

Safety and Accidents in Radiotherapy: What AAPM can and cannot do

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Safety = freedom from danger

- Radiotherapy not free from danger (NYT reports of patient deaths)
- No absolute safety
 - Some risks difficult to recognize
- Maximize safety with available resources

Safety compromised by

- Faulty equipment
- Insufficient knowledge (AAPM can help)
- Understaffing
- Insufficient authority
- **Low morale** (very sensitive issue)
- “Human errors” (major cause of accidents)

Other industries

- Manufacturing, Service
 - Fast assembly line reduces cost, some rejects acceptable
 - Hotel, restaurant, etc. Lower quality reduces cost, fewer customers – looking for optimal compromise
- Aviation industry similar to health care – errors can be deadly

Aviation

- Airlines - highest standards, strict regulations
 - No fatal crashes in last 2 years
- Commercial operators (sightseeing, medical helicopters) – some compromise to practicality
 - Some fatalities
- Private general aviation – more compromise
 - Loose standards, considerable fatalities

Message: *Intelligent regulations save lives*

FAA learns from accidents

- Investigates every accident and major incident
 - requires flight data recorders
 - voice recorders (cockpit and ground)
- Establishes causes, contributing factors, root causes
- Publishes findings
- Makes recommendations and binding regulations

Strict equipment standards

- Structural strength, “user friendly” flight characteristics
- Backup for essential items (flight controls)
- Extensive tests
- Aids to prevent pilot “human” errors
 - ground proximity warning
 - stall warning
 - gear warning

Strict operator standards (pilots, air traffic controllers, mechanics)

- Training and experience
- Knowledge (written, oral and **practical tests**)
- Health (pilots and air traffic controllers)
- Age (lower and upper limits for airline pilots)
- Performance continuously monitored
 - Practical tests
 - Medical exams
- Equipment-specific tests (type ratings) for planes >12,500 lb, jets

Strict operational standards

- Minimum air crew, including flight attendants
- Weather minimums for takeoff and landing
- Authority of pilot in command
- Crew coordination
- “*Cautious position*” prevails (Air Florida crash in 1982)

Human (operator) error prevention

- Check lists
- Verification by second person
- Minimize distractions - “Sterile” cockpit below 10,000’ altitude, no passengers in cockpit
- Maximum number of working hours, rest periods (after publicized accidents, **despite opposition by management**)
- Recognition of work intensity
- **Morale**, job dissatisfaction (**sensitive - not yet addressed**)

Medical field

- Loose standards
- 90,000+ accidental patient deaths per year
- Radiotherapy ????????
 - Overdose (publicized)
 - Underdose ???
 - Geographic miss ???

Can't learn from accidents – Probabilistic Risk Assessment (PRA) impossible

- NRC investigates only in non-agreement states if radioisotopes involved
- Linac accidents rarely investigated
- Reports not made public
 - States do not permit access to accident data
 - Legal settlements forbid disclosures
- Causes, contributing factors, root causes rarely identified

Loose equipment standards

- FDA 510(k) does not set performance standards, only that specifications are met
- Backup for essential components not required (e.g. collimator angle, jaw opening readout)
- Interlocks not required (SRS accident due to open jaws)
- Limited tests (Tyler, TX accident)
- Frequent software “upgrades” with potential flaws

Loose operator standards (physicists, therapists, service engineers)

- Licensure in only 4 states
- Training and experience not required in some states
- Knowledge: *NO practical tests*, only written and oral
- Certification voluntary
- Health - no medical checks
- Age (no upper limits for physicists, physicians)
- Performance not monitored
 - No continued tests
- No mandatory tests for new complex equipment

Loose operational standards

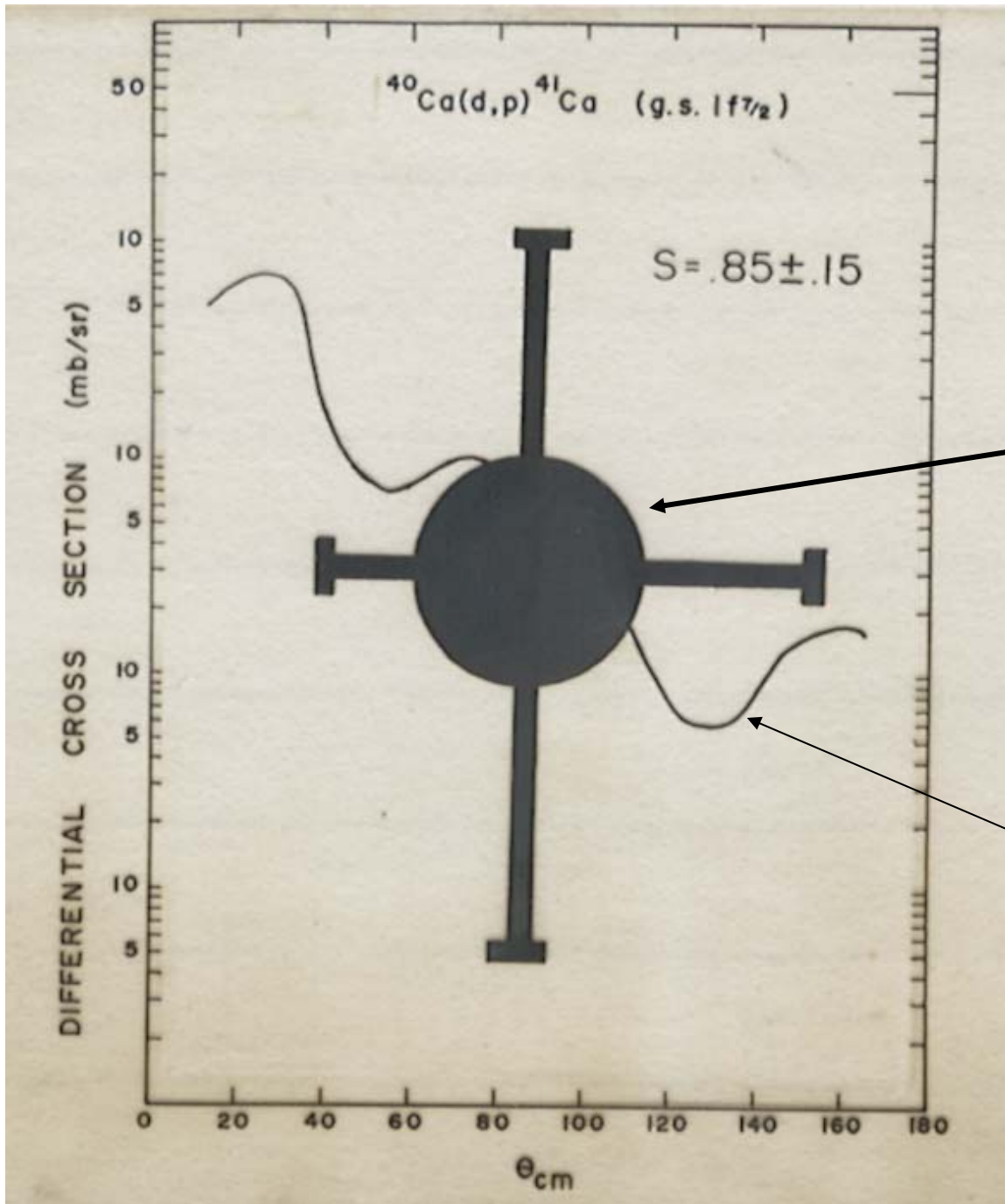
- Double-checks not required
 - **Only one Rad Onc needs to approve plan**
- Distractions (interrupting therapists)
- No minimum staffing (physicists, dosimetrists, therapists)
 - Physicist not necessarily at facility during tx
 - Rad Onc present only in > 300 bed hospitals (Medicare)
- Insufficient authority for med physicists
- Work pace set by administrators (Riverside Radiation Tragedy)
- No limits on duty hours
- **Provider status and CPT codes for Rad Oncs**
 - Enhance authority
 - Flexibility

What AAPM can do

- Provide scientific knowledge
 - Meetings
 - Summer School
 - Publications (Med Phys, JACMP)
 - Scientific task group reports (TG 51, TG 43)
- Promote licensure – relatively new effort
- Make constructive recommendations

What AAPM can't do

- Mandate safety measures
- No legal authority to
 - write regulations
 - enforce regulations
 - investigate accidents
- Base recommendations on extensive experience



Graduate student prank,
making light of
sophisticated theories
that are based on very
few data

Sparse data

Sophisticated
Theory

John Covan, 1970,
with permission

AAPM limited in developing safety recommendations

- **Insufficient resources**
 - All volunteer, clinical therapy physicists too busy to participate
 - Disproportional input by individuals with insufficient knowledge, not affected by their recommendations
 - No laboratories
- **Diverse interests within AAPM**
 - Clinical physicists vs. college professors
 - Therapy vs. diagnostic physicists, biomed engineers
 - Rad Oncs established ASTRO, ACRO to supplement ACR

AAPM limited (cont'd)

- **Conflicting interests in “professional” issues**
 - Business owners (leveraged gain from lower wages) vs. employees’ concern about safety
 - **Rad Oncs: Provider status, CPT codes**
- **Relatively weak professional standing**
 - Fear of dealing with “professional” issues
 - Authority
 - Recognition
 - Profits (provider status, CPT codes, staffing)
- **ACRO only organization to recommend specific staffing levels**

Do no harm: Caution with recommendations

- Taken out of context, become law
- TG 40 (linac QA): Speculation
 - potentially counterproductive
 - Annual tests divert substantial resources
 - Problem detection too late
- **Report 38, p.8, 1993:** "The physicist, however, should be aware of whether a prescription for a given patient is consistent with previous, similar patients, and also consider possible critical, dose-limiting structures.."
 - Unfunded Mandate (No CPT codes)
 - Great responsibility (physicists not qualified, have been sued)
 - False feel of security
- **Physicist should report to medical director**
 - May not have sufficient authority
 - Report to same individual to whom medical director reports?

“Nowadays, you must believe in miracles to be considered a realist”

(Menachim Begin, Prime minister, Israel)

- Radiotherapy will become as safe as airline travel
- FAA-like organization will address safety
- A therapy physicists' organization similar to ASTRO or ACRO will emerge to deal with professional issues, a current bottleneck in safety
- Sponsored and supported by AAPM