Incidents in Radiation Therapy

-

What can be done?

ICTP School on Medical Physics
March 25 – April 5, 2019
Miramare, Trieste

Yakov Pipman, DSc

Many recommendations. Perhaps too many!

Report	Advice
Towards safer Radiotherapy	*37*
Radiotherapy Risk Profile	*15*
Preventing Accidental …..	*15*
Hendee and Herman	*20*
Hierarchy of Actions	*19*
ASTRO	*6*
TG 100	*5*
Total	**117**

frontiers in ONCOLOGY

REVIEW ARTICLE
published: 28 September 2012
doi: 10.3389/fonc.2012.00129

Recommendations for safer radiotherapy: what's the message?

*Peter Dunscombe**

Education/ Training (7)

Staffing/skills mix(6)

Documentation/SOP (5)

Incident Learning System (5)

Communication/questioning (4)

Check lists (4)

QC and PM (4)

Dosimetric Audit(4)

Accreditation (4)

Minimizing interruptions (3)

Prospective risk assessment (3)

Safety Culture (3)

What can we do?

Education and Training

Multilayered prevention

Risk assessment – (FMEA)

Learning and Reporting Systems

Analyzing – Root Cause Analysis (RCA)

Developing a Safety Culture

IAEA Training Course

https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/AccidentPreventionRadiotherapy.htm

PREVENTION OF ACCIDENTAL EXPOSURE IN RADIOTHERAPY

Part 5: Reporting, investigating and preventing accidental exposures

IAEA
International Atomic Energy Agency

Multilayered prevention of accidental exposures

- The term "defence in depth" is defined in the BSS as "the application of more than one single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fail".

- "Defence in depth" can be viewed as several layers of safety provisions, such as physical components and procedures.

Multilayered prevention of accidental exposures

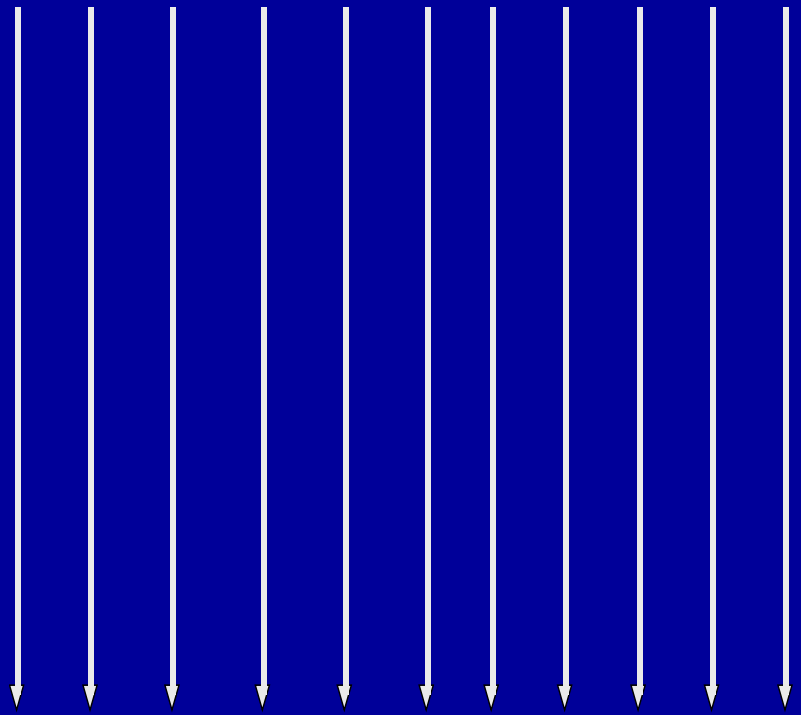
- Multilayered prevention includes aspects of “defence in depth” but also includes aspects such as awareness and alertness which could be termed “conceptual defence”

- For this multilayered prevention of accidental exposures to work, these layers need to be independent of each other.

- An implemented Quality Assurance program might provide the layers. Part of the QA should be to verify that this is the case!

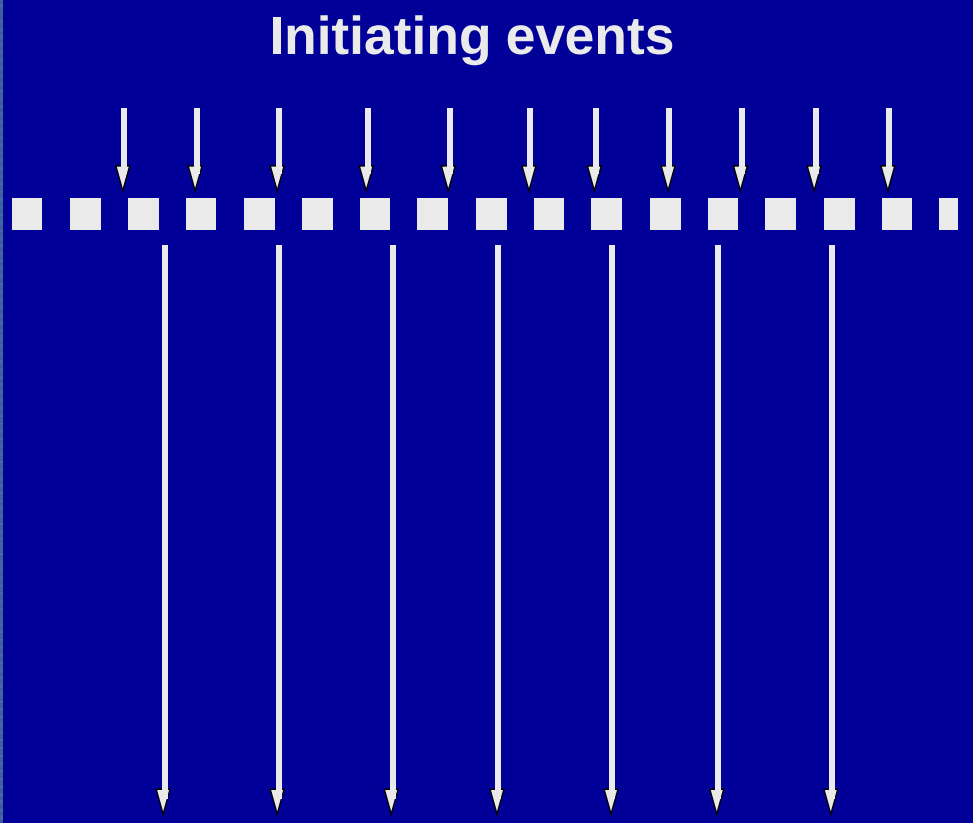
Multilayered prevention of accidental exposures

Initiating events will happen many times in any clinic



If there are no layers of safety provision, these events will lead to accidental exposures

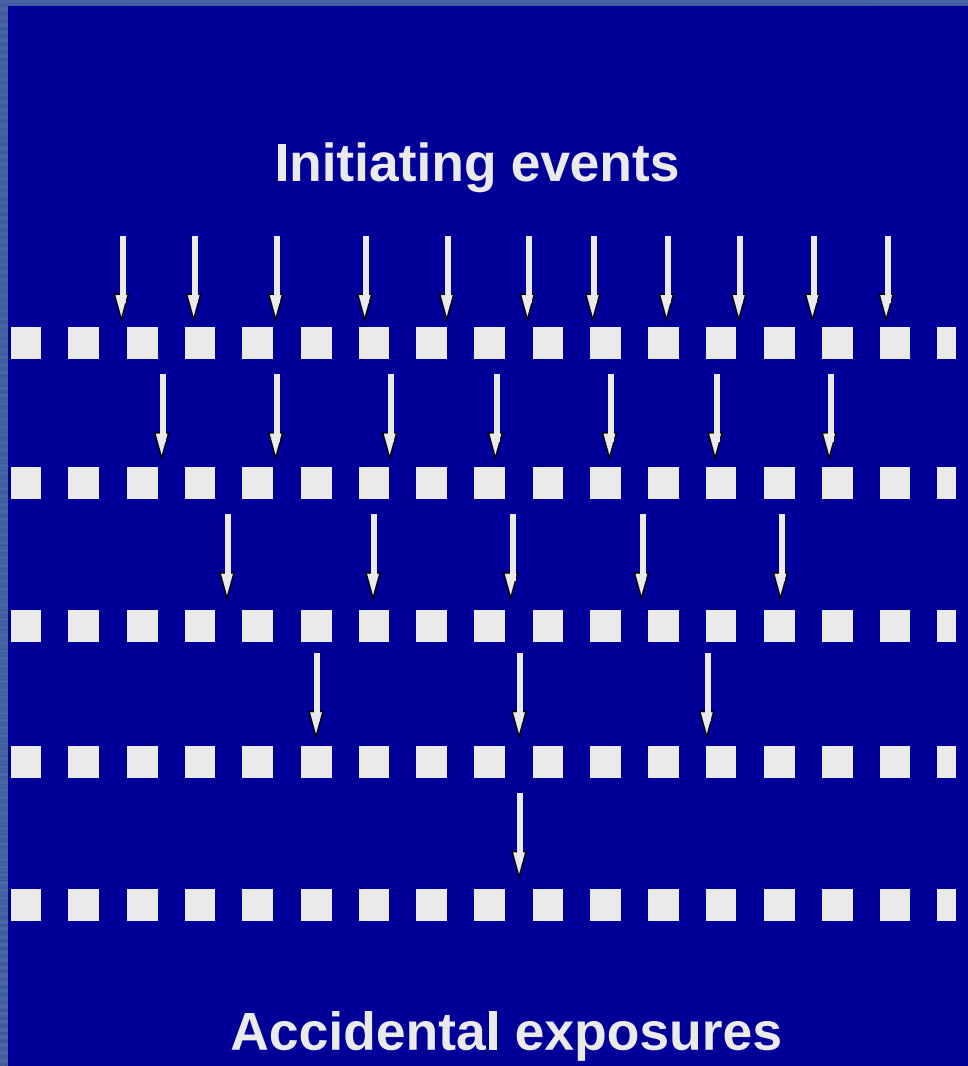
Multilayered prevention of accidental exposures



By putting in a layer of safety-provision, many initiating events are stopped from becoming accidental exposures.

When only a single layer of safety-provision is present, failure of this layer can still lead to accidental exposures.

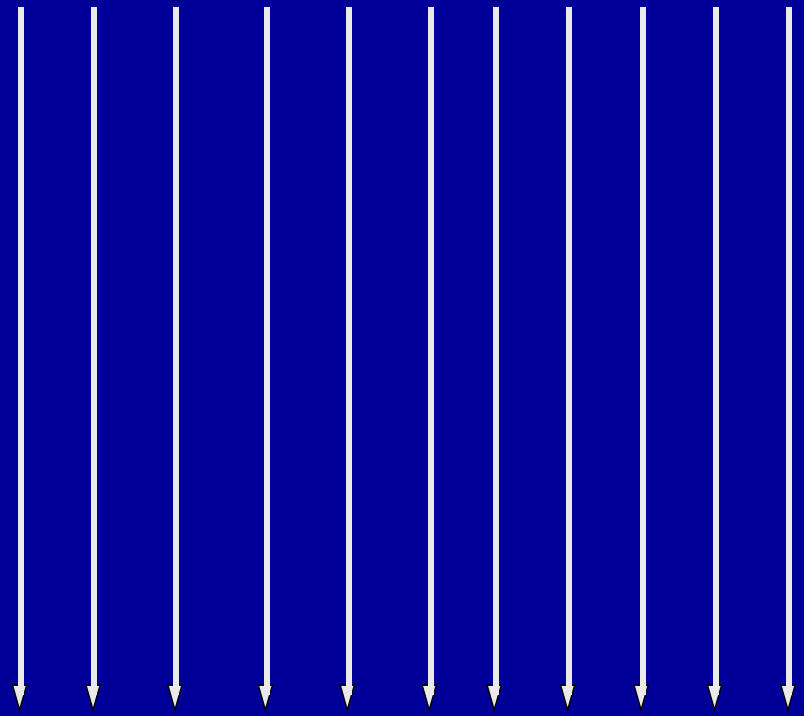
Multilayered prevention of accidental exposures



By having multiple <u>independent</u> layers of safety-provision, there is a much higher likelihood that accidental exposures are prevented.

Multilayered prevention of accidental exposures

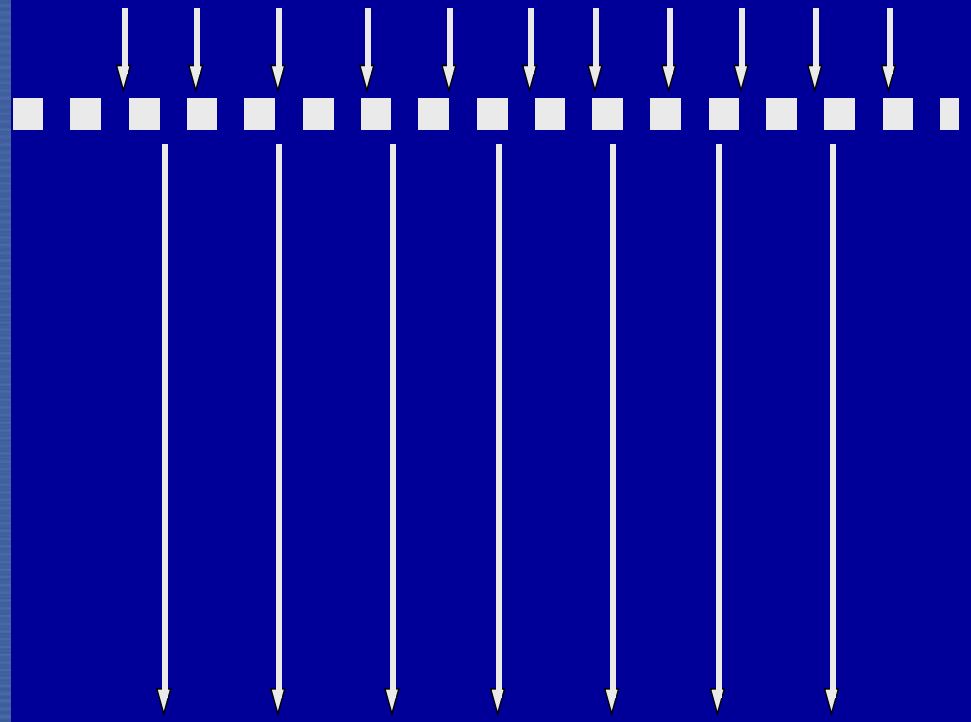
Initiating event: Mistakenly inverting SSD-correction in MU-calculation



Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation



Independent check of calculation

Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

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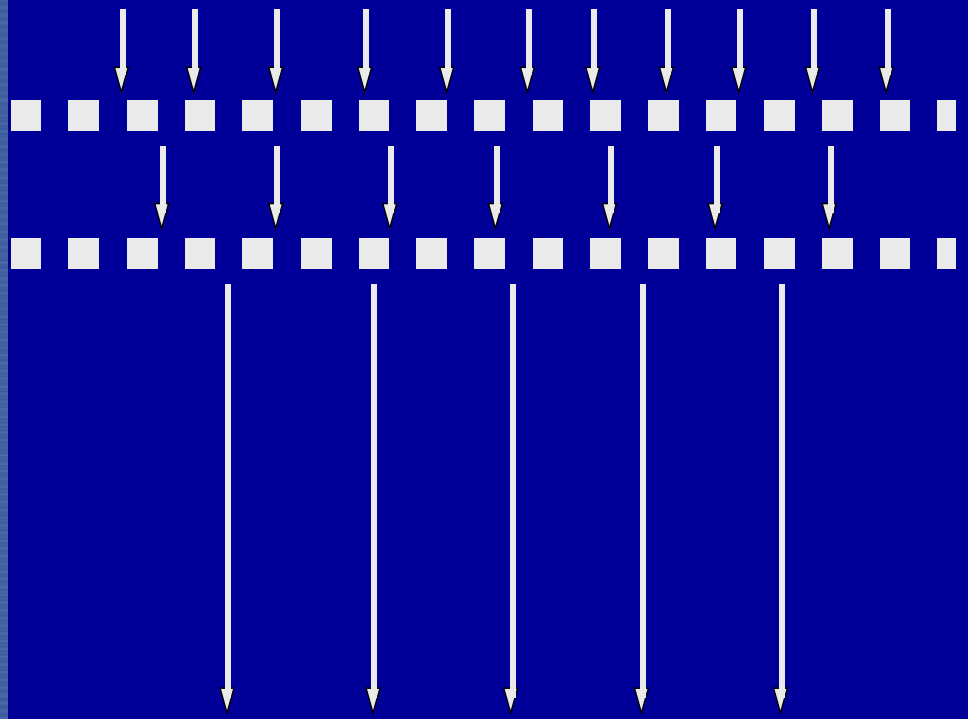


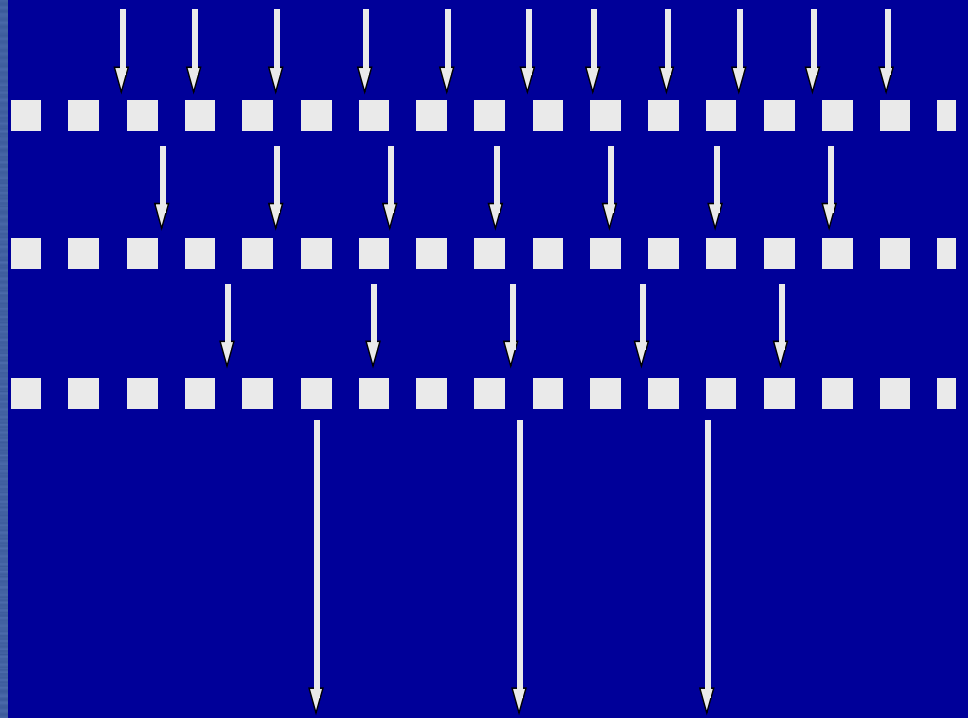
Independent check of calculation

Weekly chart-check of “reasonability”

Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation



Independent check of calculation

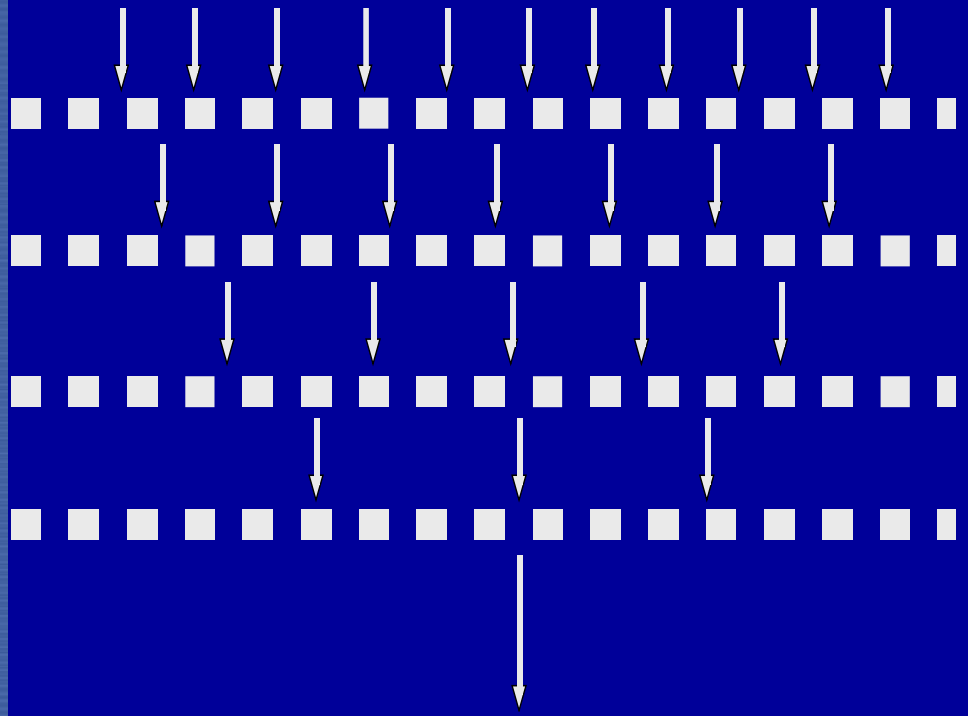
Weekly chart-check of “reasonability”

In vivo dosimetry

Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation



Independent check of calculation

Weekly chart-check of “reasonability”

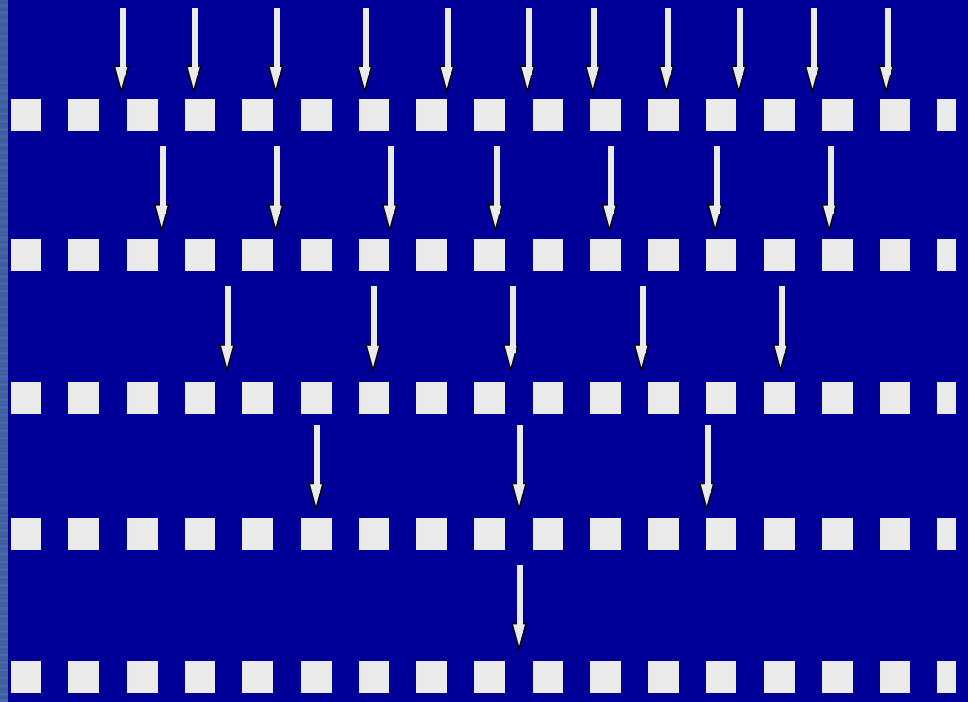
In vivo dosimetry

Written procedure for calculation methods

Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation



Independent check of calculation

Weekly chart-check of “reasonability”

In vivo dosimetry

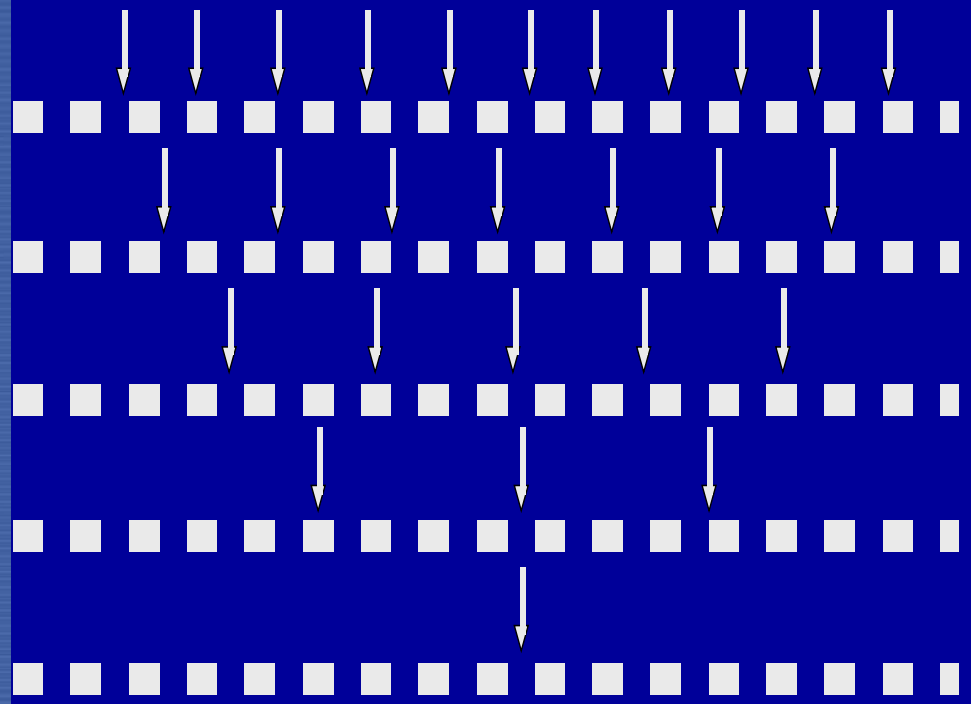
Written procedure for calculation methods

Awareness! Shorter SSD means shorter treatment time for same dose

Consequence: Very significant dose deviation for a patient

Multilayered prevention of accidental exposures

Initiating event: ?



Consequence: ?

<u>TRY IT AS AN EXERCISE!</u>

Examples of initiating events:

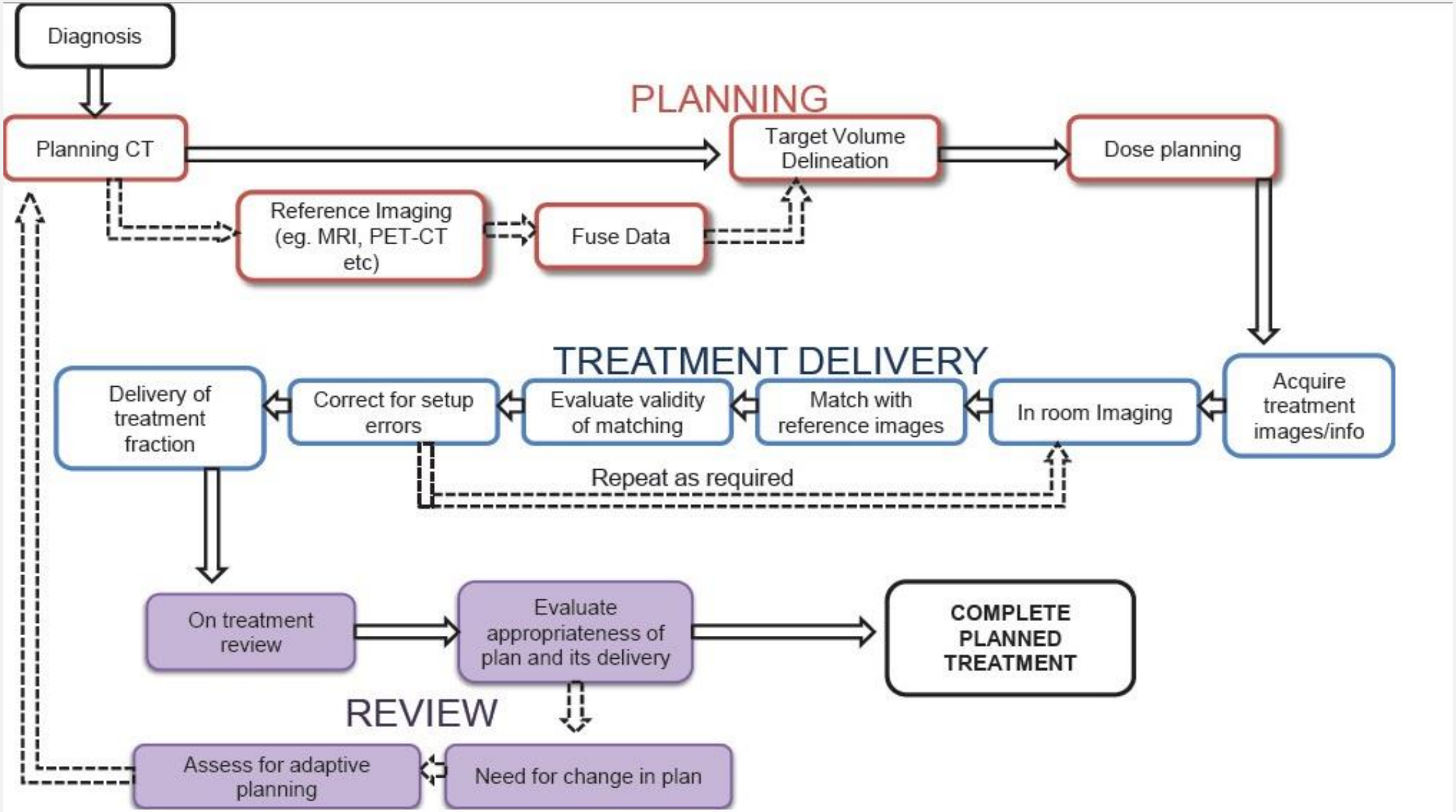
Calibration of beam made in penumbra

Pancake chamber used upside down

Use of wedge factor twice in calculation of treatment time

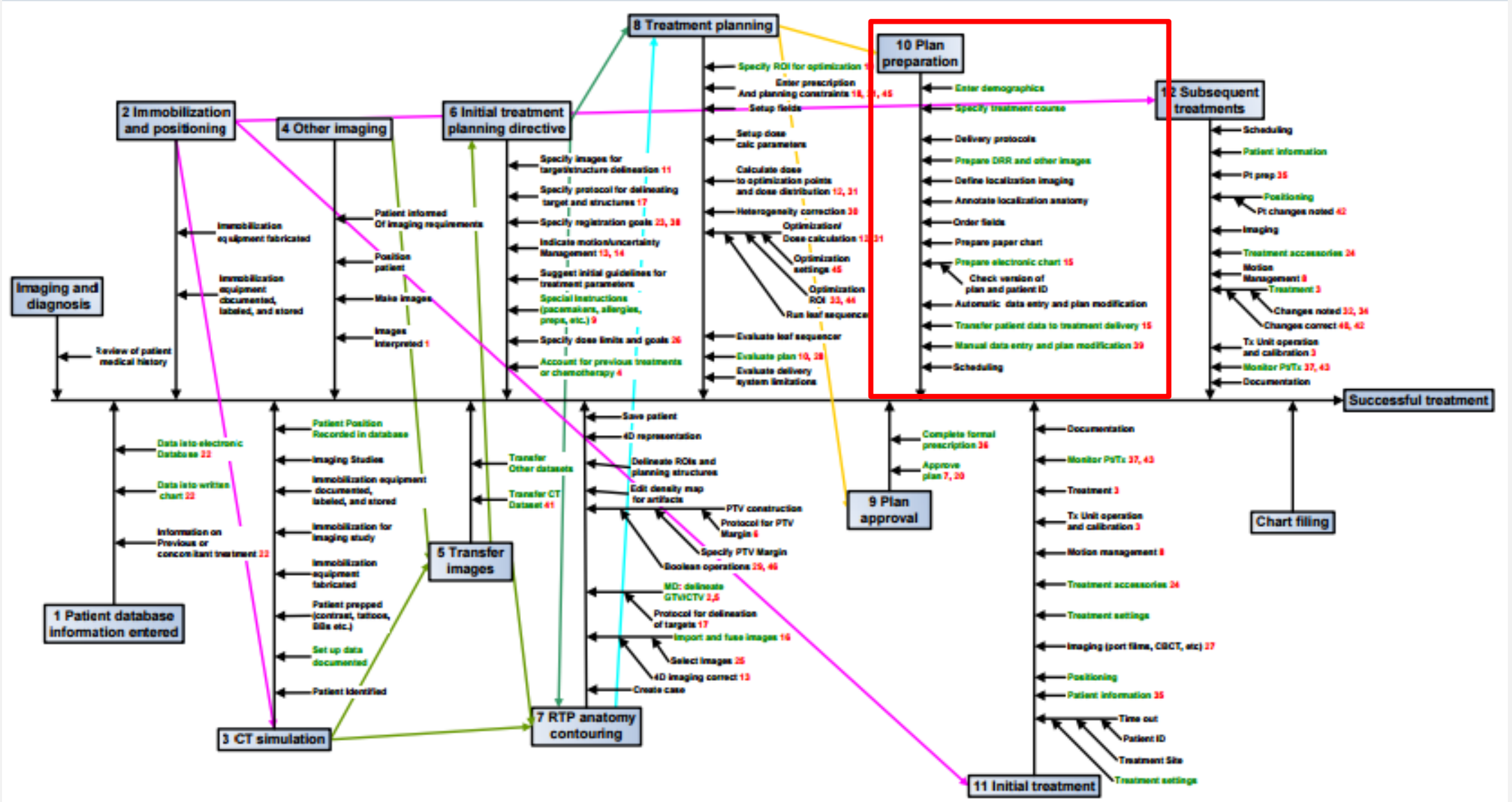
Misunderstanding of verbal prescription

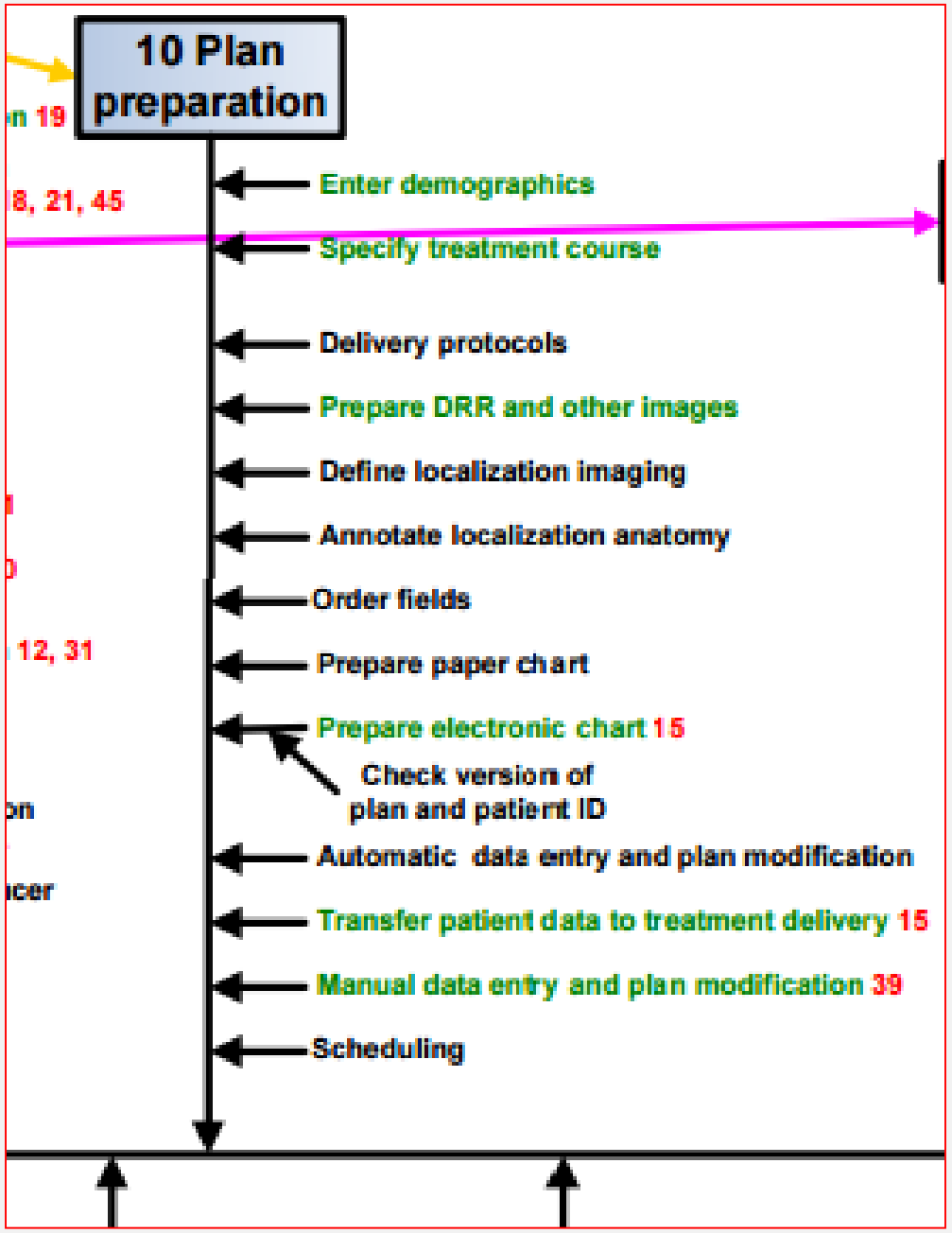
To Create Barriers we use Process Maps



Process Map for IMRT

(TG 100 Example)




10 Plan preparation
n 19
8, 21, 45
12, 31
on
ıcer
Enter demographics
Specify treatment course
Delivery protocols
Prepare DRR and other images
Define localization imaging
Annotate localization anatomy
Order fields
Prepare paper chart
Prepare electronic chart 15
Check version of plan and patient ID
Automatic data entry and plan modification
Transfer patient data to treatment delivery 15
Manual data entry and plan modification 39
Scheduling

Failure Modes and Effects Analysis-FMEA

- **Assess potential risks of each step**
  - Determine the failure modes – what can go wrong?
  - What can cause each failure?
- **Estimate the likelihood of each failure**

  O = "Occurrence" rating
    - 1 is unlikely, 10 is inevitable
- **Estimate the consequences of each failure**

  S="Severity" rating
    - 1 is mere bother, 10 is catastrophe
- **Estimate likelihood that failure will NOT be detected**

  D = "Detectability" rating
    - 1 is obvious, 10 is almost impossible to detect
- **RPN=Risk Priority Number=O×S×D**
    - 1 is minimal risk, 1000 is huge risk

From Helen Yorke- TG100

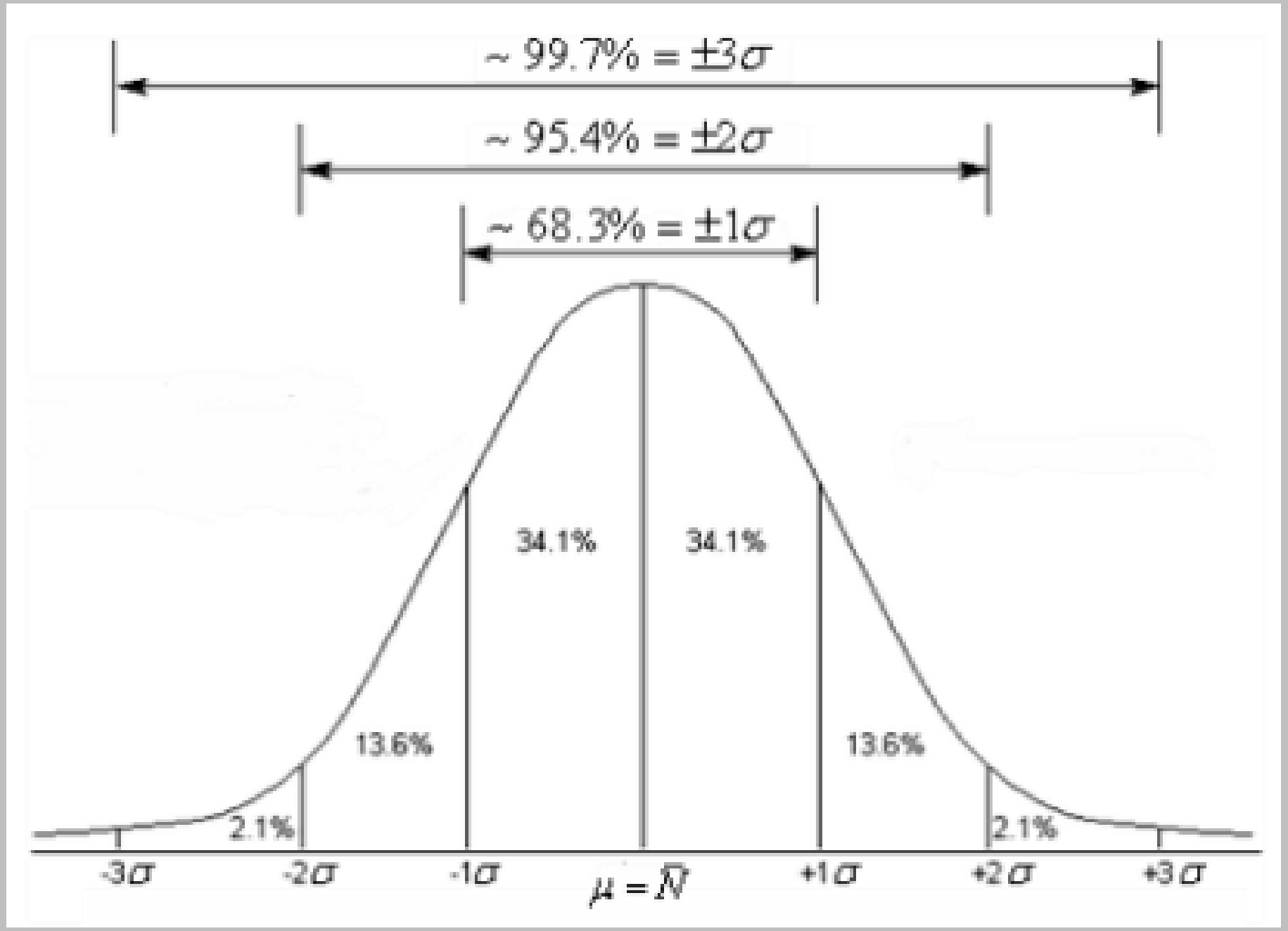
What is Safety ?

- The absence of an unacceptable risk of harm.
- What is harm in RT?
  - excess morbidity
  - sub-optimal tumour control.

Quality in Radiotherapy

The degree to which radiation therapy is consistent with current professional knowledge:

- The prescription is appropriate, i.e. evidence based
- The prescription is delivered within tolerances determined by consensus in the profession


~ 99.7% = ±3σ
~ 95.4% = ±2σ
~ 68.3% = ±1σ
34.1%
34.1%
13.6%
13.6%
2.1%
2.1%
-3σ
-2σ
-1σ
μ = N
+1σ
+2σ
+3σ

Is Safety an issue in Radiotherapy?

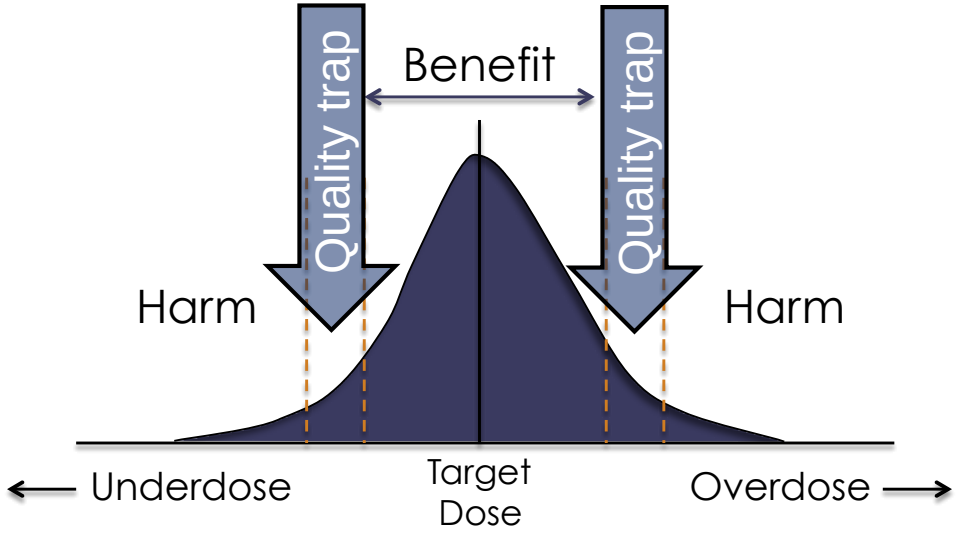
	“Serious” Incidents per course
New York State	0.012%
Varian	0.002%
UK	0.003%

The chance of dying or being injured on a U.S. domestic flight is about 0.00001%

(Ford and Terezakis, IJROBP 2010)

How many patients fall into the "Quality Trap"?

There are about 750,000 patients receiving RT per year in the U.S.



At 0.01% that would be 75 serious accidents per year in the US alone!

If we ignore retreats, that is approximately 750,000 courses per year.

2.6% of 750,000 is about 20,000

Department of Radiation Oncology
TREATMENT VARIANCE REPORT

Reported on __/__/200_ Reported by:_____ Occurrence date(s): __/__/200_, _____
Patient ID:_____ Attending M.D.:_____ Assigned Physicist:_____

Details: Blocks / MLC / MU / Wedges / Geometry / Energy / Mode / Setup / Machine_____/
Calculation / Plan / # of Fx's __ / Machine function / Identification
Other_____
Therapist(s): _____

Description of Variance (reporting staff):

_____
_____
_____
_____
_____
_____
_____
_____

Summary of Variance analysis (Physics) (report attached[ ])

_____
_____
_____
_____
_____

EFFECT CATEGORY	√	REPORTING CLASS	√
Prevented		Minor	
Corrected		Recordable	
Uncorrectable		Misadministration	

DEPARTMENTAL REVIEW: Date:__/__/200_
Comments:

_____

Corrective action:

_____
_____

Variance?

- A difference between what is expected and what actually occurs.
- An event that departs from the normal, the routine or from what we expected.

What information did we collect?

Department of Radiation Oncology

TREATMENT VARIANCE REPORT

Reported on __/__/200_ Reported by:_____ Occurrence date(s): __/__/200_, _____

Patient ID:_____ Attending M.D.:_____ Assigned Physicist:_____-

Details: Blocks / MLC / MU / Wedges / Geometry / Energy / Mode / Setup / Machine_____/

Calculation / Plan / # of Fx's __ / Machine function / Identification

Other_____

Therapist(s): _____ _____

Description of Variance (reporting staff):

_____

_____

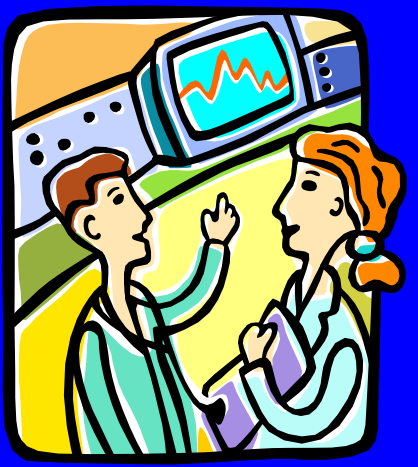
_____

_____

_____

THE ABOVE SECTION TO BE COMPLETED BY REPORTER

What did we do with it?



- Bring to the attention of the attending Physician since s/he is ultimately responsible for the patient's treatment
- As the case may be, bring to the immediate attention of a supervisor or Physics.
- "Treatment Variance" forms are collected by Sherin

What did we do with it?

- Analyzed the specifics of the variance
  - What is the effect on the patient
  - Is there a lesson to learn and/or changes to be made
  - What reporting category does the variance fall into.

Each case would be evaluated by the QA team, and the analysis reported

Summary of Variance analysis (Physics) **(report attached[ ])**

EFFECT CATEGORY	√	REPORTING CLASS	√
Prevented		Minor	
Corrected		Recordable	
Uncorrectable		Misadministration	

THE ABOVE SECTION TO BE COMPLETED BY PHYSICS

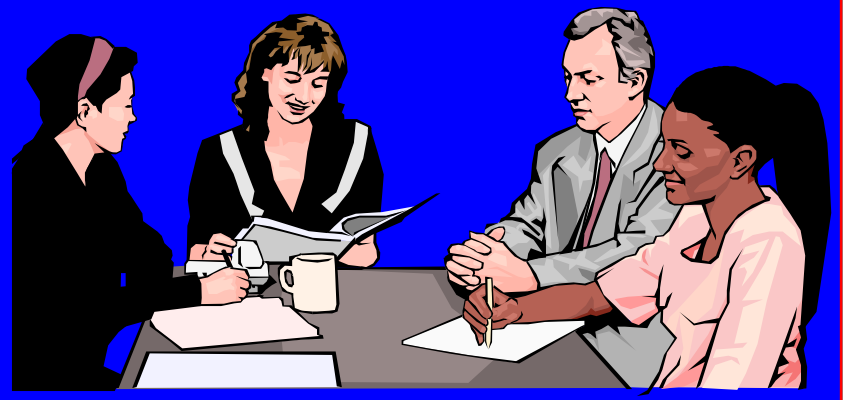
Significant error?

- When evaluating the significance of an error, its effect was evaluated on the assumption that the patient's treatment would be solely determined by that particular error.

Redundant measures?

A measure, or action, is truly redundant if it can perform the same function of a different measure, in its absence.

Proposed Corrective Action and Discussion



- Let's change "xyhp"
- We should replace "yzz" with "rstuv"
- The last one to "zxtt" will do "abcd"
- We will now use "dkfgh"!

Monthly Presentation to the departmental QA Committee

OVERALL ANALYSIS:

Number of cases reviewed: _____fields _____ESTV 's

Number of cases identified: _____

Effect Category	#	Reporting Class	#
Prevented		Minor	
Corrected		Recordable	
Uncorrectable		Misadministration	

SPECIFIC CONCLUSION:

ACTION:

Newer incident reporting systems

Nucleus

Pipman, Yakov Sign Out

IAEA | SAFRON Safety Reporting and Learning System for Radiotherapy

Select Dataset: All incident reports

Home | Process Steps | Incident Reports | Documents and Links | Statistical Reports | Help

Safer use of radiation in radiotherapy through learning and reporting

SAFRON aims to enable global shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy.

New User?

Request Registration

Actions

Browse Safety Info by Process Step

Search Reports

Search Documents & Links

See Statistical Reports

Featured Incident Reports

HDR vaginal cylinder brachytherapy treatment delivered to incorrect location

Patient received first of three intended deliveries of HDR vaginal

Featured Documents & Links

Report No. 167- Guidelines by the AAPM and GEC-ESTRO on the use of innovative brachytherapy devices

Although a multicenter, Phase III, prospective, randomized trial is

SAFRON 

Information and Instructions for Registering with NUCLEUS

Prior to registering with Safety Reporting and Learning System for Radiotherapy (SAFRON), the registrant must register with NUCLEUS, the Agency's information resource catalogue. The link to NUCLEUS is: http://nucleus.iaea.org/Home/index.html

Instructions for Registering with SAFRON

SAFRON is an integrated voluntary reporting registry of radiation oncology incidents and near misses. Its success is dependent on facilities registering and sharing incidents that occur in their institutions. The registration form includes details on the equipment, staff and environment in your centre. This information indicates the complexity of the processes within departments. It will be used to carry out trend analyses of incidents in relation to complexity of practice, working environment and educational background of professional staff in a range of clinic types. The information will not be seen by other users of SAFRON.

https://rpop.iaea.org/SAFRON/StaticContent/safron-instructions.pdf

IAEA | SAFRON Safety Reporting and Learning System for Radiotherapy

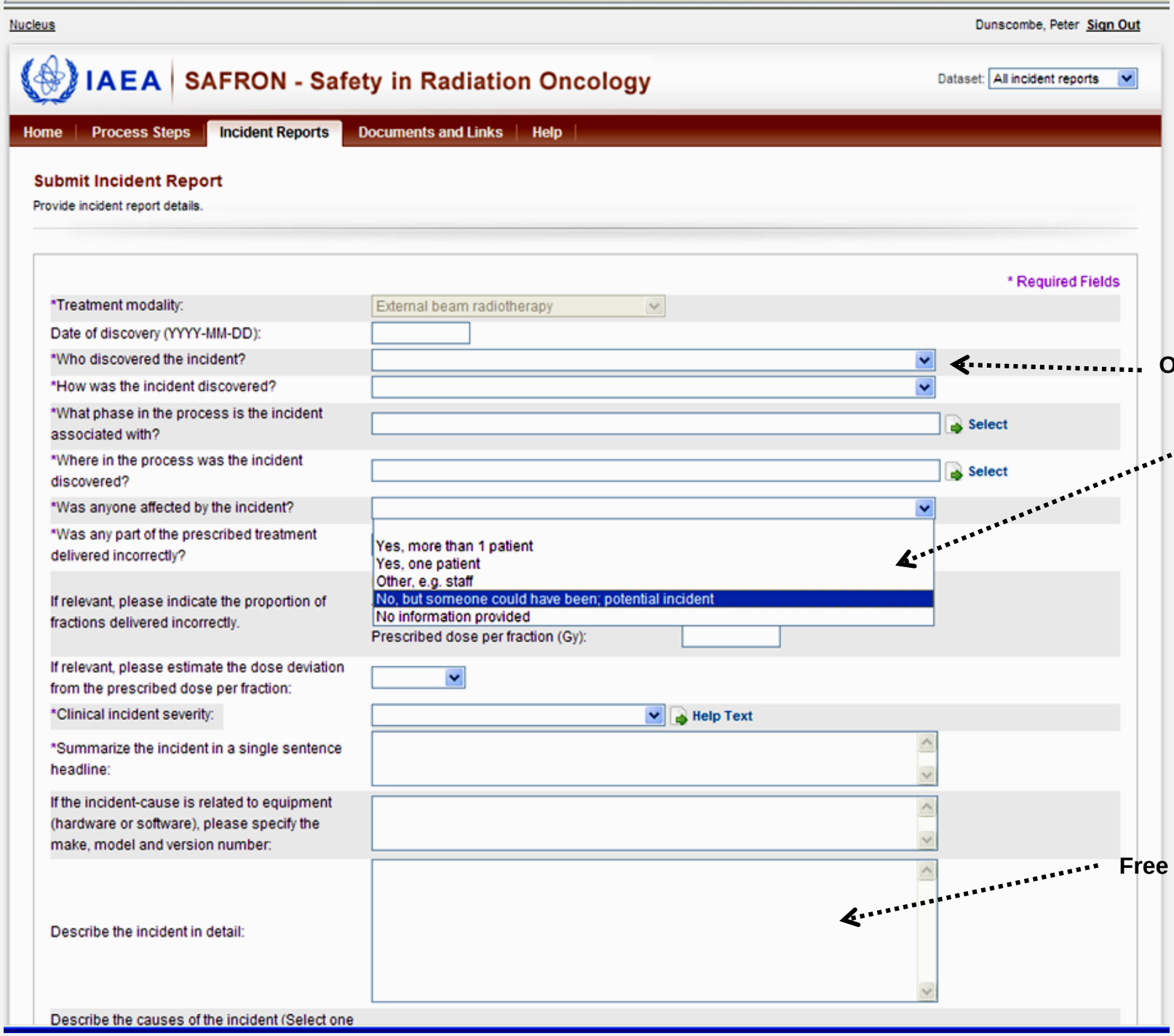
Home | Process Steps | Incident Reports | Documents and Links

All process step for: External beam radiotherapy

1.2.4.5. Other
- 2. Pre-treatment phase
  - 2.1. Assessment of patient
    - 2.1.1. Identification of patient
    - 2.1.2. Verification of diagnosis/extent/stage
    - 2.1.3. Other
  - 2.2. Decision to treat
    - 2.2.1. Completion of required information
    - 2.2.2. Recording of patient ID
    - 2.2.3. Recording of previous treatment details
    - 2.2.4. Recording of patient's specific requirements
    - 2.2.5. Recording of non-standard information/protocol variations
    - 2.2.6. Other
  - 2.3. Prescribing treatment protocol
    - 2.3.1. Choice of dose
    - 2.3.2. Choice of modality
    - 2.3.3. Choice of energy

All process step for: External beam radiotherapy

2.9. Other
- 3. Treatment phase
  - 3.1. Treatment setup
    - 3.1.1. Patient setup
      - 3.1.1.1. Patient ID process
      - 3.1.1.2. Patient data ID process
      - 3.1.1.3. Explanation/instructions to patient
      - 3.1.1.4. Patient positioning
      - 3.1.1.5. Use of reference marks
      - 3.1.1.6. Other
    - 3.1.2. Treatment unit setup
      - 3.1.2.1. Setting of treatment machine parameters
      - 3.1.2.2. Setting of collimator angle
      - 3.1.2.3. Setting of jaw position
      - 3.1.2.4. Setting of asymmetry
      - 3.1.2.5. Setting of couch position/angle
      - 3.1.2.6. Setting of energy


Nucleus
Dunscombe, Peter Sign Out
IAEA
SAFRON - Safety in Radiation Oncology
Dataset: All incident reports
Home
Process Steps
Incident Reports
Documents and Links
Help
Submit Incident Report
Provide incident report details.
* Required Fields
*Treatment modality:
External beam radiotherapy
Date of discovery (YYYY-MM-DD):
*Who discovered the incident?
*How was the incident discovered?
*What phase in the process is the incident associated with?
Select
*Where in the process was the incident discovered?
Select
*Was anyone affected by the incident?
*Was any part of the prescribed treatment delivered incorrectly?
Yes, more than 1 patient
Yes, one patient
Other, e.g. staff
No, but someone could have been; potential incident
No information provided
If relevant, please indicate the proportion of fractions delivered incorrectly.
Prescribed dose per fraction (Gy):
If relevant, please estimate the dose deviation from the prescribed dose per fraction:
*Clinical incident severity:
Help Text
*Summarize the incident in a single sentence headline:
If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:
Describe the incident in detail:
Describe the causes of the incident (Select one
Option Menus
Tables
Free text description

Wrong dose normalization in 1-fraction-radiosurgery

Treatment modality:	External beam radiotherapy
Equipment used:	Linear Accelerator
Treatment method:	Stereotactic radiosurgery (cranial or body)
Date of discovery:	2019-01-25
Who discovered the incident?	Medical physicist
How was the incident discovered?	Found at the time of first patient treatment during regular checks
What phase in the process is the incident associated with?	2.6.7. Recording of definitive treatment prescription
Where in the process was incident discovered?	2.6.6. Authorization of plan
Was anyone affected by the incident?	No, but someone could have been; potential incident
Was any part of the prescribed treatment delivered incorrectly?	No, but patient could have been affected
First day of treatment:	Yes

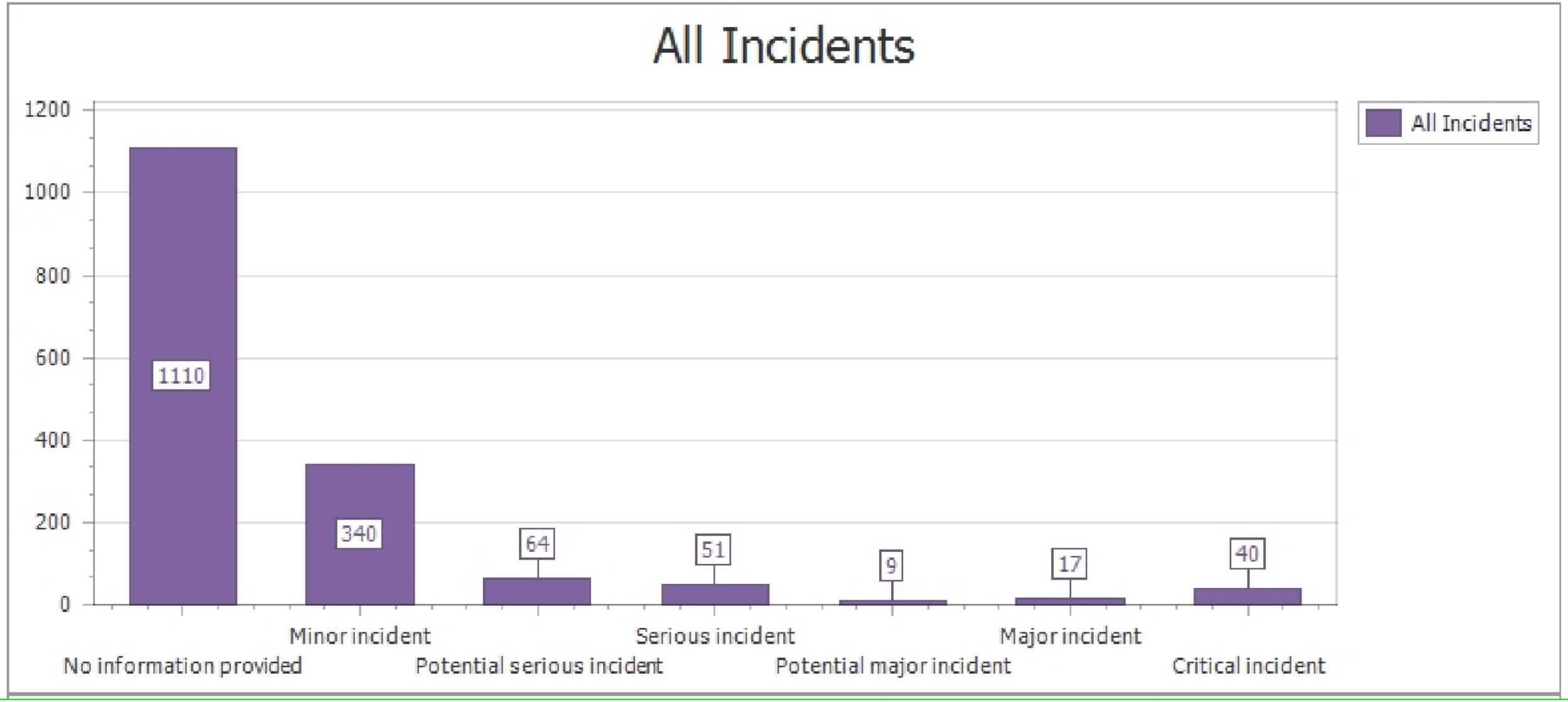
wrong electron dose calculation from 600cgy to 400cgy x2fraction dose deviate from 1200cgy to 800 cgy

Describe the incident in detail:	Doctor prescribed electron for keloid case 600 cgy x2 fraction but Physicist calculate 400 cgy x2 fraction the incident caused by no recheck (timeout) by second physicist, the incident meet by the completed chart check by the physicist
Describe the causes of the incident:	
Did the incident reach the patient?	Yes
What safety barrier failed to identify the incident?	
What safety barrier identified the incident?	Independent confirmation of dose Regular independent chart checks
What safety barrier might have identified the incident?	Post treatment evaluations (evaluation of clinical and process)
Describe contributing factors to the incident:	no timeout or recheck dose calculation by the second physicist before treatment
Suggest preventive action(s):	Dose calculation recheck by second medical physicist must be completed before patient treatment delivery

If relevant, please estimate the dose deviation from the prescribed dose per fraction:	>50%
Clinical incident severity:	No information provided

Incidents by clinical incident severity

Distribution of clinical incident severities, with which the incident is associated



*Number of staff:

*Radiation oncologists (physicians):

*Medical physicists:

*Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at treatment units treating patients:

*Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at simulator and/or in-house CT:

*Staff doing dosimetry i.e. treatment planning etc:

*Staff doing technical maintenance on radiotherapy equipment:

*How is most of your equipment maintenance performed?

Safety infrastructure in place at the clinic:
(Select all that apply to your clinic)

- There are documented policies and procedures for most of the clinical processes
- There are written policies and procedures for equipment quality control (including software)
- There are appropriate education and training for staff
- There is a committe with responsibility for on-going quality and safety improvement

Safety barriers in place at the clinic:
(Select all that apply to your clinic)

- Verification of patient ID
- Verification that pretreatment condition have been taken into account
- Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)
- Verification reference points
- Physician peer review
- Review of treatment plan
- Independent confirmation of dose
- Time out
- Use of record and verifying system
- Verification of treatment accessories
- Image based position verification
- In vivo dosimetry

https://rpop.iaea.org/SAFRON/ClinicRegistration/ClinicRegistrationEdit.aspx

ASTRO and the AAPM (2014) - medical specialty society sponsored radiation oncology PSO. Goal: Educate the radiation oncology community on how to improve safety and patient care.

What to Report or Track

- Explicit events – frequent events
- Random events
- Actual errors
- Potential errors (near misses)
- Corrective measures

Incident Reporting Depends on Factors

- Culture
- Reporting system and guidelines
- Competence to interpret reported data
- Willingness to implement
  - Changes based on collected data and analyses
- Ability to share data and provide feedback
  - Power distance index

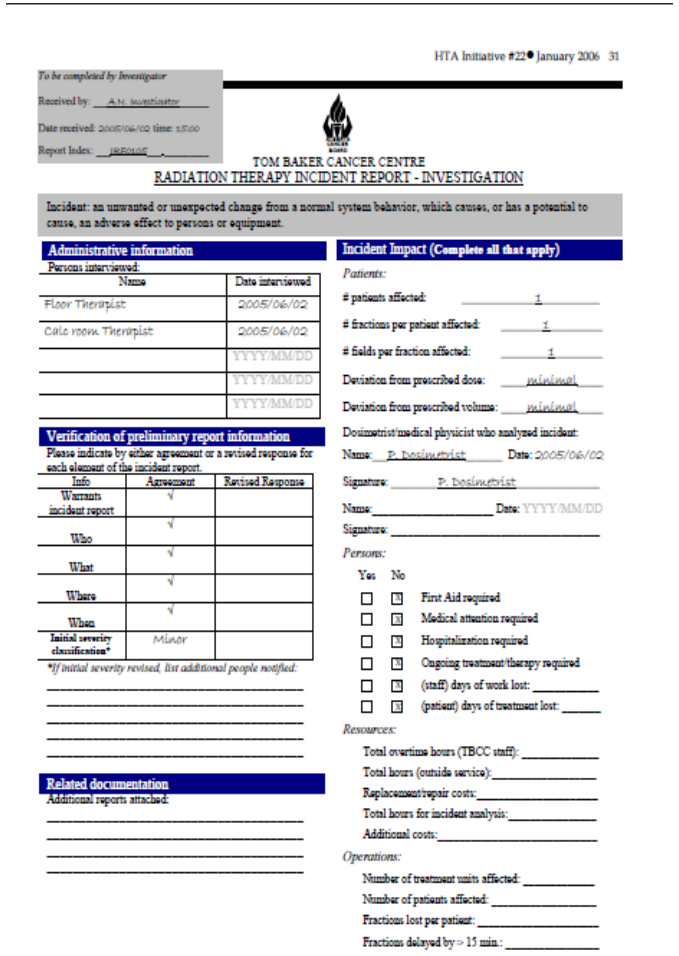
Organizational Culture

Pathological Culture	Bureaucratic Culture	Generative Culture
Do not want to know	May not find out	Actively seek it
Messengers (whistle blowers) are "shot"	Messengers are listened to if they arrive	Messengers are trained and rewarded
Responsibility is shirked	Responsibility is compartmentalized	Responsibility is shared
Failure is punished or concealed	Failures lead to local repairs	Failures lead to far reaching reforms
New ideas are actively discouraged	New ideas often present problems	New ideas are welcomed

Reason, J., Managing the risks of organizational accidents. Different organizational cultures

Final Disposition

- Resolution and corrective action
- Responsible person
- Implementation plan
- Evaluation plan
- Follow up plan



HTA Initiative #22 • January 2006 31

To be completed by Investigator

Received by: A.N. Investigator

Date received: 2005/06/02 time: 15:00

Report Index: IRE0505-1

TOM BAKER CANCER CENTRE

RADIATION THERAPY INCIDENT REPORT - INVESTIGATION

Incident: an unwanted or unexpected change from a normal system behavior, which causes, or has a potential to cause, an adverse effect to persons or equipment.

Administrative information

Persons interviewed:

Name	Date interviewed
Floor Therapist	2005/06/02
Cale room Therapist	2005/06/02
	YYYY/MM/DD
	YYYY/MM/DD
	YYYY/MM/DD

Verification of preliminary report information

Please indicate by either agreement or a revised response for each element of the incident report.

Info	Agreement	Revised Response
Warrants incident report	√	
Who	√	
What	√	
Where	√	
When	√	
Initial severity classification*	Minor	

**If initial severity revised, list additional people notified:*

Related documentation

Additional reports attached:

Incident Impact (Complete all that apply)

Patients:

patients affected: 1

fractions per patient affected: 1

fields per fraction affected: 1

Deviation from prescribed dose: minimal

Deviation from prescribed volume: minimal

Dosimetrist/medical physicist who analysed incident:

Name: P. Dosimetrist Date: 2005/06/02

Signature: P. Dosimetrist

Name: _____ Date: YYYY/MM/DD

Signature: _____

Persons:

Yes	No	
☐	N	First Aid required
☐	N	Medical attention required
☐	N	Hospitalization required
☐	N	Ongoing treatment/therapy required
☐	N	(staff) days of work lost: _____
☐	N	(patient) days of treatment lost: _____

Resources:

Total overtime hours (TBCC staff): _____

Total hours (outside service): _____

Replacement/repair costs: _____

Total hours for incident analysis: _____

Additional costs: _____

Operations:

Number of treatment units affected: _____

Number of patients affected: _____

Fractions lost per patient: _____

Fractions delayed by > 15 min.: _____

Root Cause Analysis - when

1. Any single obviously serious event
2. Systematic events
3. High frequency sporadic events

Root Cause Analysis - how

1. Collect information – WHAT happened
2. Identify causes – WHY, WHY, WHY, WHY, WHY
3. Recommendations for remediation
4. Implement and Monitor

Incident Reporting and Learning systems must be:

Friendly for reporting
Responsive
Dynamic

Safety culture – free of fear

MANY TOOLS!!

Safety culture – free of fear

Incident Learning systems-
Friendly for reporting, responsive and dynamic

Root cause analysis methods

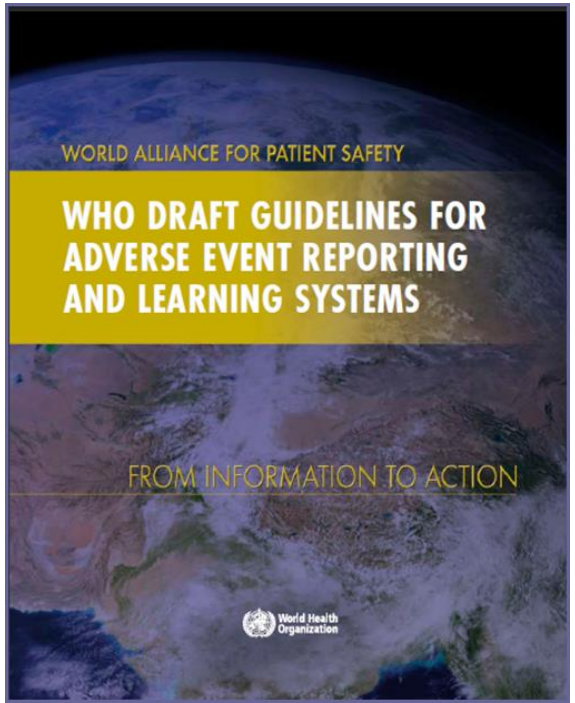
Check lists

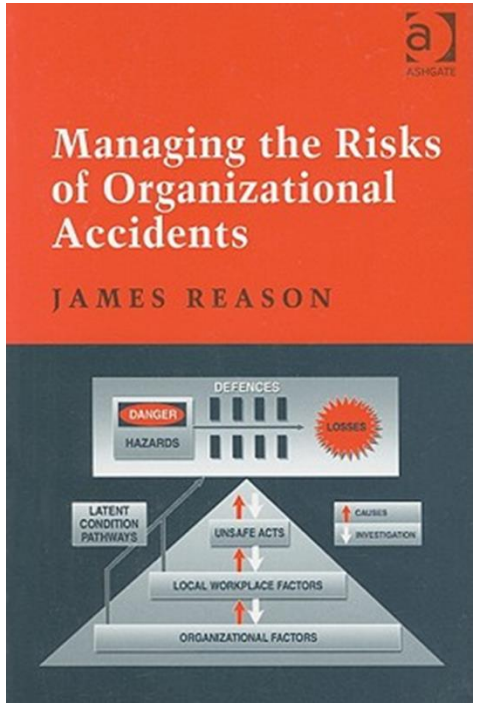
Standard procedures and handoffs

The art of learning from our mistakes

Resources

- IAEA -> http://www.iaea.org/
- Lessons learned from accidents in radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).
- ICRP-> Prevention of accidental exposures to patients undergoing radiation therapy. Publication 86, Volume 30 No.3 (2000)
- AAPM - > http://www.aapm.org/
- ASTRO -> https://www.astro.org/
- TreatSafely -> http://www.treatsafely.org/index.php
- AHRQ (Agency for Healthcare Research and Quality)
  - http://www.ahrq.gov/patients-consumers/care-planning/errors/index.html





References

ASTRO report 2012

Safety is No Accident: A Framework for Quality Radiation Oncology and Care. Zeitman A, Palta J, Steinberg M. ASTRO; 2012
Updated edition, March 2019: https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/Safety_is_No_Accident.pdf

AAPM white-paper 2012

Consensus recommendations for incident learning database structures in radiation oncology. Ford EC, Fong de Los Santos L, Pawlicki T, Sutlief S, Dunscombe P. Med Phys. 2012;39(12):7272-90.

ASTRO safety white-papers

Safety considerations for IMRT: Executive summary. Moran JM, Dempsey M, Eisbruch A, Fraass BA, Galvin JM, Ibbott GS, et al. Pract Radiat Oncol. 2011;1(3):190-5.
Assuring safety and quality in image-guided delivery of radiation therapy. Jaffray D, Langen KM, Mageras G, Dawson L, Yan D, Adams R, et al. Pract Radiat Oncol. 2013;in press.

ASRT safety white-paper

Radiation Therapy Safety: The Critical Role of the Radiation Therapist. Odle, T, Rosier, N. ASRT Education and Research Fnd. 2012.

Thank you!

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