HDR Brachytherapy

Patient Safety Focused Quality Assurance

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Fall 2011 GLC-AAPM Meeting

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2012 ABS Winter School
Quality Assurance in LDR and HDR Brachytherapy

March 16-17, 2012

Pointe Hilton Tapatio Cliffs, Phoenix, AZ

IAEA Training Course

Module 2.9: HDR unit malfunction (USA)

IAEA

International Atomic Energy Agency

HDR remote afterloader

- A small and mobile source housing installed in shielded treatment room
- Remote control console
- Source is ^{192}Ir, with nominal activity of 10.0 Ci
- Source is attached to a wire
  - can be extended under remote control through one or more catheters in succession into the patient
- A second wire with a dummy source
  - used first to verify the pathway through the catheter and to verify positions etc…

Example of HDR unit

Background

- 16 Nov. 1992: Elderly patient being treated for anal carcinoma at Indiana Regional Cancer Center (IRCC)
  - The patient was scheduled for 3 treatments of 6 Gy each
    - Omnitron 2000 HDR unit
  - Five catheters were placed into the target volume

What happened?

- The dummy source was introduced without any problems
- With the HDR source
  - Four channels went well
  - Upon attempting to direct the source into the fifth catheter, the control console reported an error
  - After several attempts, the treatment was abandoned

What happened?

- Termination of the treatment
- The staff entered the treatment room
  - Disconnected the HDR unit from the implanted catheters
  - Removed the patient

What happened?

- An area radiation alarm indicated high radiation levels, but was ignored
- Both sound and sign alarm
- The staff reported that the alarm "often malfunctioned" and were used to ignoring it

Typical room monitor system

What happened?

- A survey meter was available but was not used to confirm or rule out the area alarm's signal
- The HDR console reported that the source was "safe"
- The patient was transported back to her nursing home

Typical hand held meters

The accident

- The hospital staff did not recognize that the source had broken loose from the guide wire, and had remained inside the catheter
- The catheters remained in the patient, with the HDR source, as the patient was transported back to the nursing home
- 20 Nov. 1992 (4 days later) - the catheter containing the source fell out
  - The catheter (and source) was placed in a red “medical biohazard” trash bag
  - Later, the bag was moved to another storage location with other trash bags where it remained until 25 Nov.

The discovery

- 25 Nov. 1992: A driver from the waste handler picked up the red-bag bio-waste from the nursing home
- The package was loaded it into a truck trailer with other trash, and transported to the company's facility in Carnegie, PA.
- From there it was transported to a facility in Warren, OH.

The discovery

- A radiation detector at the Warren facility identified radiation emissions from the trailer, and the facility ordered the trailer to return to Carnegie
- The trailer remained at the Carnegie facility until Monday, 30 Nov. 1992

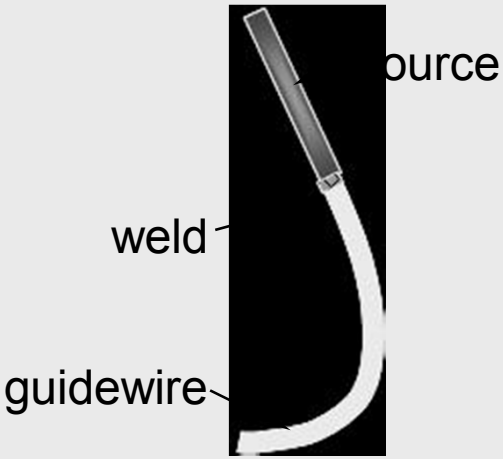
Typical vehicle meters

The discovery

- 1 Dec. 1992: The trailer was searched, the bag containing the source was found, and traced back to the nursing home
- The nursing home was contacted, and they in turn notified the hospital
- At this point, the source had been missing for 16 days without notice
- The medical physicist confirmed that the HDR source was missing
  - The unit had not been used since the event!

Cause of the accident

- The source in this type of HDR unit was welded to the guide
- The source was shipped to the Cancer Center in a shielded cask that employed Teflon near the source
- In the presence of moisture, radiolysis produced hydrogen fluoride which reacted with the Nitinol[1] wire, corroding the weld
- The corrosion ultimately weakened the weld, and the source broke off the wire when stressed



Typical emergency container

[1] Nitinol is an alloy of nickel and titanium.

Lessons to be Learned

- Ensure that all staff
  - Are properly trained in radiation safety procedures
  - Are properly trained in the operation of equipment
  - Are properly trained for emergency situations
- Include in the Quality Assurance Program
  - Formal procedures for verifying the proper operation of the HDR remote afterloading equipment before patient treatments
  - Formal procedures for verifying the operation of radiation safety equipment
  - Formal procedures for using radiation safety equipment when radioactive materials are used for therapy

Lessons to be Learned

- Routine surveys of HDR patients to ensure that the source has returned properly to the shield after treatment
- Procedures mandating the use of personal dosimeters by staff

10 CFR 35
Medical Use of Byproduct Material

- Subpart A/B/C
  - General Information and Requiremts
- Subpart D/E
  - Unsealed Byproduct Material
- Subpart F
  - Manual Brachytherapy
- Subpart G
  - Sealed Sources for Diagnosis
- Subpart H
  - Photon Emitting Remote Afterloading Units, Teletherapy Units, Gamma Stereotactic Radiosurgery Units

10 CFR 35
Medical Use of Byproduct Material

- Subpart J
  - Training and Experience Requirements
- Subpart K
  - Other Uses of Byproduct Material
- Subpart L
  - Records
- Subpart M
  - Reports
- Subpart N
  - Enforcement

(B) 35.40

- Written directive (for HDR) must include:
  - patient's name,
  - the radionuclide,
  - treatment site,
  - dose per fraction,
  - number of fractions, and
  - total dose;
  - must be dated and signed by an authorized user before treatment
  - (may include more info such as applicator size, etc)

(B)35.41

- For procedures requiring a written directive, we must have written procedures to guarantee:
  - Patient's identity is checked pre-treat.
  - The administration of treatment is in accordance with the written directive.
  - *Ours is called "Brachytherapy Quality Program" (6 pg document describing procedures to follow to make sure brachy script is delivered accurately).

Part 35 Regs continued…

- 35.61
  - survey instruments calibrated annually
- 35.67
  - Leak test and inventory requirements
- 35.604
  - Survey RA pt post-tx with portable instrument
- 35.605
  - Must be specifically licensed to exchange sources or service a RA unit. (manufacturer)

Part 35 Regs continued…

- 35.610
  - Unit secured when not in use, dual operation of machines prohibited, must have emergency procs.
- 35.615
  - Must have: door interlock, functional camera/intercom, both an authorized user and authorized physicist present for every HDR tx, emergency response equipment in place
- 35.630
  - Must have: calibrated dosimetry system
- 35.633 & 35.643
  - RA calibration and QA requirements.

Old Part 35

- Misadministration
  - Dose different by 20% from script
  - Leaking source, wrong: pt, isotope, site
- Recordable Event
  - Dose differs10% from prescription

Medical Event

- 35.3045 Report and notification of a medical event
  - Total dose differs by 20% or single fraction dose differs by 50%
  - Wrong isotope, wrong route, wrong patient or leaking source
  - Wrong site
- Notify NRC by telephone no later than the next calendar day after discovery

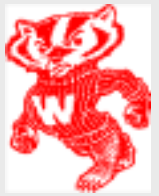
Lessons to be Learned from Misadministrations

Bruce Thomadsen

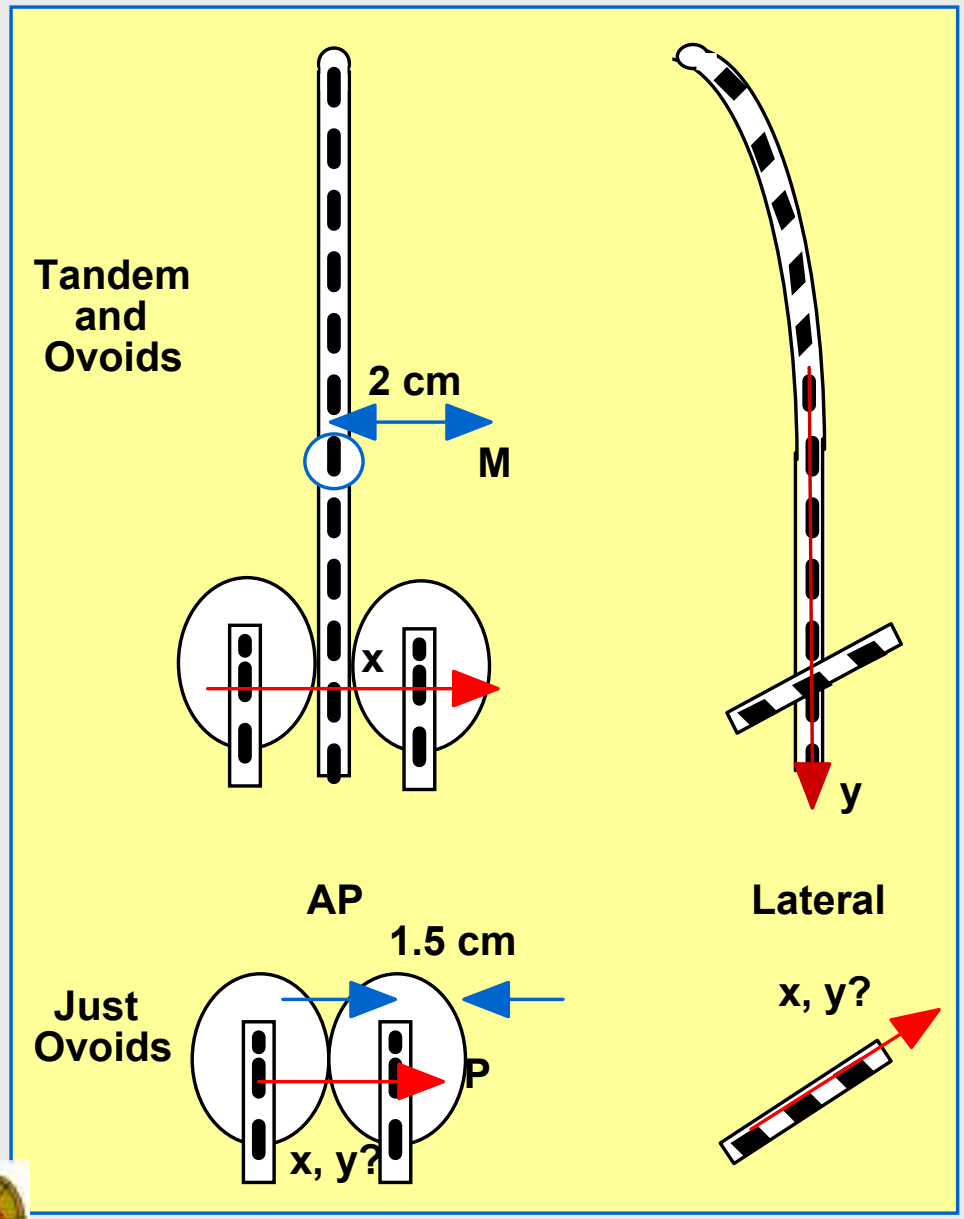
University of Wisconsin - Madison

Example 1: The 1st UW Misadministration

- After a considerable number of HDR treatments for cervical cancer using tandems and ovoids, first case for post-op endometrium with just ovoids.
- During planning, the question comes up as to the coordinate axes...



Selecting Axes for the Ovoids



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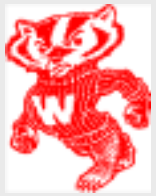
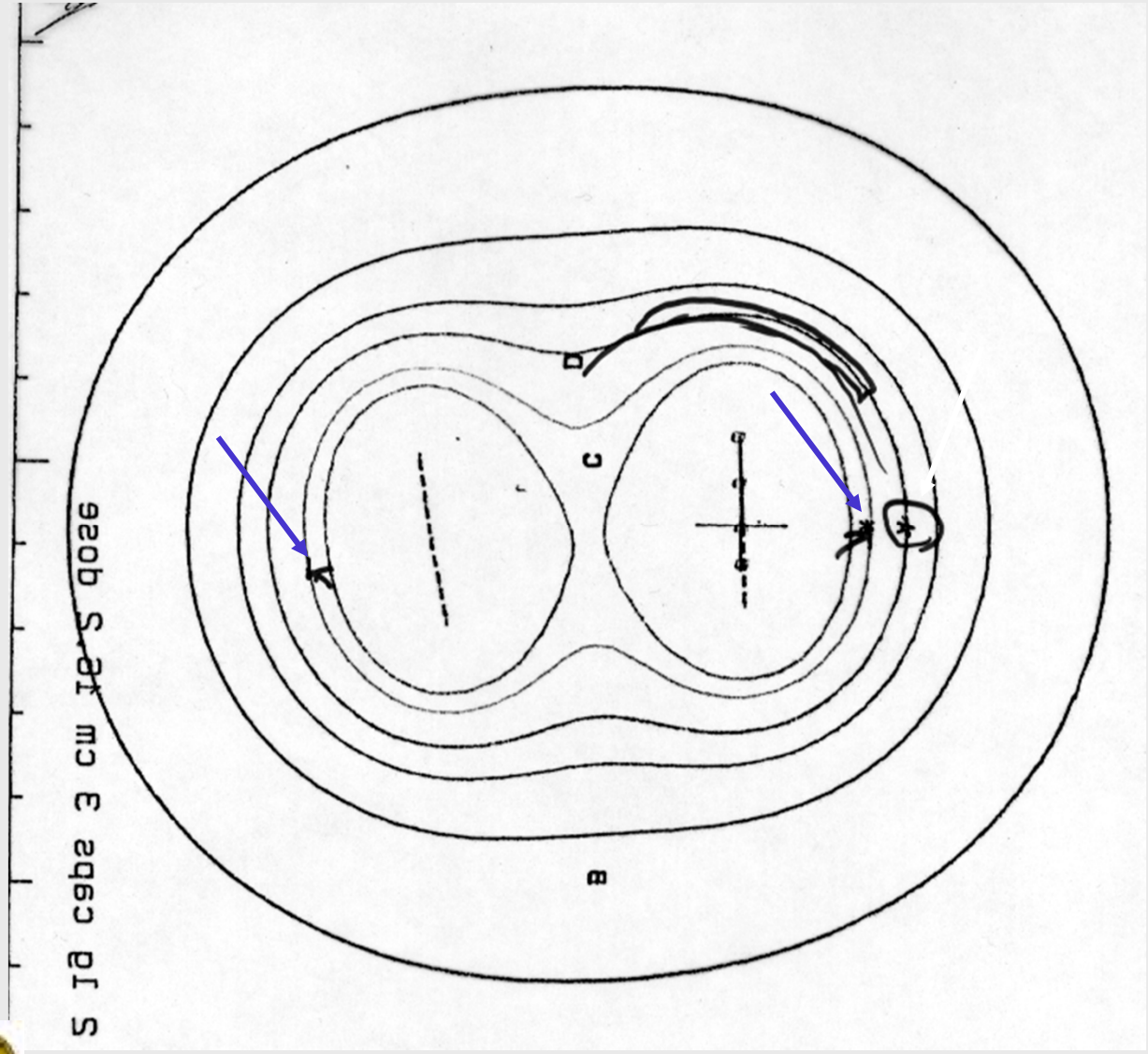
Example 1: The 1st UW Misadministration—Continued

- After determining the axes, the next task in the treatment planning system is to enter the coordinates for the applicator points (the locations at which the dose is prescribed).
- Should have been Surface: -15,0,0
- Entered as Surface: -20,0,0, the usual specification for tandem and ovoid cases.





Isodose from UW 1st

Prescription Point

Optimization point

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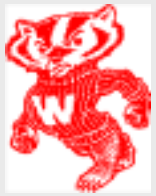
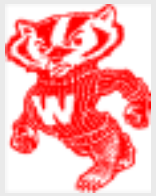
The 1st UW Misadministration—What happened

- Following intense concentration, there follows a lull in attentiveness. Mistakes often occur at this time.
- Hazard markers:
  - New Procedure
  - Lack of training (of dosimetrist on axis selection)
  - Distraction (discussion)
  - No Quality Assurance and Ineffective Quality Control
  - Expectation Bias (20 mm for prescription)

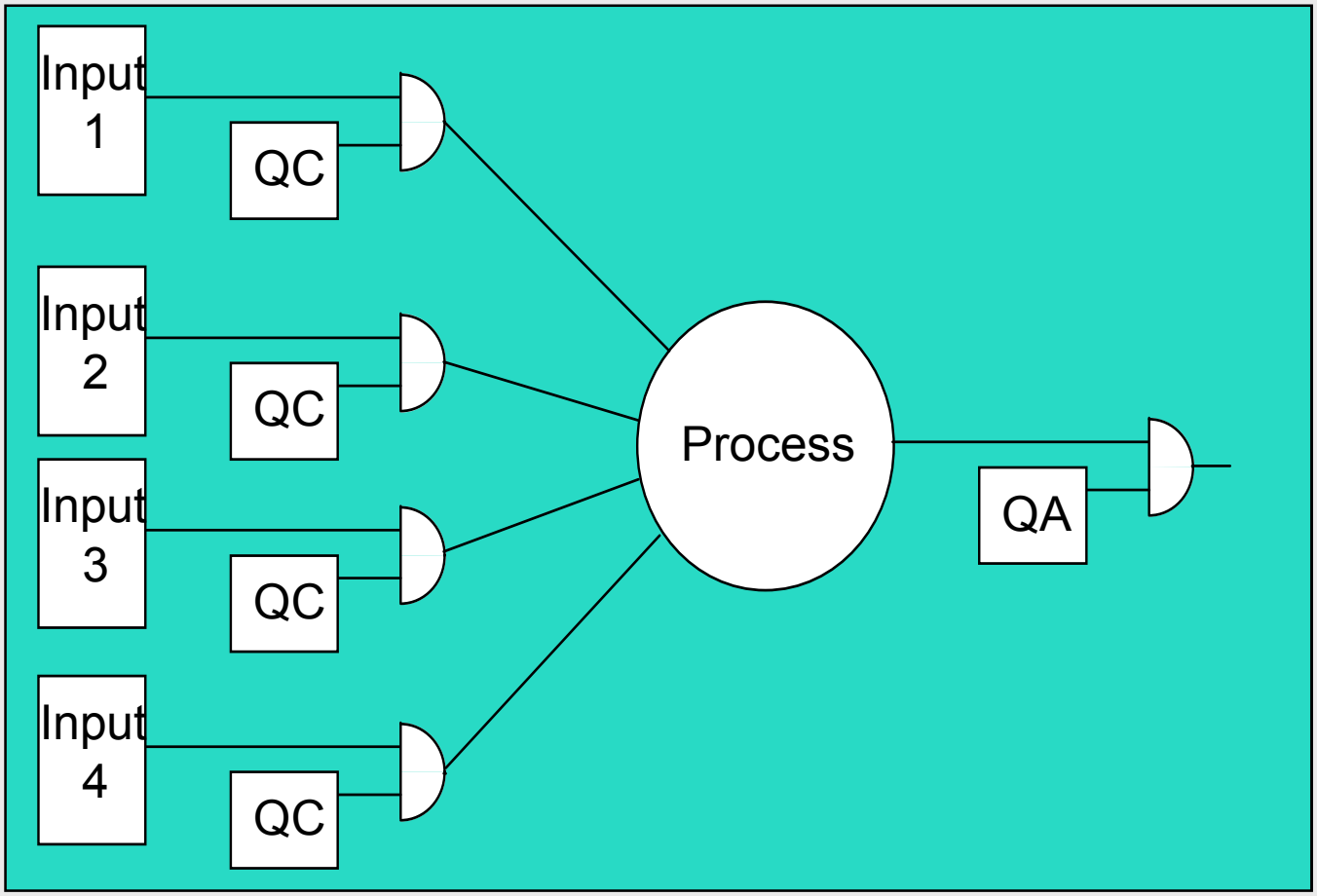


Expectation Bias

- Expecting the normal situation to the exclusion of recognizing an abnormal condition.
- Example: Alarming detectors.



Organizational Difference between QA and QC



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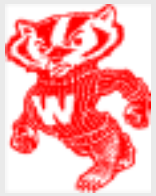
Error Reduction

Two approaches to Error Reduction:

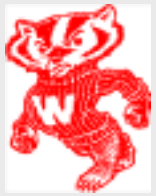
- Error Prevention (QC)
  - Consumes more resources
- Error Interception (QA)
  - Riskier

As always, they work best together



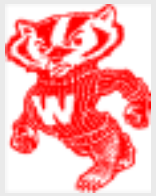
Example 1: The 1st UW Misadministration—What Happened to the QA

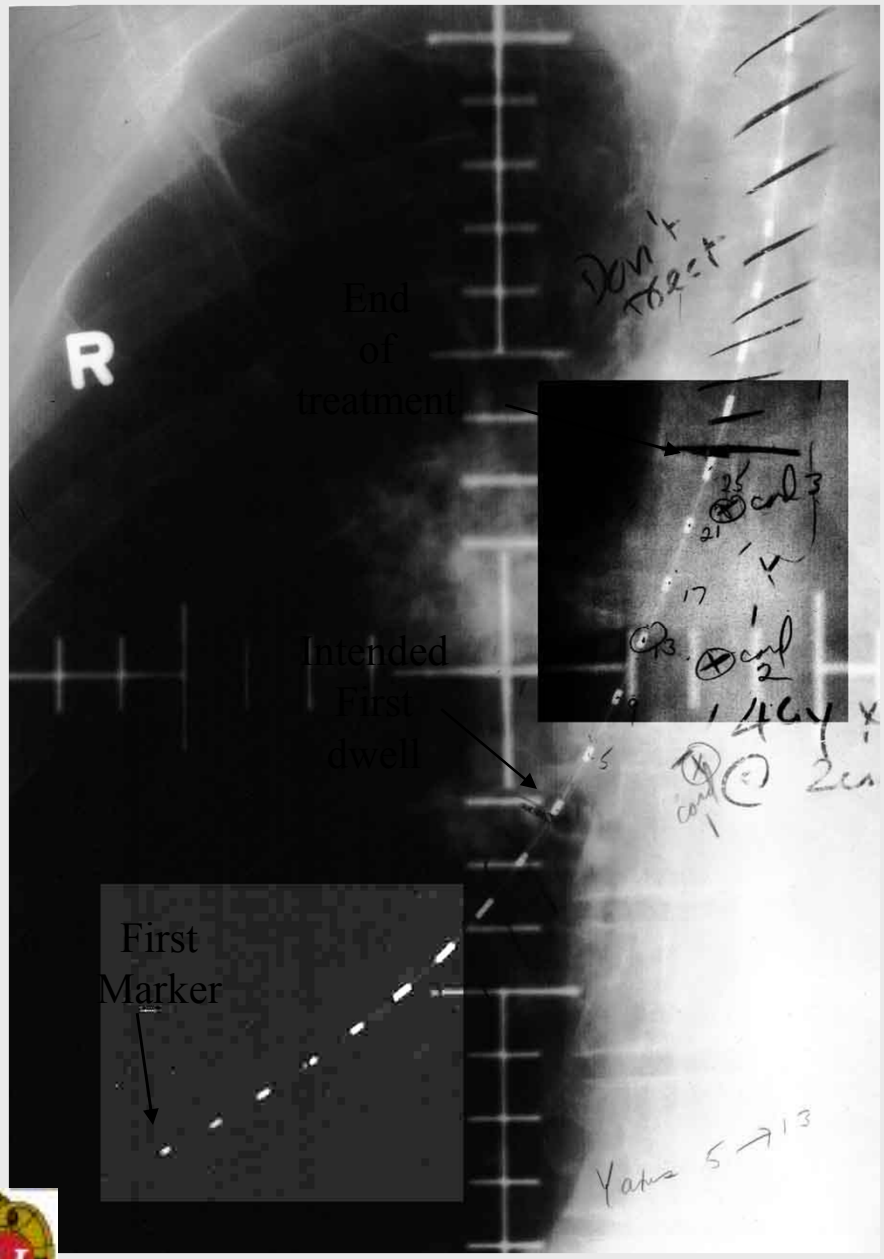
- The physicist in charge of the program did not understand the difference in function between QC and QA, and felt that the QC (a second person monitoring the input) would be sufficient to catch errors.
- After this event, QA was initiated reviewing the treatment plan following a protocol, *but without forms!*



Example 2: The 2nd UW Misadministration

- A simple endobronchial application like many treated before.
- The catheter was inserted far past the target, requiring a 90 mm offset to move the dose distribution to the tumor.





Film from the UW 2nd Misadmini-stration

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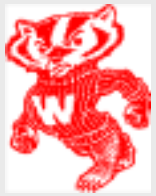
Example 2: The 2nd UW Misadministration-Continued

- The HDR source had just been changed and for the first time, the distance to send the source to have it coincide with the 1st marker was 994 mm instead of 995 mm.
- When the treatment planning for the patient got to the part where the length to send the source was to be entered, the dosimetrist was about to enter 905 (995 - 90).



Example 2: The 2nd UW Misadministration-Continued

- The physicist caught the potential 1-mm error, and said the value should be 904.
- The dosimetrist, appropriately wanted an explanation before entering the value; a discussion ensued.

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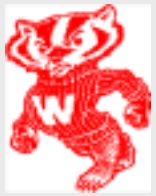
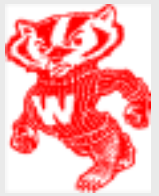
- The physicist caught the potential 1-mm error, and said the value should be 904.
- The dosimetrist, appropriately wanted an explanation before entering the value; a discussion ensued.
- At the end of the discussion, the dosimetrist, satisfied with the explanation, pressed the return key, entering the default value of 995.



Example 2: The 2nd UW Misadministration-Continued

- The error was not caught on the QA check by a second physicist.
- The first fraction was treated to the end of the catheter.
- At the second of the four fractions, the second physicist treated the patient and then noticed the lack of offset.

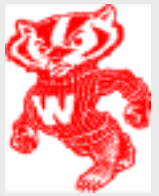


Example 2: The 2nd UW Misadministration—What Happened

- The dosimetrist and physicist entered the mental lull after the problem-solving session.
- Almost all similar cases had no offsets, and the normal action when entering the length had been a simple return, yielding the default distance.

Example 2: The 2nd UW Misadministration—What Happened to the QA

- After the first Misadministration, a QA protocol was initiated, but without forms; Checks were to be performed following a list.
- The second physicist did not perform the check on the distance, and said later, “I assumed the first physicist checked it.”
- Following this event, the checks were performed in writing on official forms.

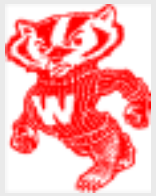


The 2nd UW Misadministration—What happened

- Following intense concentration, there follows a lull in attentiveness *again*.
- Hazard markers:
  - New Situation (change in standard length)
  - Lack of training (of dosimetrist in distance meaning)
  - Distraction (discussion)
  - Poor Quality Assurance and Ineffective Quality Control
  - Expectation Bias (return for distance)

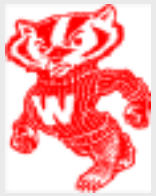
An Important Observation

- People seem to be able to handle a single bum input very well, and correct the situation before problems arise
- People have trouble managing more than one perturbing situation at a time — that is when situations turn into events



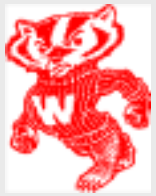
Another Observation

- Trouble lies off the beaten track
- Once off the normal path, it is much easier to keep getting farther afield than back



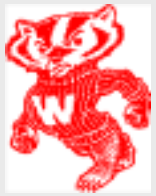
Example 3: The 3rd UW Misadministration

- Non-HDR certified authorized user wanted to treat a patient on the HDR. Dept. RSO decides (poorly) to go ahead provided:
  - The most experienced physicist handles the case,
  - A certified, experienced resident staffs the case,
  - No treatments will be given if *anything* seems at all unusual.



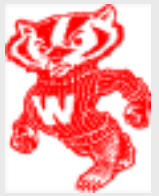
Example 3: The 3rd UW Misadministration

- Special applicator made to clip on nose with two endobronchial tubes held to nasal tumors.
- Four daily treatments given without a hitch.



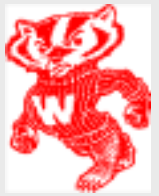
Example 3: The 3rd UW Misadministration

- At fraction 5, when the patient came for treatment, the assigned physicist was on the phone, and the therapist decided not bother him.
- The resident was out of town.
- A part-time physicist thought he would help out, picked up the chart by the unit, programmed the unit with the card, checks the times with the *uncertified* authorized user, and starts the treatment.



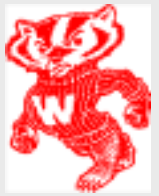
Example 3: The 3rd UW Misadministration

- Someone asked how long the treatment would last. The physicist looked at the time and answers; the physician gives a different answer from remembering the last fraction. Treatment stops.
- Physicist had picked up the chart for a different patient.



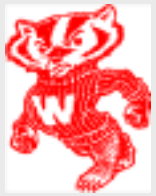
Example 3: The 3rd UW Misadministration—What Happened

- Ineffective QM (Patient ID)
- Deviations from protocols (Treating without resident or primary physicist)
- Lack of training (For physician)
- Lack of communication (Discussing the patient with the new physicist)
- Distractive Environment (Multiple charts on the counter)



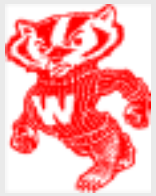
3 Somewhat related Events - #1

- The length was specified as 995 mm instead of the intended 870 mm (i.e., 12.5 cm further down the catheter) by default.
- Thus, 5 Gy was delivered to the wrong site.
- NRC: "Root cause," not having policies or procedures to check all parameters.



1st of 3

- NRC Contributing factors:
  1. Failure of Dosimterist and Physicist to enter length.
  2. Time pressures.
  3. Distractions from the number of persons around.
  4. Failure of worksheet to determine length.
  5. Inadequate review of dosimetry calculations.
  6. Failure to program unit correctly.
  7. Inadequate review of parameters.



3 Somewhat related Events - #1: What (Really) Happened

- Faulty Design (Default feature for distance)
- Ineffective QC
- Complicated by
  - Lack of staffing (resulting in time pressures)
  - Distractive work environment

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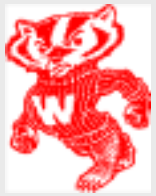
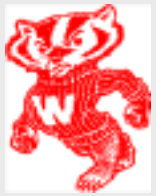
2nd of 3

- First of two HDR Brachytherapy 6 Gy fractions.
- Date entered American style (4/06/94) instead of the required European style (6/04/94).
- The unit incorrectly corrected for decay, giving 10.39 Gy instead of 6 Gy.
- Detected before the second fraction.
- This happened to be only a recordable event, but could have been worse.



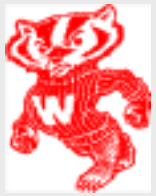
3rd of 3

- HDR brachytherapy treatment
- Rushed environment
  - Two HDR patients that day in a department usually only treating one
  - Physicists also busy with external beam patients
  - Scheduling had not checked physicist availability
  - Patient had been on the table for a long time
  - Chief Therapist (manager) urging speed
  - Planning computer card writer not functioning



3rd of 3

- Physicist programs the treatment unit by hand
- Because of the rush, no second person checked the program
- During the treatment, the Chief Therapist noticed that the source remained at one position for a long time: treatment interrupted



3rd of 3

- During the programming, the physicist entered 260 second for one dwell position instead of 26. Seconds

7	8	9
4	5	6
1	2	3
0	.	=

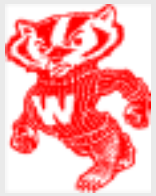
Calculator

7	8	9
4	5	6
1	2	3
←	0	.

HDR Unit

1	2	3
4	5	6
7	8	9
*	0	#

Phone



Commonalties in the three events

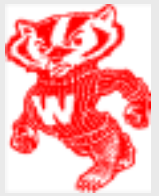
- Rushed environment from lack of staffing
- Machine design problems
  - Default input
  - Mismatched cultures (European vs. American)
  - Panel layout
- In two of the three, concomitant problems distracted attention

Commonalty in Most Events

- These people are not stupid!
- They are like almost all of us: conscientious, and trying to do a good job under less than adequate situations.
- They fall into traps, and respond like human beings.

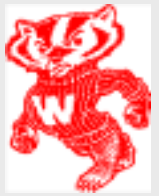
Costs of Misadministrations

- Time — About 6 months of a physicist
- Publicity — NRC press releases and news stories
- Money
  - Tens of thousands of dollars in fines
  - Hundreds of thousands of dollars in “settlements”
- The money alone could pay for additional support and for QM to prevent events



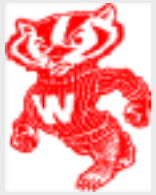
Common Causes of Events

- Design problems (frequently default settings)
- Lack of information (often due to training)
- Expectation bias (operators failing to acknowledge a change from normal)
- Distraction (due to pressures and other assignments)
- Rushing (due to pressures and lack of staffing)
- Lack of communication (between parties)



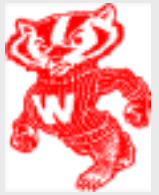
Observations on Events

- Failures in medicine parallel those in industry.
- Errors don't just happen from a single cause, but are surrounded by complicating situations.
- Errors are surrounded by indicators that are not noted.
- Errors often follow violations in protocols.
- Errors often occur with new procedures or variations on common procedures.
- Errors frequently involve less than full-time staff.



For Preventing Events

- Carefully consider QM!
  - Design QC and QA separately
  - Never bypass QM, particularly when the case is rushed.
  - In a QM check fails, STOP EVERYTHING.
  - Everyone involved should have the ability to stop a procedure if anything seems wrong.
- Do not expect things to be right.
- Consider human performance, such as when thought processes do not function well.



HDR QA Guidance Documents

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TG-41

- Intended to be used in conjunction with TG-40
- Two extrinsic factors affect QA program
  - Location of unit
  - Frequency of use
- Equipment QA Frequency
  - No legal standards for QA frequency except for those written in license
  - Frequency of QA testing often determined by frequency of use

TG-41 (Cont.)

- Equipment QA Type
  - Functionality
    - Console indicators
    - Printer and paper
    - Intercom and camera
    - Radiation monitors, door interlocks, and warning lights
    - Batteries charged
    - Test run for unit functionality

TG-41 (Cont.)

- Equipment QA Type (Cont.)
  - Source position accuracy
    - Visually
    - Autoradiograph
  - Computer-decayed source activity checked against decay chart
  - Source activity
    - Is it necessary?
  - Timer accuracy

TG-41 (Cont.)

- Equipment QA Type (Cont.)
  - Monthly or quarterly
    - Timer accuracy and linearity
    - Source position accuracy
    - Dummy position accuracy
    - Check all emergency systems
    - Measure lengths of source guide tubes and functionality of connectors
    - Review of compliance
    - QA logs completed per license

TG-41 (Cont.)

- QA in the Use of Equipment
  - Pressure to treat quickly can contribute to user-generated errors
  - Independent check of treatment parameters by a second person
  - Preparation and use of well-planned pre-treatment forms and checklists

TG-41 (Cont.)

- QA in the Use of Equipment (Cont.)
  - Typical checklist can include but not be limited to:
    - Have the pre-treatment, functional QA tests been done?
    - Is the prescription completed and signed?
    - Has the treatment plan been independently reviewed?
    - Have the treatment parameters been reviewed by a second individual?
    - Are all pre-treatment forms completed and signed?
    - Do pre-treatment autoradiographs confirm the treatment is entered correctly?

TG-41 (Cont.)

- QA in the Use of Equipment (Cont.)
  - Standard site-specific treatment methods should be adopted
    - Misadministrations most likely to occur when methods are not standardized
- Equipment QA and equipment use QA are both dynamic processes

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TG-40

- Treatment Planning Computer System
  - Dose distribution is correct for the source type
  - Spatial reproduction is appropriate for implant
  - Dose summations are calculated correctly
  - Invariant following rotation and translation

TG-40 (Cont.)

- QA tests for HDR brachytherapy sources
  - At initial purchase:
    - Physical/chemical form documented
    - Source encapsulation documented
    - Radionuclide distribution and source uniformity documented
    - Location of radionuclide within 1 mm
  - At every use:
    - Calibration verification

TG-40 (Cont.)

- QA tests for well ionization chambers
  - At initial use or following repairs:
    - ADCL calibration documented
    - Precision within 2%
    - Linearity within 1%
    - Collection efficiency within 1%
    - Geometrical/length dependence documented
    - Energy dependence documented
    - Source wall dependence documented
    - Venting documented

TG-40 (Cont.)

- QA tests for well ionization chambers
  - Every two years:
    - Linearity within 1%
  - Each use or ongoing evaluation:
    - Redundant check within 1%
    - Leakage documented

TG-40 (Cont.)

- QA tests for intracavitary applicators
  - At initial use or following repairs:
    - Source location documented
    - Coincidence of dummy and active sources, 1mm
    - Location of shields documented
  - Yearly:
    - Source location documented

TG-40 (Cont.)

- QA tests for interstitial applicators
  - At initial use or following repairs:
    - Coincidence of dummy and active sources, 1mm
  - At every use:
    - Coincidence of dummy and active sources, 1mm

TG-40 (Cont.)
Procedure Specific Parameter Verification

Accuracy of OR implant description	Direct observation	During procedure
Prescription accuracy and consistency	Consistency of prescription with disease stage, isodose plan, department treatment policies	First half of treatment
Treatment plan	Calculation of plan and check for accuracy and consistency	First half of treatment
Implant removal	Physicist present or contact nursing staff to verify	Expected removal time
Sources all removed	Patient survey	At removal
Review treatment	Verify treatment time	After completion of procedure
Record, QA audit	All QA, treatment, and radiation safety records complete	After completion of procedure

TG-40 (Cont.)

QA of remote afterloading brachytherapy units

Each treatment day	Room safety door interlocks, lights, and alarms	Functional
	Console functions, switches, batteries, printer	Functional
	Visual inspection of source guides	Free of kinks
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
Source change or quarterly	Calibration	3%
	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators	Funcitonal
Annual	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions	
	Verify source inventory	

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TG-56

- QA tests should anticipate the probable modes of system failure
  - 3 main QA endpoints:
    - Accuracy of source selection
    - Accuracy of spatial positioning
    - Control of treatment duration
  - All remote afterloaders have interlocks
  - Specific QA tests dictated by system design

TG-56 (Cont.)

- Daily tests
  - Perform only on procedure days
    - May be performed by a therapist or dosimetrist
  - Perform all tests listed in Table V
  - Perform before the first patient is treated
  - Designed to assess failure-prone QA endpoints of the treatment system
    - Reduce the likelihood of subjecting the patient to an unnecessary procedure or being caught in an emergency situation without the resources needed to manage it

TG-56 (Cont.)

- Quarterly tests
  - Focused on measurement of specific operating characteristics
    - Performed by the physicist
  - Perform all daily tests plus additional tests listed in Table VI
- Annual tests
  - Comprehensive
    - Performed by physicist
  - All tests in Tables II-VII

TG-56 (Cont.)

- Planning system QA
  - At the time of TG-56, not much written
  - QA tests listed in Table VIII
  - QA every component
    - Reconstruction accuracy
    - Source visualization
    - Accuracy of source parameters
    - Algorithm accuracy
    - Dose evaluation
    - Accuracy of hard copy scale

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TG-59
Preventing Errors

- 1995 NUREG/CR-6125
  - 3 volumes, 526 page report identifying 76 possible “root causes” of human error in remote afterloading brachytherapy.
- Mistreatments from human error are far more common than machine malfunction.
- “Misadventure” defined by TG-59 to be a situation or event that has the potential to result in a mistreatment.
- Mistreatments are most often caused by more than than one “misadventure”, or hazard marker.

TG-59
Preventing Errors (Cont.)

- "Hazard Markers"
  - New procedure, or deviation from common procedure
  - Inadequate training and/or Inadequate supervision
  - Failure of team member to follow established policies
  - Making a mistake while trying to follow policies
  - Inadequate policies and procedures
  - Distractions, hurried work conditions, lack of staffing
  - Expectation bias
  - Mental lull post-concentration phase
  - Poor communication
  - Poorly designed software interfaces
  - Machine malfunction

TG-59 (Cont.)

- Principles of HDR program design
  - Use written documentation
    - Forms, clear communication
  - Develop a formal procedure
    - Checklists, ensure compliance and guide staff
  - Exploit redundancy
    - Each key step should be independently verified
  - Exploit quality improvement techniques
    - Identify and address weaknesses
    - Comprehensive QA a la TG-40

TG-59 (Cont.)

- Develop written procedures to address:
  - Written prescription and daily treatment record
    - Forms most critical to safe HDR brachytherapy
  - Treatment day QA protocol
  - QA procedure flow checklist
  - Physicist's treatment plan/documentation review
  - Forms to document implant geometry, simulation data, and dwell-time verification
  - Written protocols or policies of treatment for commonly treated disease sites

TG-59 (Cont.)

- Report makes recommendations for:
  - Staffing requirements
    - One person to enter room emergently
    - Two-person data entry model
      - PEBKAC
    - Table I outlines typical division of labor
  - Training requirements
    - Additional expertise required above board certification
  - Training schedule
    - Once certified, remain active or undergo refresher

TG-59 (Cont.)

- Treatment specific QA
  - Applicator preparation
    - Correct size, correct operation, compatible
  - Applicator insertion
    - Physics team member attends operative procedure
  - Implant localization and simulation
  - Treatment prescription
  - Implant design and evaluation
    - Localization, computer treatment plan, review of plan, dwell-time check, patient preparation, patient setup and treatment, and post-treatment QA

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TG-53

- Appendix 5
  - Brachytherapy dose calculation commissioning
    - Source entry methods
    - Source library
    - Source strength and decay
    - Single source dose calculations
    - Multiple source dose calculations and optimization
    - Global system tests
    - Other tests

Conclusions

- Comprehensive QA program
  - Tailored to needs of department
    - Staffing levels, specific procedures
- Written procedures
- Forms
- Checklists
- Standardization
- Redundancy

Conclusions

- Adequate staffing
- Abundant training
- Errors caused by:
  - Machine malfunctions
    - Rarely
  - Human errors
    - Frequently

References

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