manufacturer Narrative

The device was not evaluated by varian, because varian was not able to obtain the necessary info from the facility. Varian has conducted an investigation, obtaining info from (b)(6) media articles and from the varian local service organization. Varian service has stated that the device was calibrated correctly, and this has been verified by an independent auditor. The site does not have a treatment planning system or an electronic record-and-verify system in use; the settings used for treatment delivery are calculated by hand, or by a non-varian software program operated by the hospital staff. It is believed that an error was made, where the entire prescribed dose of 12 gy was delivered at each of the eight treatment sessions rather than divided over the eight fractions as planned. It is reported that the prescribed dose of 150 cgy per day for eight fractions for a total dose of 12 gy, (1200 cgy). If the 12 gy were delivered at each treatment session, the total delivered dose would be 96 gy, which could explain the severe reaction to the treatment. No corrective action is suggested, as there has been no allegation or finding of device malfunction. Varian does not expect to receive further info on this event, due to legal protection of the info by (b)(6) authorities. If add'l info is obtained, a supplemental mdr will be submitted. (b)(4).

Wrong Interlock Board Installed

- Location : United States
- Year : 1991[a]
- Issue : An interlock board intended for a Varian Clinac 2100C was placed in a Clinac 1800
- Consequences : Output of the Clinac 1800 increased over 100%, but was caught during a routine constancy check
- Lesson : QA procedures work!

[a] Berkley LW and Purdy JA. The need for better communication between accelerator manufacturers and in-house service engineers. MEDICAL PHYSICS 18(3), May/June 1991, p. 608.

W ed

- Location
- Year : 2
- Issue : A ning software
- Conseq ed to 15% underdo ssioning measure
- Lesson

VARIAN medical systems

Urgent Field Safety Notice

Subject: Eclipse: Incorrect Monitor Unit calculation for Multiple Static Segments dynamic MLC fields

Affected Product: Eclipse version 8.5 build 8.2.2.X with Distributed Calculation Framework (DCF) 8.2.22

Affected Devices: see Appendix

FSCA Identifier: CP-00796

Date of Notification: 02 October 2008

Contact Information: Varian Oncology Helpdesk - 888-VARIAN5 (888-827-4265)
Email: tps.support@as.varian.com or onc.helpdesk@varian.com

We are writing to advise you that an anomaly regarding *Incorrect Monitor Unit calculation for Multiple Static Segments dynamic MLC fields* has been identified in *Distributed Calculation Framework (DCF) 8.2.22*. This advisory notice is to provide you with a description of the anomaly, to explain corrective actions, and to advise you of the steps Varian is taking to address the issue.

Anomaly:

An anomaly was discovered in the Varian Leaf Motion Calculator (LMCV) component of the Distributed Calculation Framework (DCF) version 8.2.22. It incorrectly calculates Monitor Units (MU) for IMRT, electronic compensator and irregular surface compensator fields calculated using the Multiple Static Segments (MSS) delivery technique. LMCV is the leaf motion calculator used in Eclipse for Varian, BrainLAB and Mitsubishi Multiple Leaf Collimator (MLC) models only. LMCV is not used for MLC models from other manufacturers.

Although the MU are incorrectly calculated by LMCV when the MSS delivery technique is used, the dose distribution and absolute dose displayed in Eclipse are as expected. If the plan is approved and is used for patient treatment, the dose delivered to the patient will be different than what is shown in Eclipse. The magnitude of the error is field dependent and a function of the fluence complexity. For single carriage group MSS fields, the MU displayed in Eclipse are always lower than they should be, which means that the dose delivered to the patient with these incorrect MU will be lower than what is displayed in Eclipse. For multiple carriage group MSS fields, the magnitude of the error is different from carriage group to carriage group in the same field. The MU can be under-estimated or over-estimated for the different carriage groups in a given field. The discrepancy in the plan is a mixture of over dosed and under dosed areas.

RapidArc calculations are not affected by this anomaly.

IMRT, Electronic Compensator and Irregular Surface Compensator plans calculated with the Sliding Window (SW) delivery technique are not affected by this anomaly.

MSS fields created using the Field in Field planning technique are not affected by the anomaly.

LMCV is used with Varian, BrainLAB and Mitsubishi MLC models only. When calculating IMRT, Electronic Compensator, Field in Field and Irregular Surface Compensator fields for MLCs from other

CP-00796 Page 1 of 3

QA Procedures do work!

- But they must be in place!
- They must be followed!
- "… routine quality assurance procedures would have stopped most of the horrific events that have happened in radiation therapy."*
- Where can we find guidance and recommendations for implementing well-thought out and comprehensive QA procedures and policies?

* Eric Klein, Point/Counterpoint, Med Phys (38)11.

Sources of Guidance

- AAPM
- ACR
- ASTRO

AAPM Task Groups

- TG25 and TG70 – electrons
- TG42 - SRS
- TG53 – QA for TPS
- TG40, TG45, TG142 – linacs
- TG101 – SBRT
- TG103 – physicist peer review
- TG106 – linac commissioning
- TG114 – MU verification for non-IMRT
- TG119 – IMRT commissioning

Task Group 40 Outline*

- Comprehensive QA Program
- QA of EBRT Equipment
- Treatment Planning Computer System
- External Beam Treatment Planning
- Brachytherapy
- QA of Clinical Aspects

*TG142 has updated the TG40 recommendations

Role of Radiation Oncologists

- Patient consultations
- Prescribe dose
- On treatment supervision
- Treatment summary
- Follow-up evaluations
- Experienced radiation oncologists can detect overdoses of 10% during OTV

Role of Medical Physicists

- Calibration of therapy equipment
- Specifications of therapy equipment
- Acceptance testing, commissioning, and QA
- Treatment planning
- Weekly chart checks
- Outline written QA procedures

Role of Dosimetrists

- Accurate patient data acquisition
- Treatment planning
- Documentation of treatment plan

Role of Therapists

- Accurate delivery of planned course of radiation therapy
- Recognize any change in patient's condition
- Detect any equipment malfunctions
- Understand safe operating limits of equipment
- Understand treatment planning methods

TG 142 Recommendations

- A comprehensive QA program
- QA team to draft policies and procedures
- Establish baseline reference values for QA measurements
- Qualified Medical Physicist should lead the QA team
- End to end system check recommended any time a new or revised procedure is introduced

QA Program

- Should be written
- Detail all tests and procedures, their frequency, action criteria, and records required
- Personnel to perform the tests

QA Committee

- At least one physician, one therapist, one physicist and one dosimetrist
- Oversees the QA program
- Set action levels and define actions to correct problems
- Review instances where action levels are exceeded or errors are made
- Led by QMP

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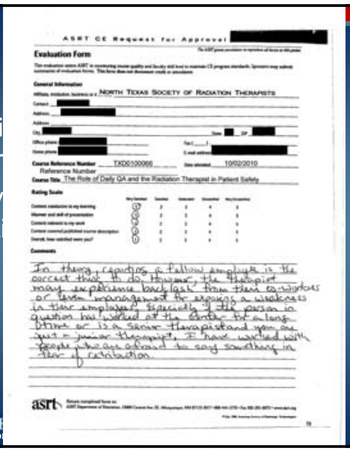

ASRT CE Request for Approval [redacted]

Evaluation Form

General Information

NORTH TEXAS SOCIETY OF RADIATION THERAPISTS

Contact [redacted]

Address [redacted]

City [redacted] State [redacted] ZIP [redacted]

Office phone [redacted]

Home phone [redacted]

E-mail address [redacted]

Course Reference Number TXD0100066 **Date attended** 10/02/2010

Reference Number

Course Title The Role of Daily QA and the Radiation Therapist in Patient Safety

Rating Scale

Comments

In theory, reporting a fellow employee is the correct thing to do. However, the therapist may experience backlash from their co-workers or team management for exposing a weakness in their employee, especially if the person in question has worked at the center for a long time or is a senior therapist and you are just a junior therapist. I have worked with people who are afraid to say something in fear of retribution.

asrt

Quality Audit

- Performed at the frequency stated in the policies and procedures manual
- JCAHO requires at least an annual reappraisal of the radiation oncology QA program as part of hospital's QA program annual review
- Performed by an outside group whenever possible

QA of external beam radiation therapy equipment

- Consists primarily of evaluating the functional performance characteristics
- Influence the geometric and dosimetric accuracy of the dose given to patients

Functional Performance Characteristics

- Can change suddenly due to electronic malfunction, component failure, or mechanical breakdowns
- Can change slowly due to deterioration and aging of components

Frequency of Tests

- Based on likelihood of failure or change
- Based on severity of impact on the patient

Are these procedures outdated?

Big mistakes today usually result from:

1. Mistakes made during commissioning: Wrong dosimeter to calibrate a stereotactic radiosurgery (SRS) beam; corrupted computer file or software bug; not understanding a "hidden equation" underlying an Excel spread sheet, or the data format required for a computer program.
2. Being rushed or complacent and not following existing procedures.

Amols HI and Klein EE. QA procedures in radiation therapy are outdated and negatively impact the reduction of errors. Med Phys 38(11), 5835 – 5837, 2011.

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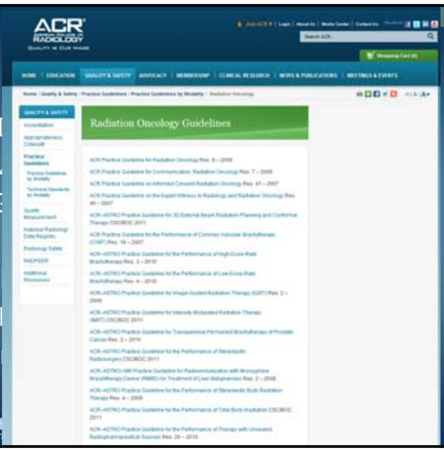

Radiation Oncology Guidelines

UT SOUTH
DEPT OF RADIA

ASTRO

- ASTRO's Six Point Action Plan
- Target Safely – IMRT Safety White Paper
- Target Safely – SBRT/SRS Safety White Paper
- ASTRO – Safety is no accident – A framework for quality radiation oncology and care

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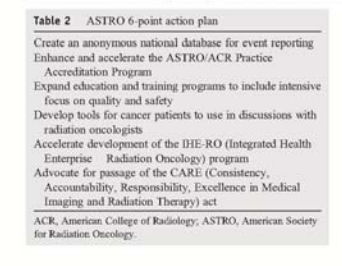
ASTRO's Six Point Action Plan



Practical Radiation Oncology: January-March 2011

Table 2 ASTRO 6-point action plan

Create an anonymous national database for event reporting
Enhance and accelerate the ASTRO/ACR Practice Accreditation Program
Expand education and training programs to include intensive focus on quality and safety
Develop tools for cancer patients to use in discussions with radiation oncologists
Accelerate development of the IHE-RO (Integrated Health Enterprise Radiation Oncology) program
Advocate for passage of the CARE (Consistency, Accountability, Responsibility, Excellence in Medical Imaging and Radiation Therapy) act

ACR, American College of Radiology; ASTRO, American Society for Radiation Oncology.

Hendee WR and Herman MG. Improving patient safety in Radiation Oncology. Med Phys 38(1): 78-82, 2011

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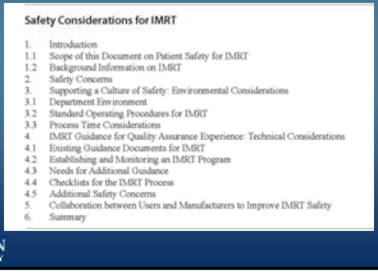
IMRT White Paper

- Moran et al. Safety considerations for IMRT. PRO 2011.



Safety Considerations for IMRT

1. Introduction
1.1 Scope of this Document on Patient Safety for IMRT
1.2 Background Information on IMRT
2. Safety Concerns
3. Supporting a Culture of Safety: Environmental Considerations
3.1 Department Environment
3.2 Standard Operating Procedures for IMRT
3.3 Process Time Considerations
4. IMRT Guidance for Quality Assurance Experience: Technical Considerations
4.1 Existing Guidance Documents for IMRT
4.2 Establishing and Monitoring an IMRT Program
4.3 Needs for Additional Guidance
4.4 Checklists for the IMRT Process
4.5 Additional Safety Concerns
5. Collaboration between Users and Manufacturers to Improve IMRT Safety
6. Summary

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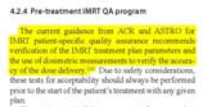
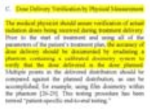
IMRT White Paper

- Recommendations for IMRT QA



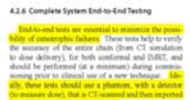
4.2.4 Pre-treatment IMRT QA program

The current guidance from ACR and ASTRO for IMRT patient-specific quality assurance recommends verification of the IMRT treatment plan parameters and the use of dosimetric measurements to verify the accuracy of the dose delivery.[24] Due to safety considerations, these tests for acceptability should always be performed prior to the start of the patient's treatment with any given plan.



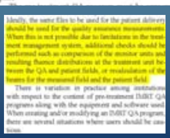
C. Dose Delivery Verification by Physical Measurement

The medical physicist should assure verification of actual radiation doses being received during treatment delivery. Prior to the start of treatment and using all of the parameters of the patient's treatment plan, the accuracy of dose delivery should be documented by irradiating a phantom containing a calibrated dosimetry system to verify that the dose delivered is the dose planned. Multiple points in the delivered distribution should be compared against the planned distribution, as can be accomplished, for example, using film dosimetry within the phantom [20-29]. This testing procedure has been termed "patient-specific end-to-end testing."



4.2.6 Complete System End-to-End Testing

End-to-end tests are essential to minimize the possibility of catastrophic failures. These tests help to verify the accuracy of the entire chain (from CT simulation to dose delivery), for both conformal and IMRT, and should be performed (at a minimum) during commissioning prior to clinical use of a new technique. Ideally, these tests should use a phantom, with a detector (to measure dose), that is CT-scanned and then imported into the treatment planning system.



Ideally, the same files to be used for the patient delivery should be used for the quality assurance measurements. When this is not possible due to limitations in the treatment management system, additional checks should be performed such as comparison of the monitor units and resulting fluence distributions at the treatment unit between the QA and patient fields, or recalculation of the beams for the measured field and the patient field.

There is variation in practice among institutions with respect to the content of pre-treatment IMRT QA programs along with the equipment and software used. When creating and/or modifying an IMRT QA program, there are several situations where users should be cautious.

ACR

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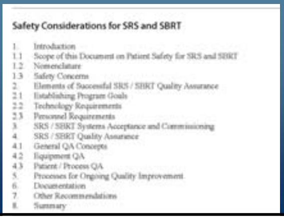
SRS/SBRT White Paper

- Solberg et al. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy. PRO 2012.



Safety Considerations for SRS and SBRT

1. Introduction
1.1 Scope of this Document on Patient Safety for SRS and SBRT
1.2 Nomenclature
1.3 Safety Concerns
2. Elements of Successful SRS / SBRT Quality Assurance
2.1 Establishing Program Goals
2.2 Technology Requirements
2.3 Personnel Requirements
3. SRS / SBRT Systems Acceptance and Commissioning
4. SRS / SBRT Quality Assurance
4.1 General QA Concepts
4.2 Equipment QA
4.3 Patient / Process QA
5. Processes for Ongoing Quality Improvement
6. Documentation
7. Other Recommendations
8. Summary

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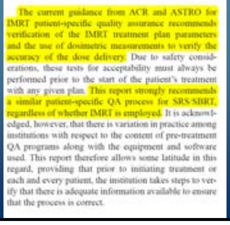
SRS/SBRT White Paper

- Focus on personnel and technology requirements
- Commissioning/credentialing



The current guidance from ACR and ASTRO for IMRT patient-specific quality assurance recommends verification of the IMRT treatment plan parameters and the use of dosimetric measurements to verify the accuracy of the dose delivery. Due to safety considerations, these tests for acceptability must always be performed prior to the start of the patient's treatment with any given plan. This report strongly recommends a similar patient-specific QA process for SRS/SBRT, regardless of whether IMRT is employed. It is acknowledged, however, that there is variation in practice among institutions with respect to the content of pre-treatment QA programs along with the equipment and software used. This report therefore allows some latitude in this regard, providing that prior to initiating treatment on each and every patient, the institution takes steps to verify that there is adequate information available to ensure that the process is correct.

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Appendix 2—Institution 1: Spine SBRT worklist example

SBRT Spine Worklist:

Patient Name: ______________ MR#: ______________

Date of Implant: ______________ Target Area: ______________

Rad Oncologist: ______________

Preplan:
Planned Dose/ Fractions: ______________
Markers to Surgery (3 pre-loaded needles)
Load Pet, MRI, to iPlan.

Target Volume & Coverage:		**IMRT Constraints Volume/ Dose**
Review and approve Image Fusion	______	PTV 18 Gy at 50%
PTV = 1-5 mm margin on GTV (per case)	______	Spinal Canal (listed below Volume
%/ Dose %):		
Table and External Are edited	______	100%/0%, 90%/25%, 55%/30%,
20%/5%, 40%, 0%		
Patient localized to BB marks	______	Esophagus (listed below Volume
%/ Dose %):		
At least 7 beams, (or at least 340 Deg of arc)	______	100%/0%, 90%/25%, 60%/35%,
40%/5%, 50%, 0%		
RX line is between 70-90% (100% is at center)	______	Start 25 Step-n-Shoot segments
Hot spots is in the PTV	______	Adaptive Resolution
Rx isodose cover approximately 95% of PTV	______	
90% of PTV gets at least 90% of RX dose	______	

Normal Tissue Contraints:
Cord: (contoured as canal +/- 6 mm of PTV length) ______
< 10% of canal at 10 Gy (8Gy for Rx 14Gy) ______
Transection canal < 8 Gy (6 Gy if RX is 14 Gy) ______
Lung: Both lungs as one structure (no dose limits) ______
Esophagus: +/-10 cm of PTV length: Max 10 Gy to > 2cc ______
Other: Heart, Bowel Liver, Kidney, Brachial plexus, Max Surface dose, stomach.

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TARGETING CANCER CARE

SAFETY
IS NO
ACCIDENT

A FRAMEWORK FOR
QUALITY RADIATION
ONCOLOGY AND CARE

DEVELOPED AND ENDORSED BY:

Minimum Process Time

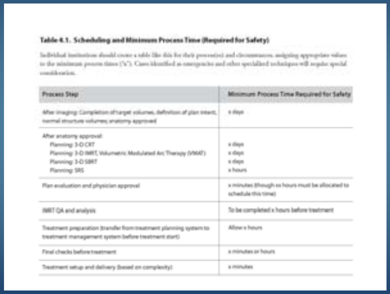


Table 4.1. Scheduling and Minimum Process Time (Required for Safety)

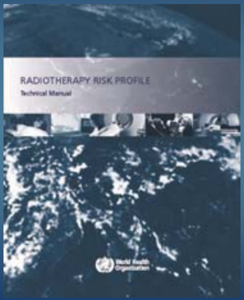
Individual institutions should create a table like this for their procedure(s) and circumstances, assigning appropriate values to the minimum process times ("x"). Cases identified as emergencies and other specialized techniques will require special consideration.

Process Step	Minimum Process Time Required for Safety
After imaging: Completion of target volumes, definition of plan intent, normal structure volumes; anatomy approved	x days
After anatomy approval: Planning: 3-D CRT Planning: 3-D IMRT, Volumetric Modulated Arc Therapy (VMAT) Planning: 3-D SBRT Planning: SRS	 x days x days x days x hours
Plan evaluation and physician approval	x minutes (though xx hours must be allocated to schedule this time)
IMRT QA and analysis	To be completed x hours before treatment
Treatment preparation (transfer from treatment planning system to treatment management system before treatment start)	Allow x hours
Final checks before treatment	x minutes or hours
Treatment setup and delivery (based on complexity)	x minutes

Staffing

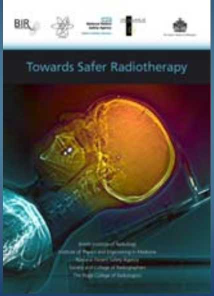
A sample worksheet for calculating medical physics and dosimetry staffing in radiation oncology:

International Resources



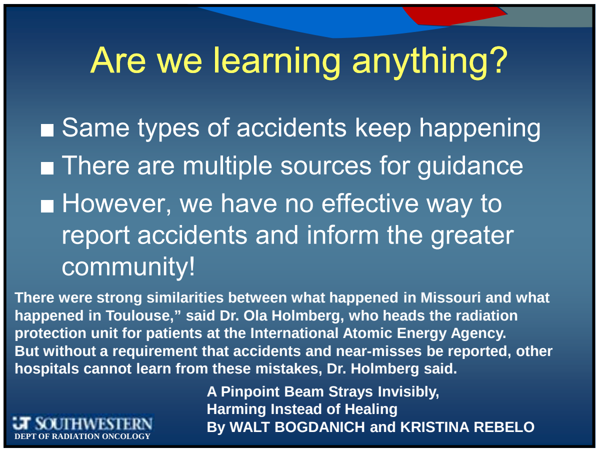
RADIOTHERAPY RISK PROFILE
Technical Manual

World Health Organization



BIR

Towards Safer Radiotherapy



Are we learning anything?

- Same types of accidents keep happening
- There are multiple sources for guidance
- However, we have no effective way to report accidents and inform the greater community!

There were strong similarities between what happened in Missouri and what happened in Toulouse," said Dr. Ola Holmberg, who heads the radiation protection unit for patients at the International Atomic Energy Agency.
But without a requirement that accidents and near-misses be reported, other hospitals cannot learn from these mistakes, Dr. Holmberg said.

A Pinpoint Beam Strays Invisibly,
Harming Instead of Healing
By WALT BOGDANICH and KRISTINA REBELO

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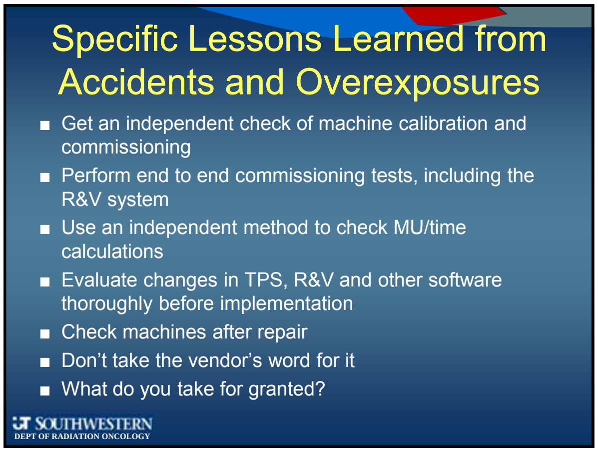

Specific Lessons Learned from Accidents and Overexposures

- Get an independent check of machine calibration and commissioning
- Perform end to end commissioning tests, including the R&V system
- Use an independent method to check MU/time calculations
- Evaluate changes in TPS, R&V and other software thoroughly before implementation
- Check machines after repair
- Don't take the vendor's word for it
- What do you take for granted?

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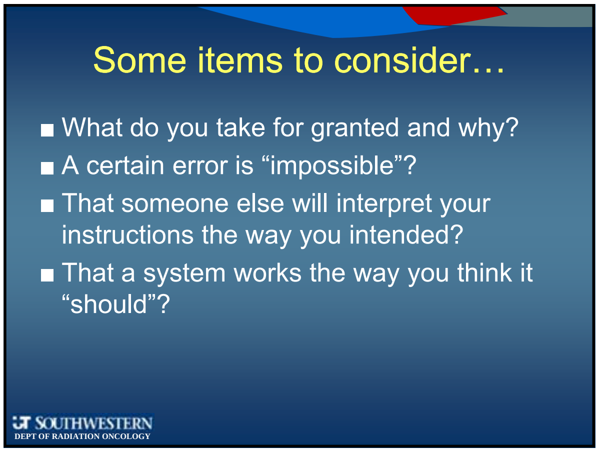

Some items to consider…

- What do you take for granted and why?
- A certain error is "impossible"?
- That someone else will interpret your instructions the way you intended?
- That a system works the way you think it "should"?

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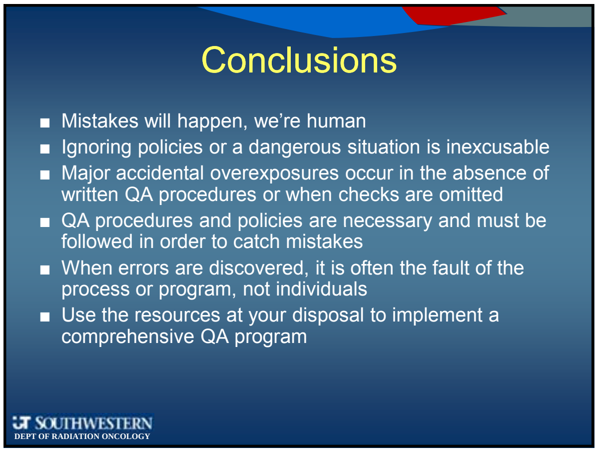

Conclusions

- Mistakes will happen, we're human
- Ignoring policies or a dangerous situation is inexcusable
- Major accidental overexposures occur in the absence of written QA procedures or when checks are omitted
- QA procedures and policies are necessary and must be followed in order to catch mistakes
- When errors are discovered, it is often the fault of the process or program, not individuals
- Use the resources at your disposal to implement a comprehensive QA program

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