Human Performance and the Quality and Safety of Radiation Therapy

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- Examples given in the presentation might not actually be happened

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Outlines

- Introduction
- Knowledge-based Performance
- Rule and Skill-based Performance
- Errors Related to Human Performance
- Summary

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Does Uncertainty Related to Human?

This train crash involved both human and natural factors

- Errors/mistakes do happen in radiation therapy
- Do errors relate to human performance?
- All complex machines
  - Highly automated and do not rely on human intervention for normal function
  - Human support for proper operations and services
- Errors are associated with human performance

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Purpose

- To discuss human performance issues that contribute to errors/failures during the different steps of the treatment process
- To propose strategies for minimizing human factor–related events that compromise the quality and safety of patient treatments.

Human Performance Levels

We can discuss error management strategies by broadly linking them to Rasmussen's three categories of human performance:

- **Knowledge-based performance**
  - Clear goal with unfamiliar situation and no know-how or rules
  - Related to education and potential mistakes
- **Rule-based performance:**
  - Stored rules or derived empirically, know-how
- **Skill-based performance:**
  - Sensory-motor operation
  - Related to training and potential errors

How to Assess Uncertainty?

- How to assess uncertainty of human performance?
- How to assess uncertainty of human error?
- What are “means” and “standard deviations”?
- Performance: to be assessed by the rate of human errors
- Errors: assessed by the change of clinical outcome

Knowledge-based Performance

- Generally, we acquire knowledge through educational activities of various types
- Every practicing medical physicist needs continuous learning and knowledge acquisition are essential prepared for rapid development of new technologies
- Discuss educational activities from 3 aspects:
  - General
  - Specific
  - On-going

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General Education: Graduate Programs

- **Medical physics graduate programs**
  - **Offer graduate-level medical physics courses**
  - **Based on a standard curriculum (TG197, 197S, AAPM)**
  - **Be recognized (or accredited) by an agent, i.e., CAMPEP**
  - **Provide the majority of medical physicists in the future**
- **Accreditation provides**
  - **Students: quality of educational experience**
  - **Employers: some guarantee of a "quality product"**

General Education: Post-Doctorates

- Post-doctoral fellows from other fields
  - Bringing the benefits of their unique experience and training to the field
  - Demonstrated their academic rigor in their original fields
  - Undertake comprehensive, in-depth medical physics coursework (TG 197,197S, AAPM)
    - radiological physics and dosimetry, radiation protection, radiation safety, imaging fundamentals, radiobiology, anatomy and physiology, and radiation therapy physics

General Education: Combined Programs

- **Medical physics residency**
  - **Transition programs for physicists trained in fields other than medical physics**
  - **Enrich medical physics profession by bringing a greater range of diverse knowledge and experience to bear on clinical problems**
- **The emergence of professional doctorate programs (DMP)**
  - **Combine the educational component of advanced graduate studies with the practical training**

Specific Education: Demands and Venues

- **Deficiencies in course education:**
  - **Applications of new theories, principles, and technologies in cancer treatment and equipment development (emerging/evolving knowledge)**
  - **Not available at the time of classroom teaching**
- **Venues:**
  - **Organizations (AAPM, ASTRO, etc.) offer many refreshment courses, delivered by experts in the relevant field), can form the basis for specific education**
  - **Other special short courses offered by professional organizations**

Specific Education: Sample Topics

- **Specific education of each treatment modality prior to clinical implementation:**
  - **image-guided focused ultrasound radiosurgery requires extensive knowledge of ultrasound imaging and radiosurgical techniques which may not have been fully covered in general education**
- **The ethics of practicing medical physics and codes of practice in radiation therapy**
  - **Unethical behavior can lead to many undesirable outcomes including errors arising from the violation of established procedures.**

Specific Education: Sample Topics

- **Error management and patient safety**
  - **Methodology such as Root Cause Analysis and Failure Modes and Effects Analysis (FMEA)**
- **Communication strategy**
  - **"I need this patient to be treated this afternoon!"**
  - **In improving** communication **between physics staff and other team members in patient care**
  - **In creating an environment where everyone feels comfortable speaking up, regardless of academic degrees**

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On-going Education

- Life long learning as one of a true professional's activities
  - Recertification, etc.
- To broaden perspective and may trigger innovation while implementing clinical technologies
- To critically review practice (considered as competency) and identify possible weaknesses that may compromise the quality and safety of patient care
- On-going education activities: specific refresher courses and schools organized by AAPM, ASTRO, ACR, and RSNA

Rule and Skill-based Performance

- Training related: teach basic clinical skills for those with the appropriate medical physics education
- Rules:
  - One purpose of a training program is to learn the “rules” of medical physics
  - May be written
  - May be traditions developed over a period of time
  - Frequently the way we practice (i.e., TG-51 calibration)
- Skill development clearly accompanies acquiring familiarity with the rules

General Training: Apprenticeship

- Mode: apprenticeship, or on-the-job training
- Quality: vary considerably
  - Mentor and training resources
  - Depth and breadth of training
  - Committed length of time of the mentor(s)
  - Knowledge and experience of the mentor(s)
- Additional concerns:
  - Trainees are promised robust and comprehensive training, but have ended up as underpaid laborers
  - Example: requiring trainees to perform IMRT QA without explaining the rationale behind test procedures

General Training: Residency Program

- **Structured medical physics residency programs**
  - **Eliminate many of the weaknesses of apprenticeships**
  - **Provide the necessary hands-on training and skill development**
- **CAMPEP accreditation:**
  - **Set a minimum standard of quality and reasonable assurance of a comprehensive and appropriate training experience (TG90,AAPM)**
- **Program components:**
  - **Adequate faculty/resident ratio (minimum 2:1)**
  - **Comprehensive resources of equipment for imaging, planning, delivery, QA, ……**
  - **Methods of establishing competency via testing and demonstration**

General Training: Residency Program

- **ABR requirements for taking Part 1 2014 or later:**
  - **must have completed a CAMPEP-accredited 2-year residency program before being eligible to take Part 2 in Radiological Physics**
- **As many of the incidents reported in *The New York Times* during 2010 pointed to under-trained physicists, catastrophic errors can only diminish with properly certified and well-trained physicists**
- **Residency program connects junior physicists with a large network of senior physicists, all of whom probably have different specialties. They have people to call on for help when beginning to practice independently**

General Training: Specific Topics

Acceptance testing procedures (ATP) and commissioning for new equipment and devices:

- **There is a very clear link between commissioning and patient safety. There have been several reports of major incidents resulting from incorrect commissioning**
- **The resident needs**
  - **to know that a set of acceptance and commissioning tests should be performed on all new treatment equipment, measurement devices, dosimetry tools, etc.**
  - **hands-on experience in how to design appropriate tests, select endpoints, perform the tests, and validate and document the endpoints.**

General Training: Case Example

Performing water-tank ion-chamber scans to steer beam flatness and symmetry:

- ***Observed: Flatness/symmetry of all electron fields changed between acceptance testing and commissioning. What could be wrong? What to do?***
- ***Tank geometry?***
- ***Detectors?***
- ***Beam path hardware? Software?***
- ***Forget about?***
- ***Re-steered two additional times without fixing the problem. The vendor's on-site engineer could not explain. So ….***
- ***Eventually senior vendor team discovered that a new step had been added to the beam steering procedure, but was not effectively communicated to the on-site vendor staff.***
- ***Problem were fixed after recalibration.***
- ***The physicist re-verified the stability with repeated measurements***
- **When a new linear accelerator is installed, the physicist should perform these checks as part of commissioning, rather than simply accepting the installer's data.**

Specific Training: Topics and Venue

- Specific training: specific equipment prior to its use
- Vendor-based training, “short courses,” and on-site training in another clinic (well-established procedures)
- Self-establishment:
  - Thorough and careful testing on a phantom or patient study under IRB protocol and be documented prior to routine patient application
  - Treatment procedures, necessary protocol, QA procedures, and documentation should be developed with clearly defined responsibilities for each member involved
  - Particular attention should be given to possible failure modes that could lead to patient harm.

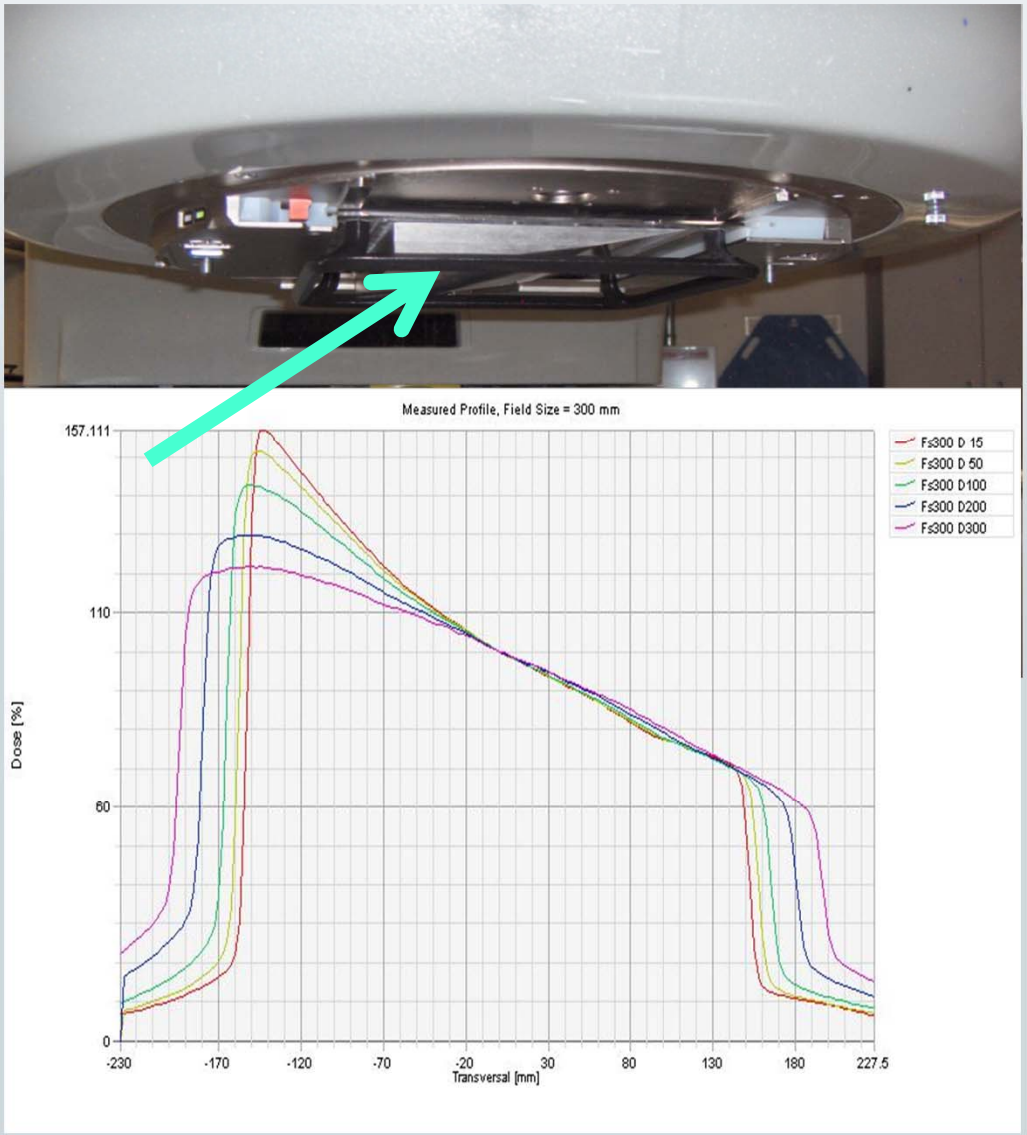
Specific Training

- To implement any new and emerging technology or treatment procedure: SRS, SBRT, IMRT, PET/CT imaging and analysis, IGRT, gated treatment, motion management, etc.
- To gain confidence and competence for each identified emerging technology and/or procedure.
- To gain the skill of organizing a team to address the why, what, who, and how. The clinical goal should be well defined for any implementation of new technologies and procedures. Through their areas of expertise, team members should identify and address each implementation issue.

Specific Training: Adverse Effect Case

- **Which is right?**
- **What could be wrong?**
- **What is the consequence?**

This example illustrates the benefit of having at least two physicists perform safety testing on any system. What one misses, hopefully the other will catch.



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Specific Training: Computer Software Error

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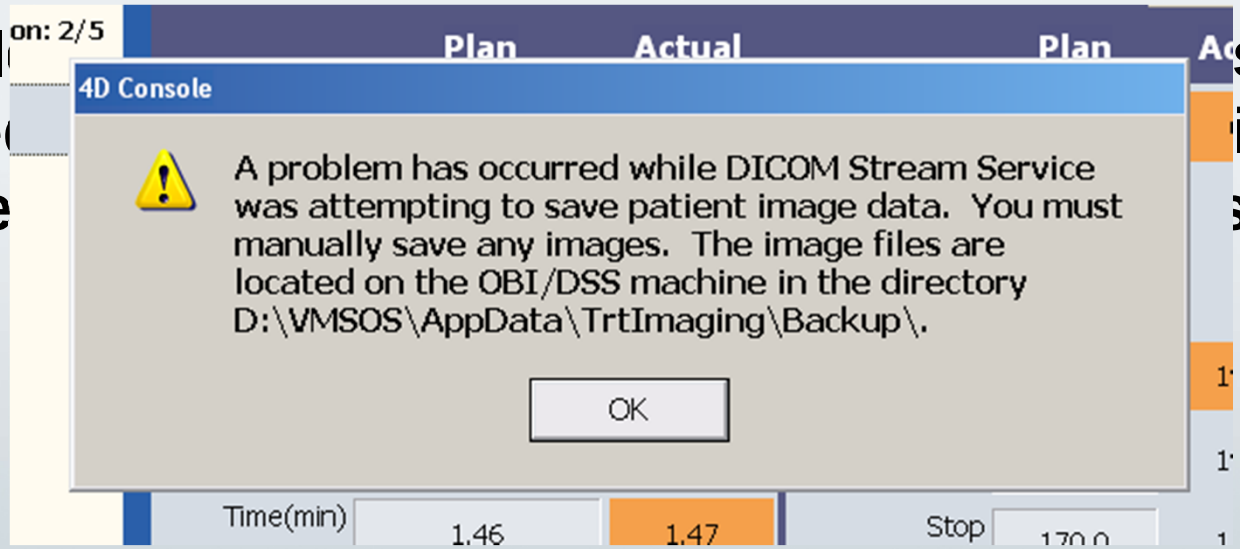

- **Understanding logistics and error management** are daily practice of many clinical medical physicists. Special training on **how to handle computer errors** should always be available to staff. This information may be provided by **vendors and/or internal experienced staff.**

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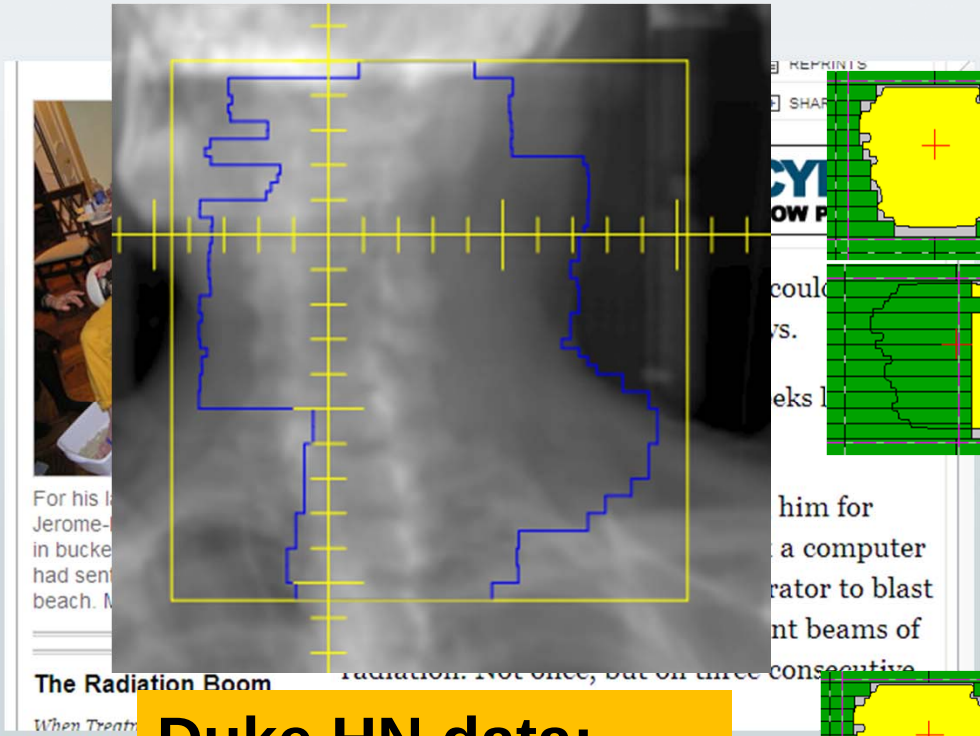
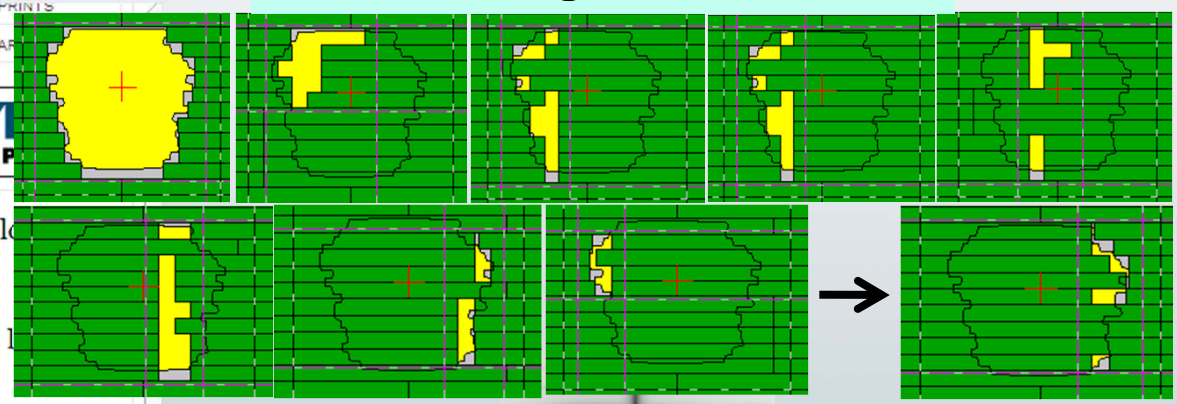
Specific Training: Preventive Action

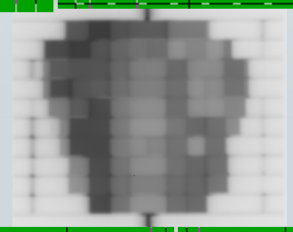
- **Practical error prevention strategies.**
  - ***Example, when a treatment case is complicated and disruptions occur (MD modified CTV of IMRT plan requiring reoptimization right before treatment), what should a physicist do?***
  - ***Call a "time-out" to ensure all involved are in full understanding of the procedures and are confident that all steps are in place and logical.***
- **A time-out is increasingly recognized as a valid and effective safety measure and, a brief training session can serve to reinforce its implementation and value.**
  - ***the physicist must declare that the IMRT patient-specific QA is mandatory, even if the patient's treatment regimen (e.g., chemotherapy) is disrupted.***

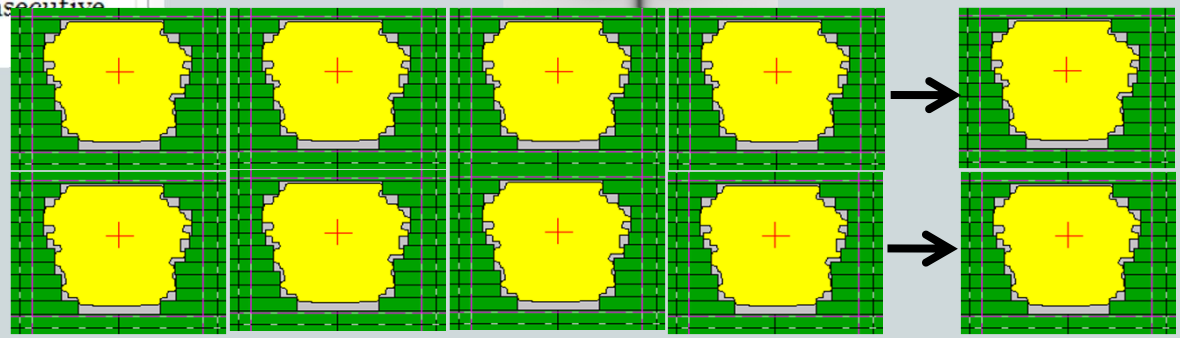
Radiation Accidents Reported in New York Times – IMRT Related

Severity of error









Duke HN data:
1324 segments
1619 MUs
~ 16 Gy/Fx

Specific Training: Stress Management

- **How to handle difficult situations when concerns arise about a supervisor's decision or activities?**
  - ***Example: Chief therapist convinced senior MD and wanted to skip W-L test for a SRS case due to machine problem when warming up***
  - ***What should the SRS physicist do?***
  - ***Can not skip!***
  - ***But if you do not do it, you may be troubled/fired if …..***
- **It is important to work coherently between groups, teams, and different ranks and also not to blindly follow another person's directions, especially when concerns about quality and safety are the issue**

Specific Training: QA Management

- The physicist must lead the team when composing and executing procedures, especially the QA components.
- Physicist should be responsible for these two aspects:
  - Provide the necessary training including demonstrating how errors could appear. For example, demonstration of a test case that has technical information MLC shape, wedge direction, etc. that differs in the record and verification (R&V) system compared with the treatment plan
  - Devise tests to document that the technical staff understands all aspects of the procedures. It may take diplomacy to get administrative support for these activities, but it is essential for the safe practice of medical physics

Specific Training: Equipment Selection

- Selection of equipment purchasing, basing the recommendation not just on what other people are using but also on functionality, accuracy, reliability, and safety.
- Example: QA device selection for small field IMRT/VMAT
  - whether the detector array spacing will provide sufficient dose resolution for radiosurgical fields and the rotational deviations of MLC and gantry speed change could be identified.
  - Suboptimal selection of a device may lead to less than optimal QA. Purchase of an inappropriate or incompatible piece of equipment not only wastes valuable resources but can also compromise quality and safety.
  - Management issues of this type are frequently overlooked in the training of the clinical physicist.

Specific Training: Competency Evaluation

- **Competency certification for specialized procedures: an issue for some radiotherapy facilities**
- **Formalized training with documented evaluations:**
  - **Multidisciplinary teams are engaged in complex procedures such as prostate brachytherapy, SRS, etc.**
  - **It is not possible for a physicist to provide safe and effective support of these techniques without specialized training**
- **Expect to see more facility-specific competency certification programs being developed. Professional organizations, such as the AAPM, could consider developing templates for the production of such programs.**

On-going Training

- With the advance of technology it is essential that the medical physicist maintains her/his ability and skill to safely implement new treatment strategies at the highest level.
- Our training is never complete and we must continue to avail ourselves of opportunities that will contribute to the reduction of errors and the enhancement of quality.
- While professional organizations are clearly limited in their ability to provide practical hands-on training, they are in a position to suggest how such training might be conducted and perhaps to provide some of the basic tools for evaluation.

On-going Training: Linac QA Protocols

- Linear accelerator QA protocols:
- Demonstrated compliance with TG-40 protocol for 20 years
- In 2010, TG-142 report is available. One aspect of ongoing training could be how to implement TG-142 by physicists
- When the report of TG-100 is published, the landscape will change again
- As a community we need to guide the development of training modules to facilitate the efficient and effective implementation of new ways of doing old things

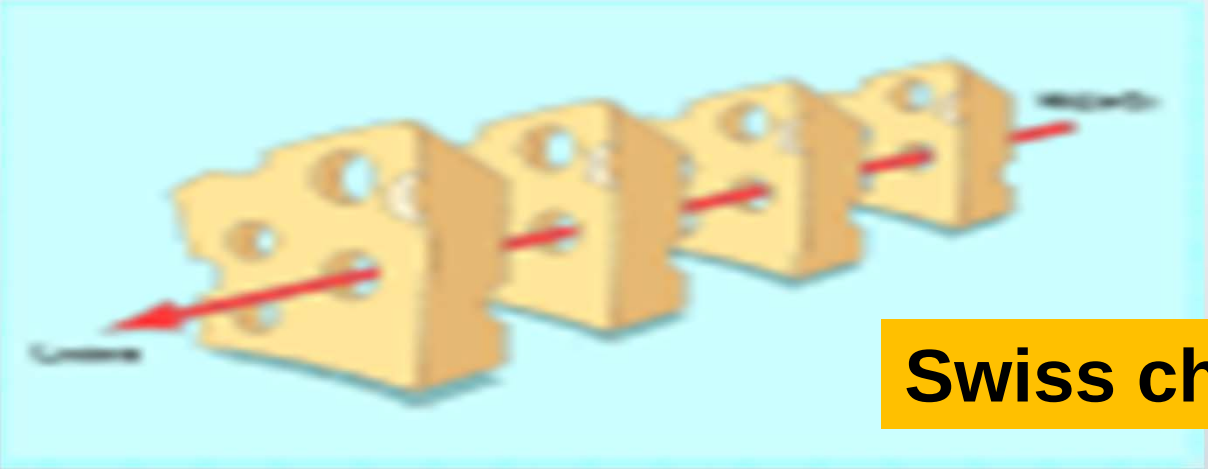
Errors Related to Human Performance

- Modern radiation therapy is a multidisciplinary field involving clinical experience, biology, radiation physics, and computational knowledge.
- The process of radiation therapy involves clinical patient consultation, patient immobilization and simulation imaging, target delineation and dose/volume prescription, radiation treatment beam design and optimization, target localization/verification in the treatment room, and radiation delivery and verification.
- Safety and quality procedures are the keys to providing the best possible outcome for the patient.

Errors Related to Human Performance

- For complex work flow and processes, system engineering tools have been applied to analyze the work flow, failure modes and effects, and human factors.
- Examples of common causes of incidents related to unsafe situations and deficiencies in education and training
  - Communication weaknesses
  - attention loss
  - situational violations (failure to follow established or good practice procedures)
  - ……
- Rarely can a particular incident be attributed to a single cause or system weakness

Human Error Management Strategies



Swiss chees model

The person approach (by James Reason):

- **Focuses on the error perpetrators, blaming them for forgetfulness, inattention, or moral weakness**
- **Direct most of their management resources at trying to make individuals less fallible or wayward**
- **Limiting the incidence of dangerous errors**

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Human Error Management Strategies

The system approach (by James Reason):

- **Concentrates on the conditions under which individuals work, and tries to configure the overall environment to avert errors or mitigate their effects.**
- **Strive for a comprehensive management program aimed at several different targets: the person, the team, the task, the workplace, and the institution as a whole.**
- **Creating systems that are better able to tolerate the occurrence of errors and to contain their damaging effects.**

Error Analysis: Education Related

Insufficient education and training lead to unsafe practices

- ***One medical physicist: PhD in engineering***
- ***Training in medical physics (post-doctoral fellowship)***
  - ***Research: hyperthermia instrument development***
  - ***Clinic: mainly IMRT QA delivery and observation of some linac QA***
- ***Job: solo staff medical physicist in a small clinic***
  - ***To deal with commissioning SRS program with circular cones only***
  - ***Felt comfortable proceeding with the SRS commissioning***
  - ***Used an ionization chamber with a diameter comparable to the size of measured field was used for depth dose, profile, and output factor***
  - ***Result: significant miscalibration of the radiation output of this SRS beam***

Error Analysis: Education Related

What can we learn from this event?

- **Lack of education: didn't know what didn't know**
- **Lack of training: didn't know small field dosimetry**
- **Lack of oversight**
- **Lack of policy for implementing new procedures**
- **Lack of practice ethics**
- **…..**

Yin et al Med. Phys. 2002

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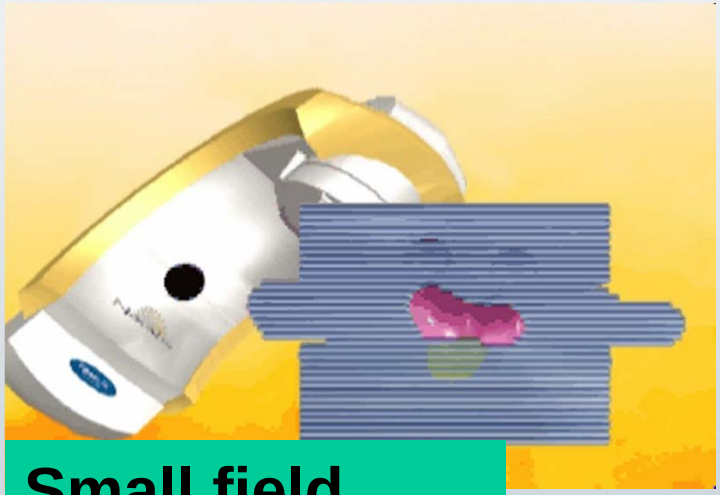
Radiation Accidents Reported in New York Times – Small Field Dosimetry



Small field
Small margin
Large dose

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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 period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

The hospital, CoxHealth in Springfield, said half of all patients undergoing a particular type of treatment — stereotactic radiation therapy — were overdosed by about 50 percent after an unidentified medical physicist at the hospital miscalibrated the new equipment and routine checks over the next five years failed to catch the error.

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Error Analysis: Training Related

- **Training, if properly designed, will familiarize the resident with the "rules" of clinical physics and guide her/him in the acquisition of the necessary practical skills**
  - ***A junior medical physicist: MS in medical physics , 2 yrs of experience in IMRT planning and QA***
  - ***Called by therapists to the treatment machine: A patient was being treated with a full conformal arc which ran through two 2-cm thick aluminum bars.***
  - ***Question: whether this would affect the dose***
  - ***The physicist asked the therapists to take the patient from the table while attenuation through the aluminum bars was measured***
  - ***As a result, the patient treatment was cancelled. Training efficiency?***

Error Analysis: Communication Related

- **Patient care: multiple processes performed by different professionals for optimal treatment. Effective communication between team members is recognized as critical for safety and quality**
  - ***As a physicist was performing a second chart check, he found the dose to one of the reference points indicated the wrong anatomical site***
  - ***However, he assumed it was a typo and did not investigate further***
  - ***Result: wrong treatment labeling was carried on to the treatment room and the patient was treated to the wrong treatment site***
- **Lack of communication between involved staff**
- **A communication policy was vigorously implemented**

Error Analysis: Improving Communication

- Within a department, there needs to be an easy system for the staff to communicate: from standardized naming conventions, to designating checkers at various check points, to a standard time-out check list.
- As an individual staff member, one needs to follow established workflow procedures and check each designated step without presumptions.
- A continuing process and the department and its smaller teams should have mechanisms to facilitate this.

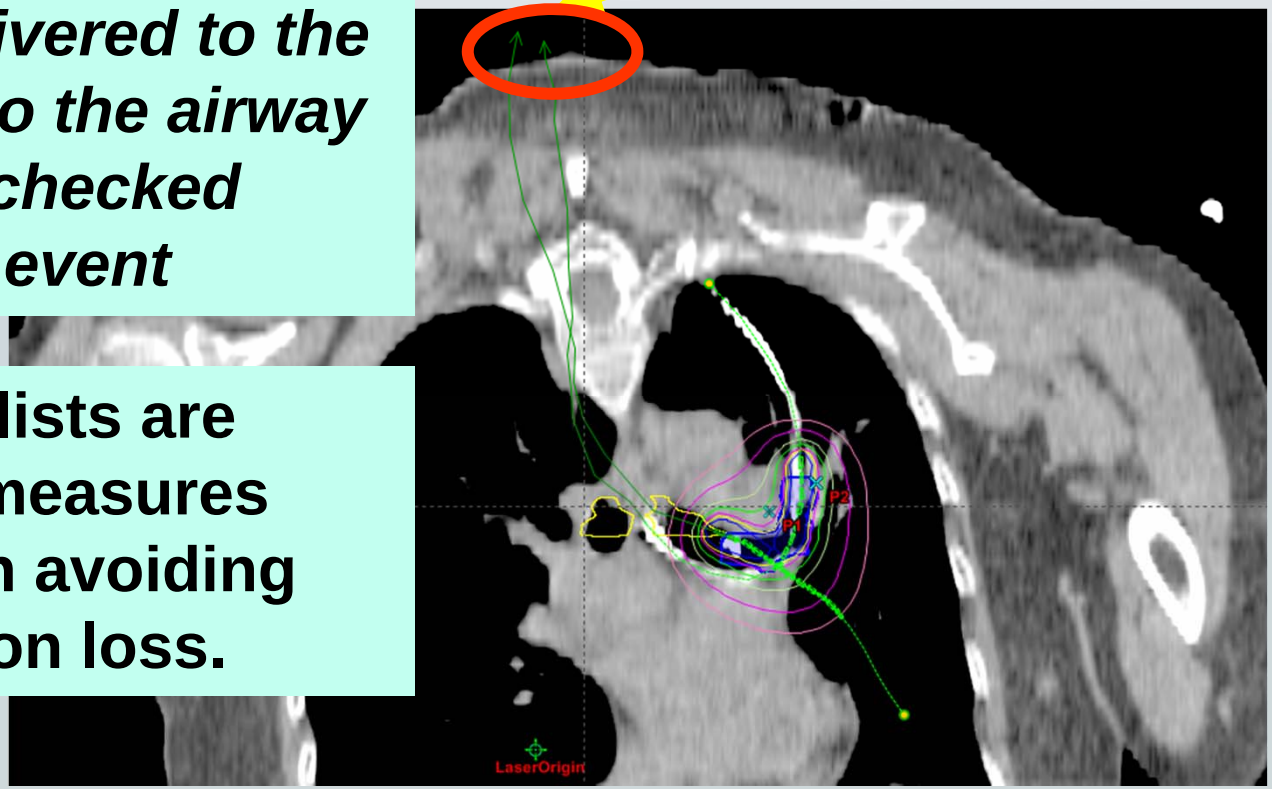
Error Analysis: Attention Loss

- **What may happen for repetitive and tedious clinical medical physics duties?**
- **Attention loss can be a consequence of the perceived trivial nature of the task at hand or, frequently, due to interruptions**
- **Even well-educated and well-trained physicists make errors due to loss of attention. For example:**
  - ***Two different lesions located at different sides of lung: treated in the same session***
  - ***Treatment beams were configured correctly but were attached to different setup fields, which were used for localization***
  - ***Result, the right lesion plan was delivered to the left lesion and the left lesion plan was delivered to the right lesion***

Error Analysis: Attention Loss

- *The prescription: 10 Gy × 2 fx*
- *The distal ends of catheters were reversed*
- *The actual dose for the first treatment was delivered to the larynx instead of to the airway*
- *Missed in double checked*
- *Lead to a medical event*

Arrows indicate the distal aspect of catheters



Time-out and check lists are widely regarded as measures that can be helpful in avoiding the effects of attention loss.

Error Analysis: Violations

Situational violations: departures from established procedures

- **"To get the job done"**
- **Are perceived as being unnecessary**
- **Many QA procedures are repetitive with infrequent failures**
- **Gain gradually the reputation of infallibility**
- **The following incidence may happen: checker may skip the required tests assuming no confirmation is needed:**
  - ***A 7-field IMRT plan with 5–7 mm CTV to PTV margin***
  - ***Gold seeds for daily localization with orthogonal MV → 9 mm shifts***
  - ***Guideline: ve lly check***
  - ***The staff felt***
  - ***Result, the p 18 mm***

Corrective actions?

- **Staff education**
- **Set a new guideline**

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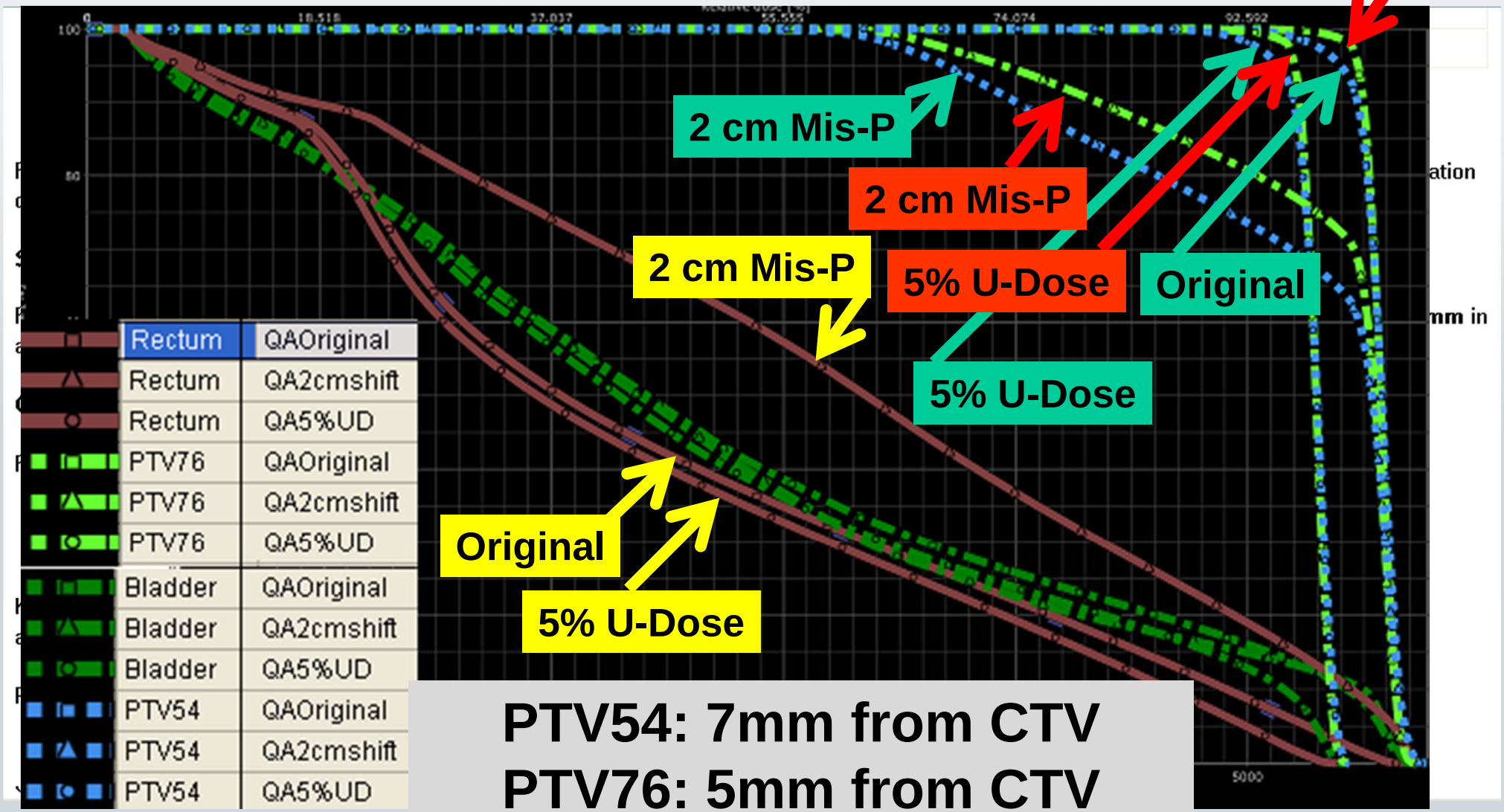
Tired of IGRT QA?



PTV54: 7mm from CTV
PTV76: 5mm from CTV

Effect of IGRT Inaccuracy

What can you learn from this?

- **Would you consider to IGRT with this uncertainty?**
- **Should we do IGRT QA?**
- **How about 2 mm in daily IGRT QA?**
- **Would do SRS with 2 mm uncertainty?**
- **Assume the system can be as accurate as 1 mm, but daily QA says 2mm?**
- **…..**

Error Analysis: Violations and Ethics

- ***A new graduated MS with limited clinical experience was hired in a small clinic to work with another senior physicist.***
- ***The senior physicist was trained as an engineer but had worked in medical physics for many years***
- ***The junior physicist was assigned to complete annual QAs for two linacs and was looking for previous reports, which were not available***
- ***The Junior followed guidelines TG-51 protocol and noted output for one electron energy was off by more than 10%***
- ***The Junior confused about why daily and monthly QA tests had been passing throughout the years at the clinic and asked the senior physicist for assistance***

Error Analysis: Violations and Ethics

How to look at this case?

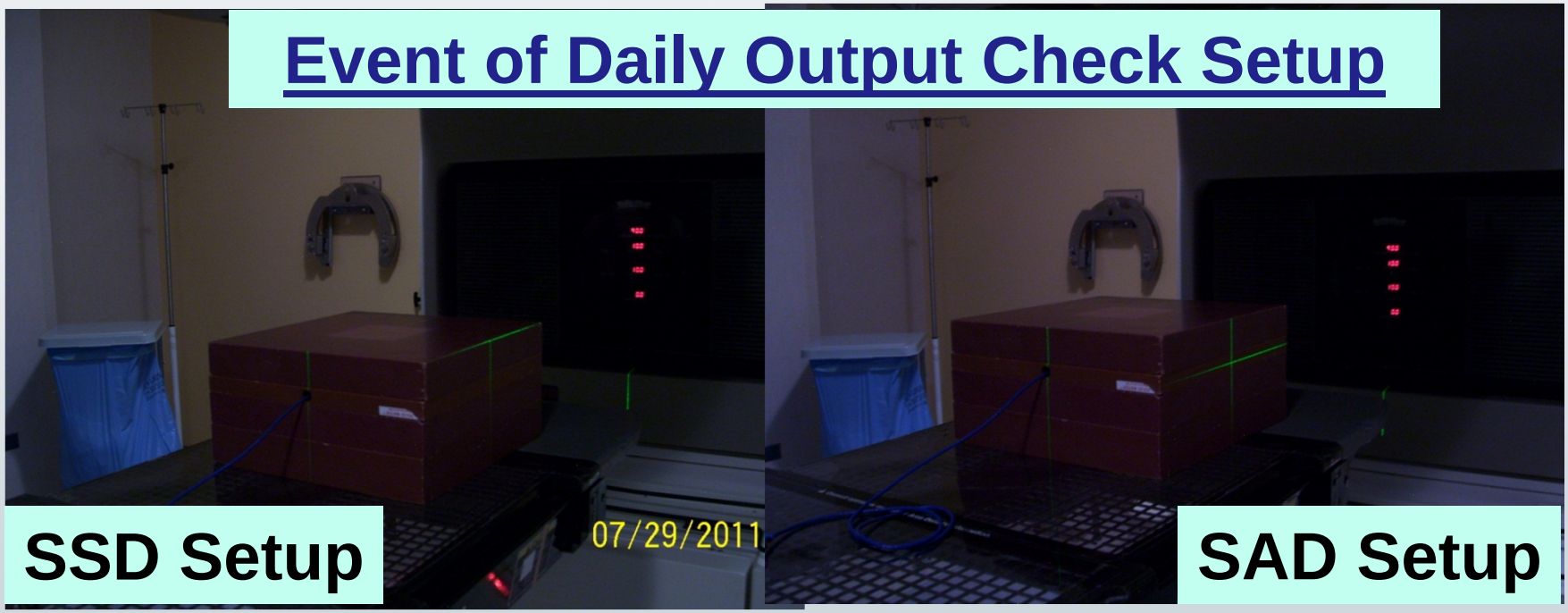
- **Procedure violation**
- **Isolation of the junior physicist**
- **A disinterested administration**
- **Lack of responsibility for mentoring**
- **Shortcomings in adhering to basic ethical principles**
- **……**

Error Analysis: Violations

- We use many types of instruments and phantoms to perform QA procedures. Proper functionality of that equipment is not always guaranteed but plays a critical role for meaningful QA
- Sometimes people may skip proper acceptance testing procedures, commissioning, and QA for new devices, assuming they are as good as other similar devices.
- What would you do when you buy any detectors, phantoms, and other instruments?
- Functionality, safety, accuracy, and efficiency, etc

Error Analysis: Multiple Factors

Event of Daily Output Check Setup



- *2 physicists/2 linacs, each for one linac and backup for the other linac. This primary/backup arrangement was switched once a year.*
- *Each physicist independently designed his own monthly output check, one using an SSD setup and the other an SAD setup.*
- *One day when Physicist A was on-site alone, the therapists reported ~3% daily output based on diode measurements) on his backup linac.*

Error Analysis: Multiple Factors Related

- ***Physicist A decided to perform a monthly output check after patient treatments for the day were complete (follow the guideline).***
- ***In the evening, Physicist A assembled the monthly output check in SSD setup rather than the designed SAD setup.***
- ***The measurements showed that the photon beam outputs were 8% low, and the electron beam outputs were 2%–4% low.***
- ***After attempting to contact Physicist B without success, Physicist A decided to increase the machine outputs based on his measurements.***
- ***The next morning, the two physicists discussed this issue. On hearing of such a large adjustment of all energies and modalities, Physicist B investigated further, and discovered the setup discrepancy.***
- ***The outputs were immediately corrected, but unfortunately six patients had already received 8% higher doses that day.***

Error Analysis: Multiple Factors

- So what can we learn from this description?
  - Education: two different QA procedures for the two linacs (importance of standardized procedures)
  - Communication: not clearly understood setups by both physicists
  - Results of lack of education for Physicist A:
    - the linac worked (outputs for each modality/energy are controlled by separate boards, making it highly unlikely for all of them to suddenly be 2%–8% low)
    - the daily QA measurement worked (knowing that the diode response changes over time due to radiation damage, probably causing the observed underdose).

Error Analysis: Multiple Factors

- **Results of lack of training for Physicist A**
  - **in output adjustment (not performing an independent check of output after adjustment with the daily QA device**
  - **not minimizing the risk of such a large change by adjusting by 50% of the measured difference pending further investigation)**
- **Results of lack of communication by Physicist A**
  - **failing to contact other physicists at nearby affiliated facilities for advice when Physicist B was reached.**

- **Corrective actions: unify the calibration protocol; set guideline for output adjustment; …**

Summary

- Human performance is a major source of incidents in radiotherapy
- An effective approach to minimizing the effect of performance issues is to implement effective educational and training programs
- There remains an unpredictable human element associated with the proper execution of these tasks, which may require interventions at the psychological, environmental, and societal levels
- Education and training are not exclusively a physicist's tasks. They need to be facilitated by team members.

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Summary

- The quality and safety of radiation therapy depends on the quality of staff performing the care
- The administrative leadership should always allocate sufficient resources for physicists to be recharged through continuing education and training activitie
- Accountability and responsibility should clearly be defined
- An systematic approach should be established to minimize human errors, including procedures and documentation
- Root-cause analysis and FMEA are important for each incidence with corrective actions

Thank you for your attention

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