Patient Risk (Safety) in Radiation Therapy

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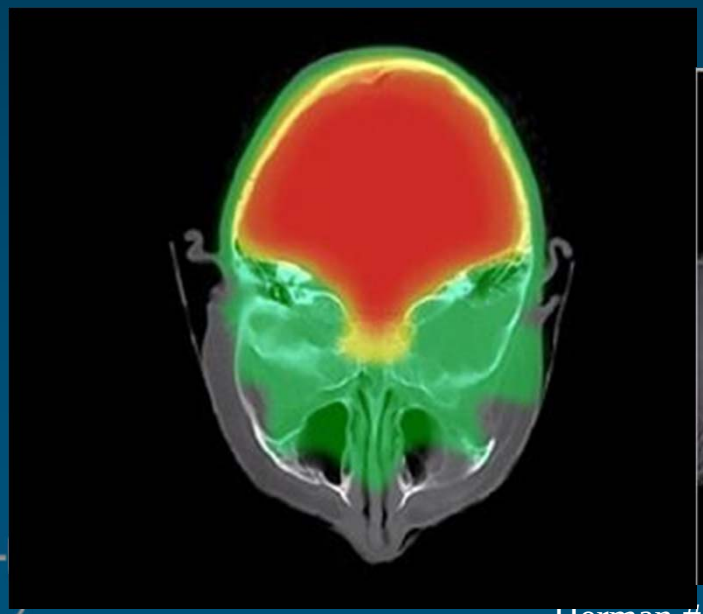
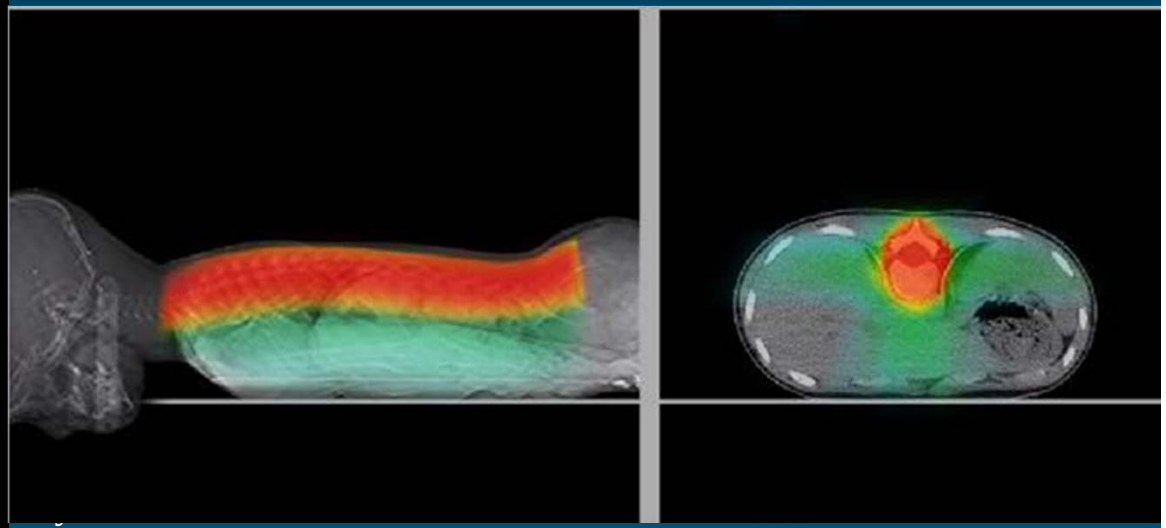
Outline

- Radiation Therapy
- What Can/Did Happen?
- Is Patient Safety at Risk?
- What Have We Learned/Done?

Radiation Therapy

- Delivery of therapeutic (2-80Gy) ionizing radiation –photon, electron, proton
- Specifically targeted to conform to tumor and to spare healthy tissue

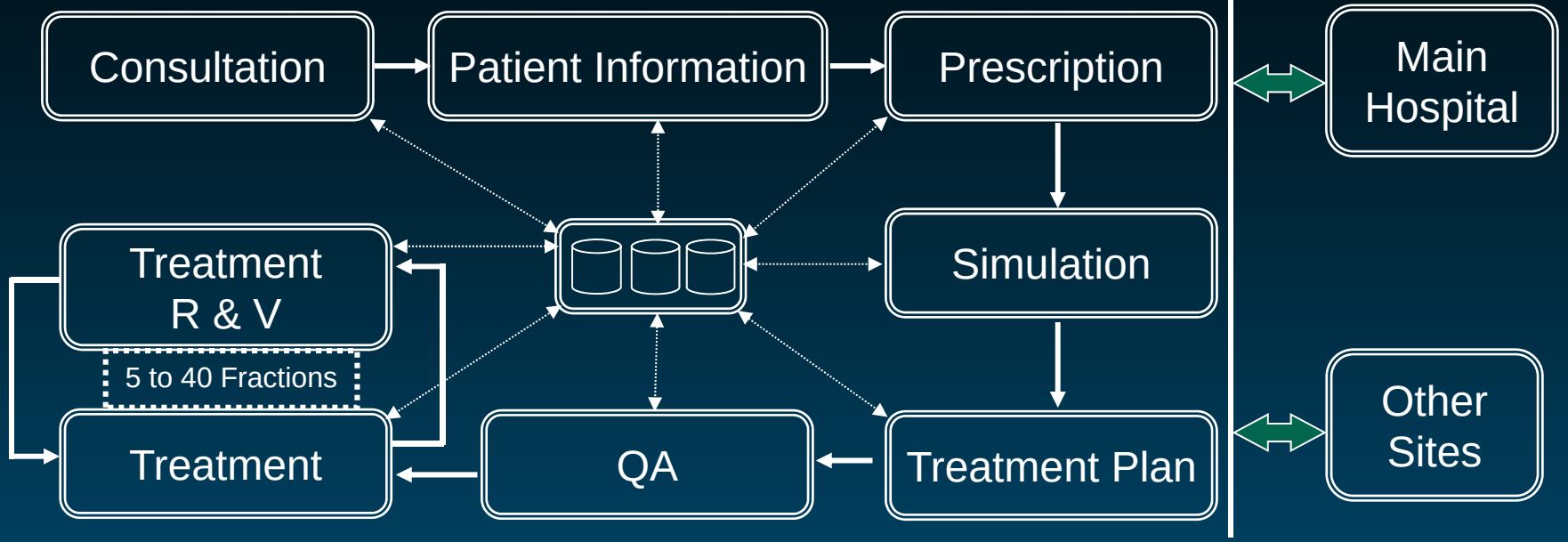




Radiation Therapy

- Has evolved from manual calculations and analogue delivery systems to computer-optimized preparation and computer – controlled delivery

The Radiation Therapy Process



- Different types of cancer
- Different treatment techniques
- Several technologies

Multi- vs. single-vendor environments

Different users:
- Physicians
- Physicists
- Therapists
- Dosimetrists
- IS Staff
- Administrative Staff

Technological Innovations:
- EPID
- kV localize
- CBCT
- Other IGRT

- Research
- Clinical activities

Analysis:
On-line
Off-line

Paper vs. Paperless

A lot of Information
Communication
CUSTOMIZED

Radiation Therapy Team

Assessment/Rx	Physician
Simulation	Physician, Therapist Dosimetrist, Physicist
Dosimetric Planning	Physician, Dosimetrist, Physicist
Treatment Verification/QA	Therapist, Physicist Dosimetrist
Treatment Delivery	Therapist (Physician, Physicist)
Follow Up	Physician

Radiation Therapy IS Safe

- Expectation is that the treatment will be beneficial
- Educated, professional teams deliver millions of treatments safely and effectively each year
- Complex system of technology and humans plus many variables

IS Radiation Therapy Safe?

- The best people + the best technology NOT = the best System!
- SAFE, but not perfect
- There are many causes of errors
- There are many mechanisms by which safety can be improved.

Excerpted/edited from the IAEA Training Course

Prevention of accidental exposure in radiotherapy

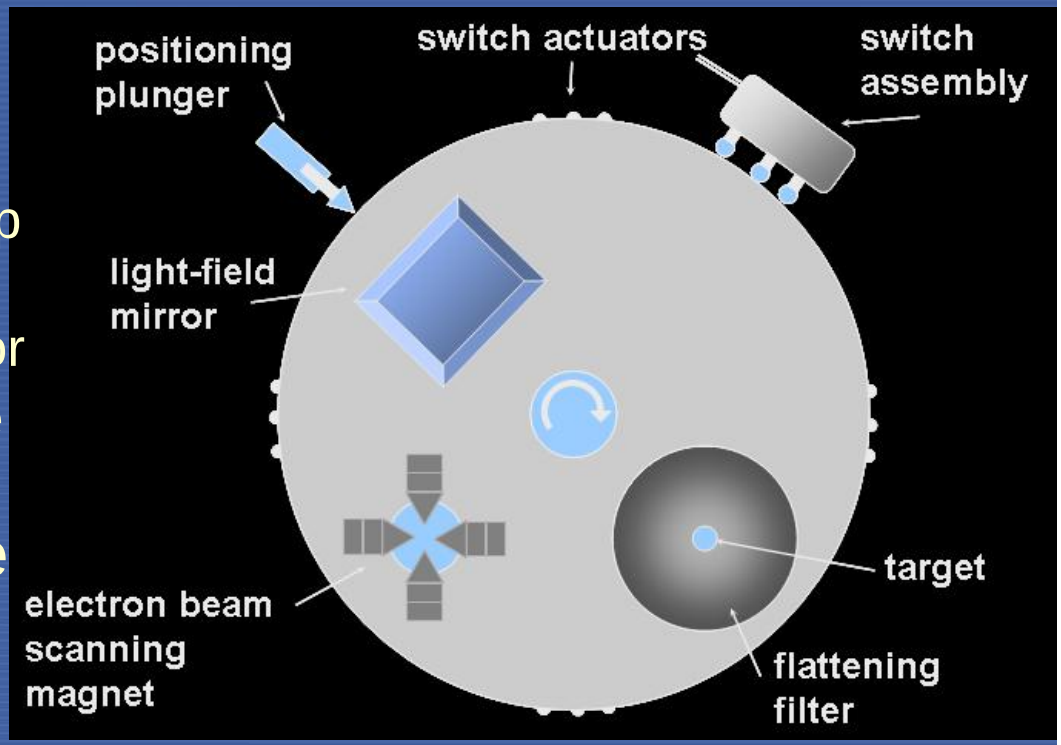
Module 2.3: Accelerator software problems (USA and Canada) Therac 25

IAEA

International Atomic Energy Agency

Background

- Mid 1970s - AECL developed a new double-pass concept for electron acceleration
  - needs less space to develop similar energy levels
  - dual-mode linear accelerator
  - more compact and versatile than the older Therac-20
- Therac 25 took advantage of computer's abilities to control and monitor hardware

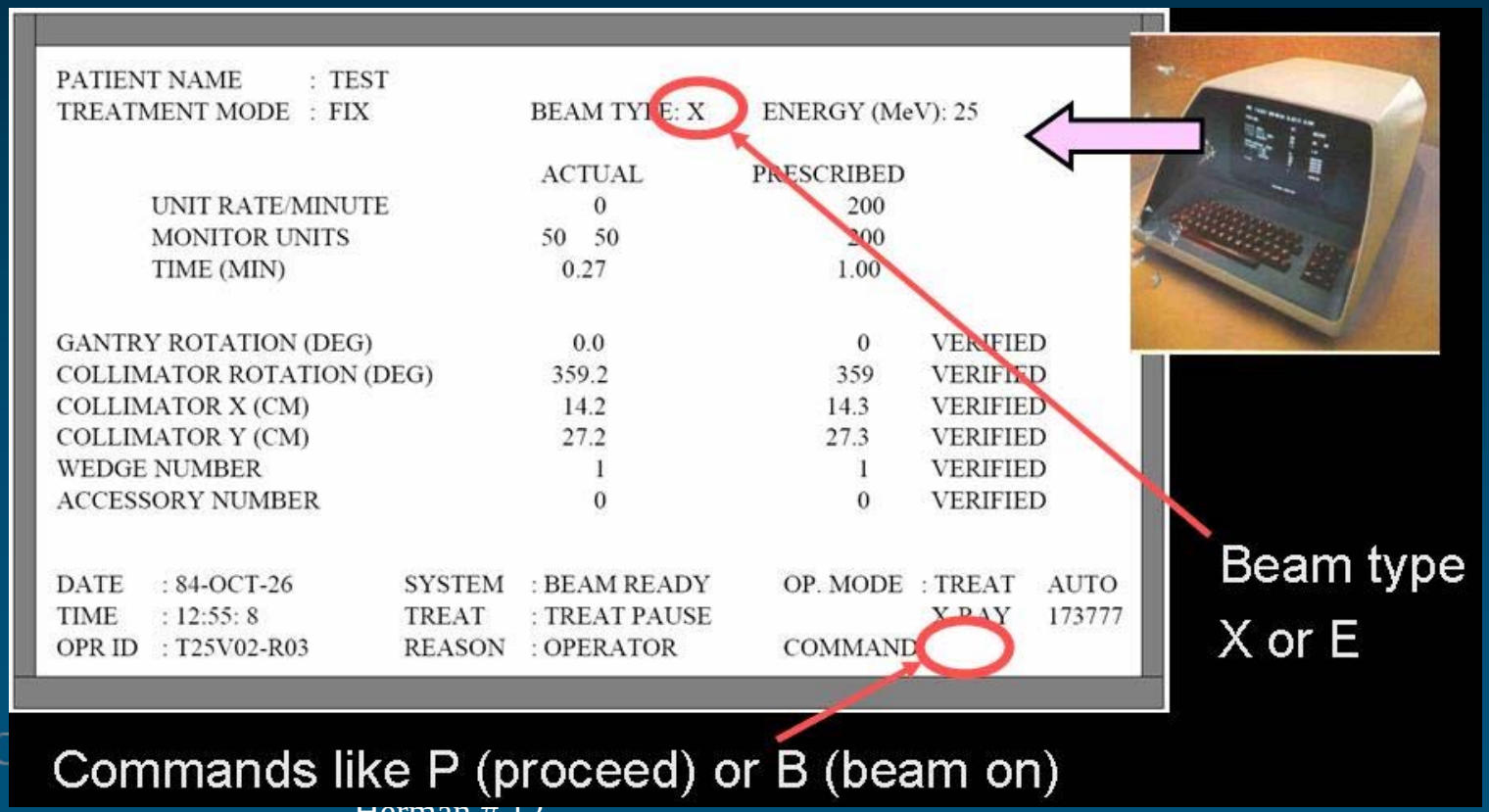


Therac 25 Events

- Marietta, GA – June 1985
  - Patient “burned” by radiation
- Hamilton Ontario – July 1985
  - Machine error, multiple retries, severe patient overdose
- Yakima, WA – December 1985
  - Strange skin reddening pattern, no apparent cause

Therac 25 Events

- Tyler, TX – March 1986
  - Operator edited modality at console
  - Electron patient – felt burned/shocked



Therac 25 Events

March ‘86 Conclusions

- Patient must have received electrical shock!
- No other events known

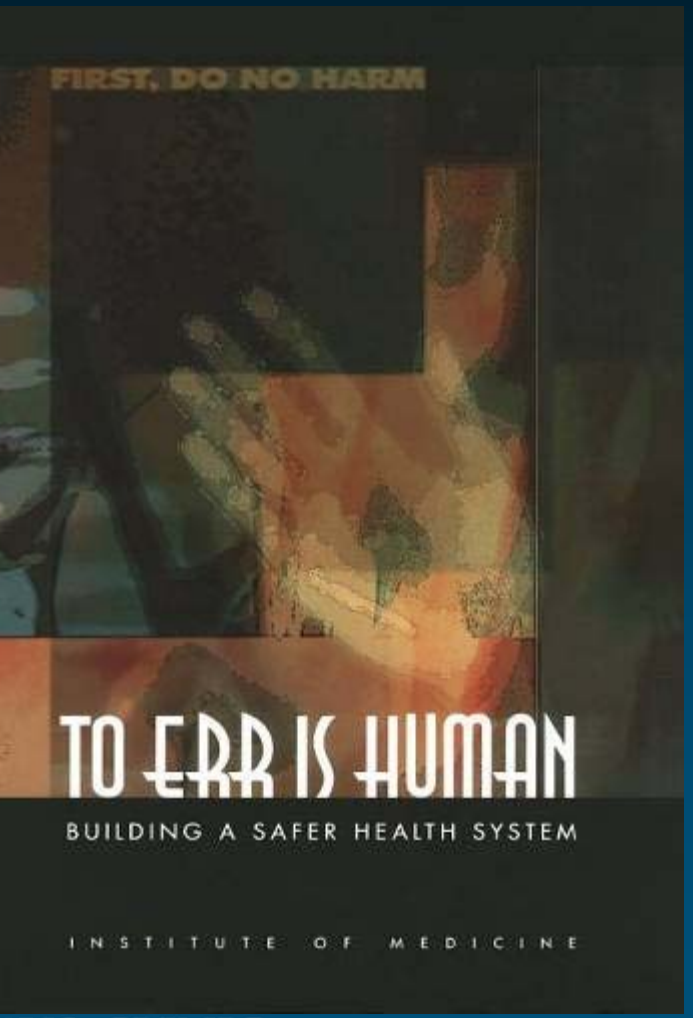
Tyler, TX – April 1986

- Operator edited modality at console
- Electron patient – felt pain/hit in face
- Medical physicist reproduces error
- All Therac 25 units taken out of service

Summary of Therac 25

- Manufacturer recycled software with complete integration testing.
  - Allowed machine to deliver electron beams with photon currents (>100x)
- There was no mechanism for investigating, porting , sharing information on accidents any substantial level.
- July1986 - FDA approved improvements
  - Therac 25 used without reported incident

TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM



OK that was THEN,

1999 - Errors are not caused by bad people, but by bad systems

And Now?

Extracted/Modified from IAEA Training Course

Module 2.10: Accident update – some newer events (UK, USA, France)

IAEA

More Recently

2005 – Incorrect parameter transfer
- Team handoff, new process flow, QA miss
- Dose multiplier occurred twice → 60% O.D.

2007 – Incorrect detector size used
- Large systematic calibration error

2007 – image reversed – wrong site Tx

h example: Incorrect IMRT planning (USA)

IAEA

IMRT Error 2005

March 2005 – Head and neck pt begins normal IMRT treatment – plan had been done, approved and checked per standard practice.

On Tx 4, MD requests plan change (to spare teeth)

New plan done, but system crash during data save – incomplete data saved.

IMRT Error 2005

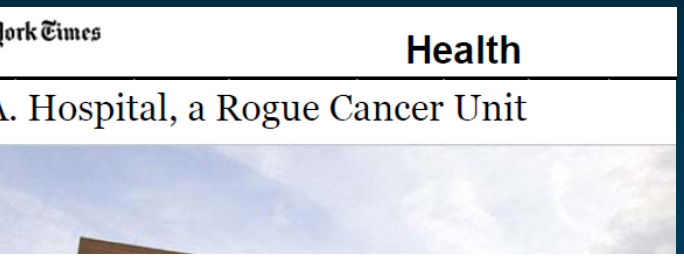
Attempt to recover plan appeared to succeed

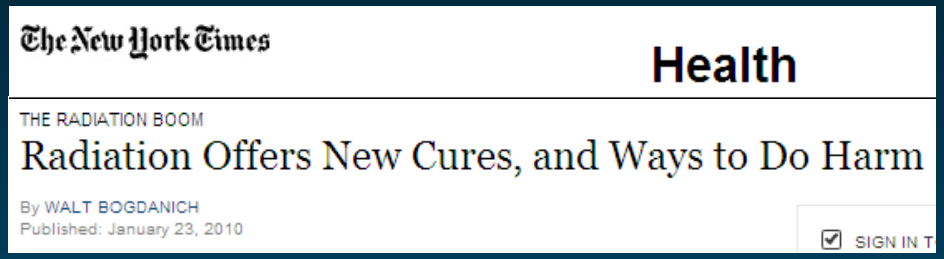
- Planner did not notice subtle differences
- Required second check not performed
- Treating team did not notice missing data
- After 3 more Tx, second check done
- **OH NO!!**

Massive overdose to patient

Attention!

Much has been done on error analysis, reduction, …. BUT


York Times
Health
A. Hospital, a Rogue Cancer Unit


The New York Times
Health
THE RADIATION BOOM
Radiation Offers New Cures, and Ways to Do Harm
By WALT BOGDANICH
Published: January 23, 2010
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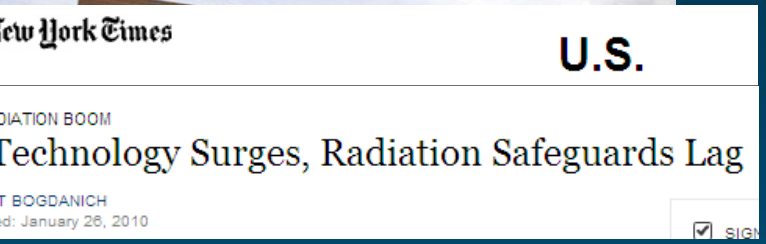
ew York Times
U.S.
DIATION BOOM
Technology Surges, Radiation Safeguards Lag
T BOGDANICH
d: January 26, 2010


The New York Times
U.S.
Radiation Errors Reported in Missouri
By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010
A hospital in Missouri said Wednesday that it had overradiated 76 patients, the vast majority with brain cancer, during a five-year

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February 4, 2010

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Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy

the potential benefits and risks of the use of radiation in medicine.

AYO CLINIC

Radiation Therapy is #1!

OP 10 HEALTH
ECHNOLOGY HAZARDS
OR 2011

eprinted from Volume 39 Issue 11
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erly- Emergency Care Research Institute

1. Radiation Overdose and Other Dose Errors during Radiation Therapy

Radiation misadministration during radiation therapy can have devastating health consequences, from causing critical damage to normal tissue and organs, which can lead to severe morbidity and death, to creating an avenue for disease recurrence through improper or incomplete treatment of a tumor. The

AYO CLINIC

Quantify the Risk?

~ 1500 mild to moderate injuries per million treatment courses (patients) ….
~1% prove to be fatal

– WHO – radiotherapy risk profile 2008.

Compare with IOM report where 10s of thousands of injuries/events per million (for adverse drug reaction for example).

We CAN do better.

Why Does It Happen?

Excerpts from

60 – 80% →Human factors

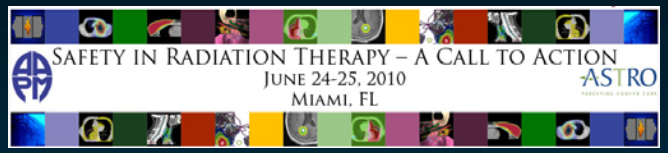
(not) Following policies/procedures

"Errors often follow violations in protocols, particularly failures to perform verification procedures, and indicators that things are not correct are often present yet ignored during events." Thomadsen 2003

No one knows what happened elsewhere

Why Does It Happen?

Excerpts from



Lack of standards
- practice
- regulatory

Limited training and communication

Excessive complexity, problems hidden

Distractions, confusion

Intimidation

Safety in Radiation Therapy: Recommendations

- As complexity increases, control should be simplified
- Use of FMEA and RCA
- Develop a usable reporting system
- Therapist workstation needs human factors engineering
  - Return control to operator at point of care
  - Provide improved early warnings
  - Minimize cognitive clutter

BM, ASA, LFS, DLS

Practice Values: Safety, Accuracy, and Efficiency

External Beam dSOP Reporting Form (Pote

dSOP: deviation from Standard Operating Proced

e-submission: Complete page one, then select the "**Submit by**
If prompted, select "**Desktop Email Application**" as the em

FX #: **Anatomic Site:**

te: **Time:** **By Whom:**

overed during: (program

Procedure Type:
(mark all that apply)

TBI	4DCT	SBRT
TSE	Sim/TX (calc only)	Complex (non-3D
IORT	Sim/TX (with plan)	Field-in-Field

the dSOP, how it was discovered, and initial actions taker

If the dSOP is adverse, please complete the *Radiation Oncology Manage*

g form, place completed form in drop-box outside therapis

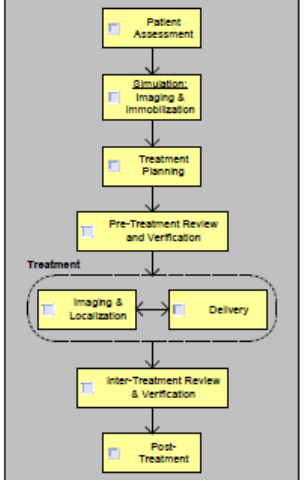
SIG Group

Last Revision: June 21, 2011

Primary Author(s): LBM, ASA, LFS, DLS

THIS PAGE IS FOR USE BY dSOP COMMITTEE ONLY!

Where in Process Flow dSOP Occurred



Root Cause(s)

- New technique, new staff, or trainee involved
- Training
- Poor communication
- Patient Intervention

Working Conditions:
- Messy, noisy, lighting, etc.

Human Factor:
- Fatigue, distraction, stress, transcription

Written Procedure or Checklist:
- Poor quality
- No Written Procedure/Checklist

Equipment/Software:
- Failure or confusing to use
- Poor/incomplete commissioning
- Insufficient resources

Other:

Technology associated with dSOP
(mark all that apply)

- CT Sim
- 4DTC
- GE Adv Sim
- MimVista
- Eclipse
- MOSAIQ
- RadCalc
- Linac
- MLC
- OBI (planar img)
- OBI (CBCT)
- TRAC
- RPM
- Gating
- Other:

Likelihood of Recurrence

dSOP is likely to occur	Score
in the next procedure	4
within next 25 procedures	3
within next 100 procedures	2
not again	1

Score (1 - 4):

Likelihood of QA Failure

QA currently in place will	Score
always miss the dSOP	4
often miss the dSOP	3
occasionally miss the dSOP	2
always catch the dSOP	1

Score (1 - 4):

Actual time required to correct dSOP

Time utilized:	Score
More than 8 cum. hrs	4
More than 2 cum. hrs	3
More than 0.5 cum. hrs	2
None to minimal	1

Score (1 - 4):

Potential Non-Dose Severity

Effect of dSOP on patient / staff / public:	Score
Severe injury or death	16
Injury requiring hospitalization	9
Injury not requiring hospitalization	2
No effect	1

Score (1 - 16):

Potential Dose Severity

Dose error to patient:	Score
> 20%, or a reportable event	16
> 10%	9
> 5%	2
≤ 5% (no violation of regulations)	1

Score (1 - 16):

Primary Group(s) for Follow-Up

- RTT
- Dosimetry
- Physics
- MD
- RN/PA/MLP
- Tech
- Clinical Assistant
- Secretary
- Other:

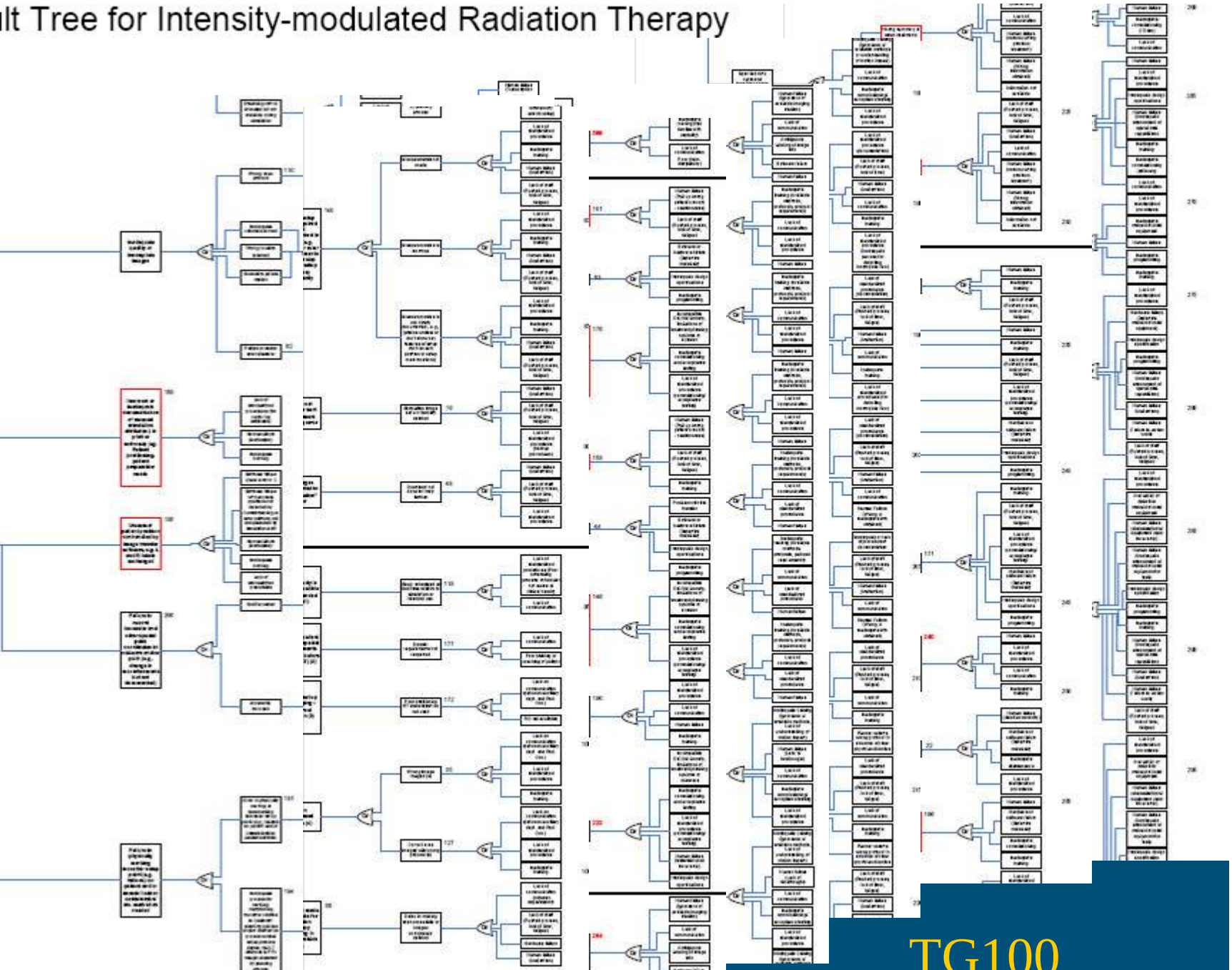
Risk Priority Number (RPN) = Product of five scores above =

Disposition of dSOP after review by SIG: CPC to Review CPC Reviewed

Resolution (e.g., forcing function, automation, protocol, training, etc.):

Export to XML File

lt Tree for Intensity-modulated Radiation Therapy



TG100

Safety in Radiation Therapy: Recommendations (cont'd)

Team covenant and safety commitment

Time outs – called by any team member

Check lists,

Facility accreditation

– audits, SOPs

Profession-sponsored user groups

Safety champions

Safety in Radiation Therapy: Recommendations (cont'd)

- Billing process must be simplified
- Team member qualifications consistency, recognized.
- Improve FDA equipment process
- Vendors should address concerns intelligibly
- Recommend staffing levels (Blue Book revision)

*Hendee & Herman, PRO, MedPhys 2011

Safety in RT

xcerpts from

- Safety can **NOT** be improved by
  - A new QA test
  - Doing only simple procedures
  - Creating error free systems
- A big error can happen to anyone
- We need to continually pursue improvement

ation Level Effort on Patient Safety:

Recognizing Qualifications

demonstrate competence through nationally recognized and consistent qualifications …..

Accreditation

that qualified people in appropriate staffing numbers perform medical radiation procedures following national consensus best, safe practices.

Event Reporting

Uniform, consistent, quantitative, accessible national reporting and notifications

mproved Manufacturing/FDA Process

Long Term, Ongoing

- Radiation Treatment is very safe, it can be better
- There is no overnight, quick fix to improve safety
- We have been working
- All are responsible to be vigilant and to work together to develop safer, more effective use of radiation in medicine.

THANK YOU !

Solutions

Excerpts from

- Central database, updated, analyzed and disseminated – learn from others
- Comply with policy, Follow YOUR QA program – practice standards
- Be alert – computer crash…
- Understand properties/limitations of technology, humans
- Independent checks!

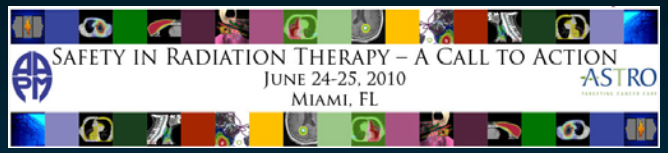
Solutions

Excerpts from

- Consistent regulations and reporting for all therapy machines regardless of the type of device
- Only qualified individuals providing radiation therapy
- Team commitment to quality
- Use checklists, time outs, limit access

Solutions

Excerpts from



- Leaders have to own it
- Safety requires
  - Standardization
  - Accountability
  - Mutual respect
- Vigilance for every team member