Prospective risk management

Ben Mijnheer

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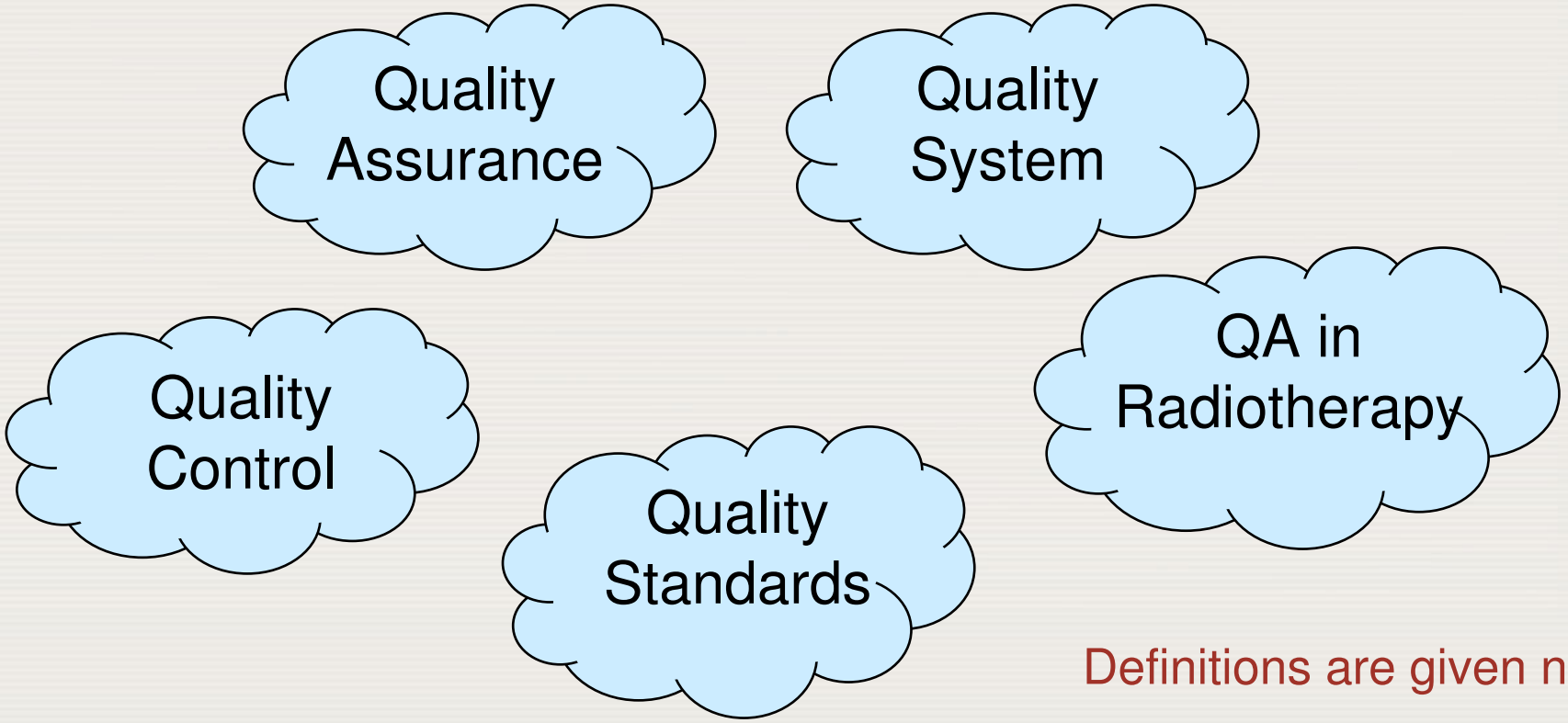
12.1 INTRODUCTION

12.1.1 Definitions

- A commitment to **Quality Assurance (QA)** needs a sound familiarity with some main relevant terms such as:



Definitions are given next

12.1 INTRODUCTION

12.1.1 Definitions

Quality Assurance

- "Quality Assurance" is all those **planned and systematic actions** necessary to provide **adequate confidence** that a product or service will satisfy the **given requirements** for quality.
- As such **QA** is wide ranging, covering
  - procedures;
  - activities;
  - actions;
  - groups of staff.
- The management of a QA program is also called a **Quality System Management**.

Quality Control

- "Quality Control" is the **regulatory process** through which the actual quality performance is measured, compared with existing standards, and the actions necessary to keep or regain conformance with the standards.
- Quality control is part of **a quality management system**.
- It is concerned with operational techniques and activities used:
  - To check that quality requirements are met;
  - To adjust and correct performance if the requirements are found not to have been met.

Quality Standards

- "Quality standards" is the set of accepted criteria against which the quality of the activity in question can be assessed.
- In other words:

Without quality standards, quality cannot be assessed.

Quality System

- A "Quality System" is a system consisting of the
  - organizational structure,
  - responsibilities,
  - procedures,
  - processes and
  - resources

  required to implement a quality assurance program.

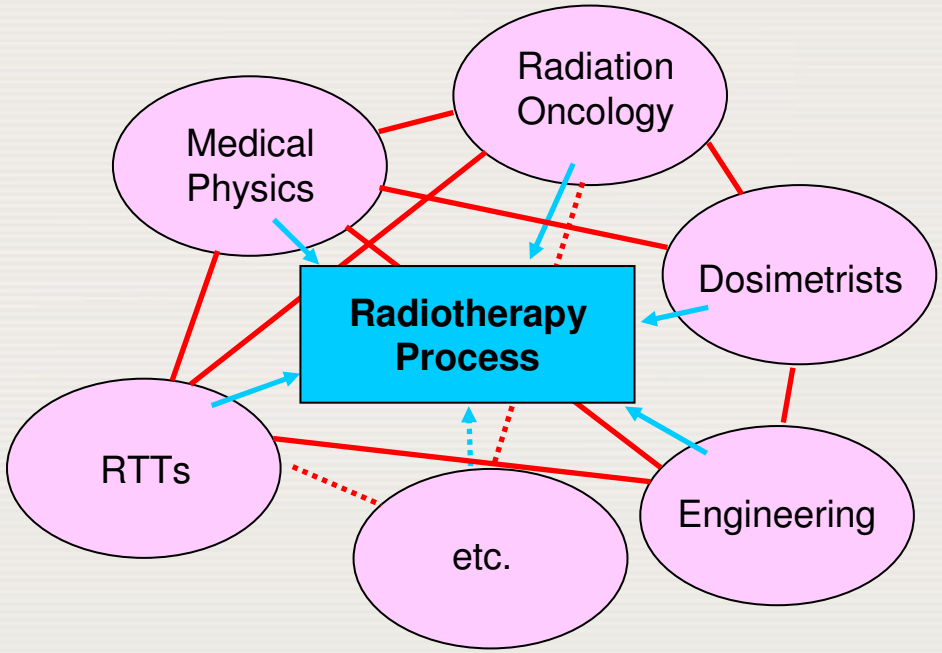
Quality assurance in radiotherapy

- "Quality Assurance in Radiotherapy" is all procedures that ensure consistency of the medical prescription, and safe fulfillment of that radiotherapy related prescription.
- Examples of prescriptions:
  - the dose to the tumor (to the target volume)
  - minimal dose to normal tissue
  - adequate patient monitoring aimed at determining the optimum end result of the treatment
  - minimal exposure of personnel

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.1 Multidisciplinary radiotherapy team

- One of the needs to implement a Quality System is that radiotherapy is a multidisciplinary process.
- Responsibilities are shared between the different disciplines and must be clearly defined.
- Each group has an important part in the output of the entire process, and their overall roles, as well as their specific quality assurance roles, are inter-dependent, requiring close cooperation.



12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.1 Multidisciplinary radiotherapy team

The multidisciplinary radiotherapy team consists of:

- **Radiation oncologists**
- **Medical physicists**
- **Radiotherapy technologists**
  - sometimes referred to as radiation therapist (RTT), therapy radiographer, radiation therapy technologist, radiotherapy nurse
- **Dosimetrists**
  - in many systems there is no separate group of dosimetrists; these functions are carried out variously by physicists, medical physics technicians or technologists, radiation dosimetry technicians or technologists, radiotherapy technologists, or therapy radiographers
- **Engineering technologists**
  - in some systems medical physics technicians or technologists, clinical technologists, service technicians, electronic engineers or electronic technicians

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

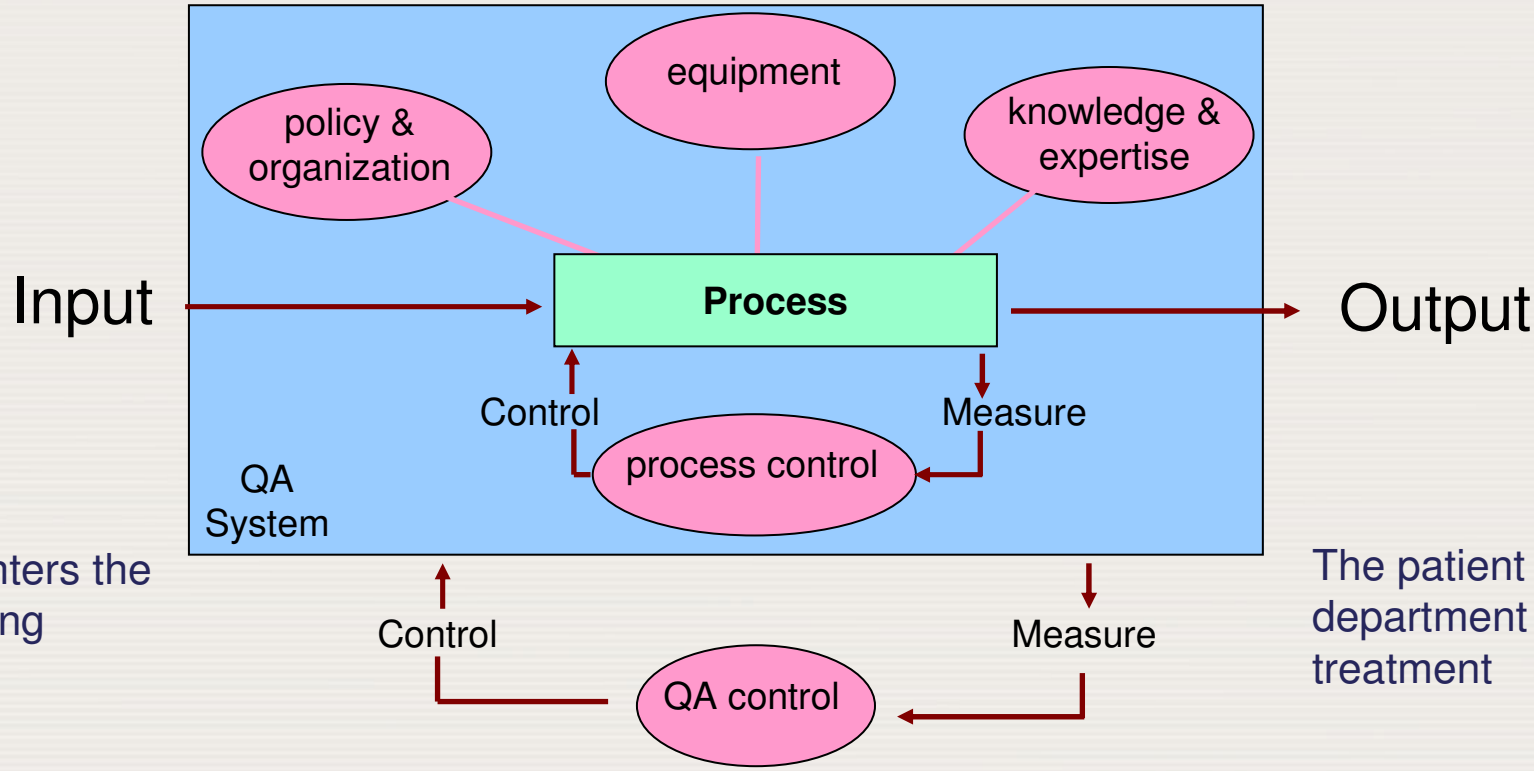
12.2.2 Quality system/comprehensive QA program

- It is now widely appreciated that the concept of a Quality System in Radiotherapy is broader than a restricted definition of technical maintenance and quality control of equipment and treatment delivery.

- Instead it should encompass a comprehensive approach to all activities in the radiotherapy department:
  - Starting from the moment a patient enters it
  - until the moment he leaves,
  - and also continuing into the follow-up period.

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



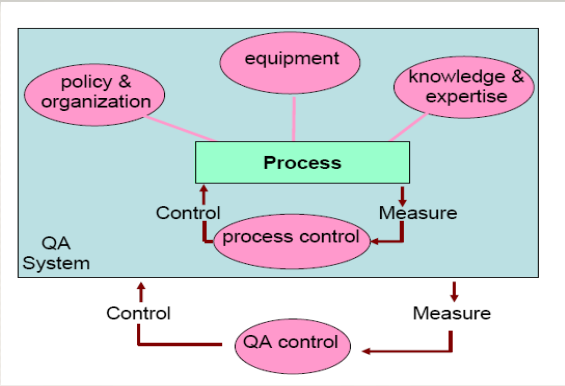
The patient enters the process seeking treatment

The patient leaves the department after treatment

The outcome can be considered to be of good quality when the handling of the quality system well organizes the five aspects shown in the illustration above.

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



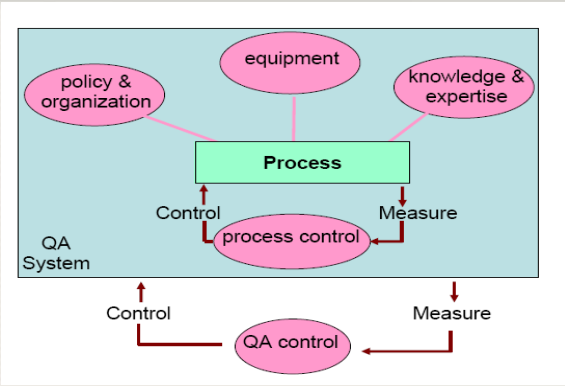
- A comprehensive quality system in radio-therapy is a management system that:

policy & organization

  - Should be supported by the department management in order to work effectively.
  - Must have a clear definition of its scope and of all the quality standards to be met.
  - Must be regularly reviewed as to operation and improvement. To this end a quality assurance committee is required, which should represent all the different disciplines within radiation oncology.
  - Must be consistent in standards for different areas of the program.

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



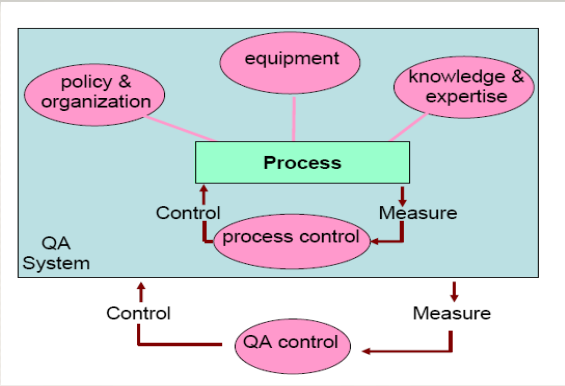
- A comprehensive quality system in radio-therapy is a management system that:

equipment

  - Requires availability of adequate test equipment

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



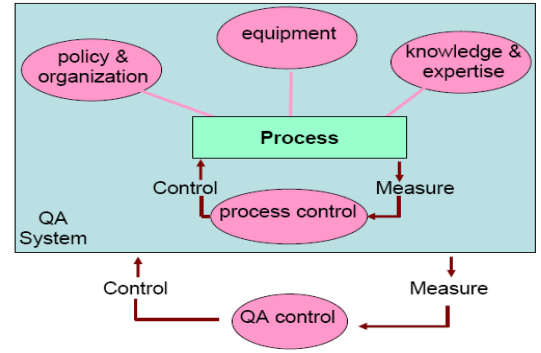
- A comprehensive quality system in radio-therapy is a management system that:

knowledge & expertise

  - Requires that each staff member must have qualifications (education, training and experience) appropriate to his or her role and responsibility.
  - Requires that each staff member must have access to appropriate opportunities for continuing education and development.

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



- A comprehensive quality system in radio-therapy is a management system that:

process control

- Requires the development of a **formal written quality assurance program** that details the quality assurance policies and procedures, quality control tests, frequencies, tolerances, action criteria, required records and personnel.
- Must be consistent in standards for different areas of the program.
- Must incorporate compliance with all the requirements of national legislation, accreditation, etc.

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program

- The **formal written quality assurance program** is also referred to as the "**Quality Manual**".
- The quality manual has a double purpose:
  - external
  - internal
- Externally to collaborators in other departments, in management and in other institutions, it helps to indicate that the department is strongly concerned with quality.
- Internally, it provides the department with a framework for further development of quality and for improvements of existing or new procedures

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program

Practical guidelines for writing your own quality manual:

ESTRO EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

ESTRO Booklet 4:

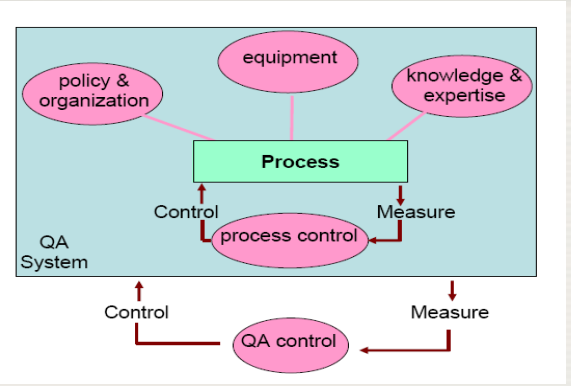
PRACTICAL GUIDELINES FOR THE IMPLEMENTATION OF A QUALITY SYSTEM IN RADIOTHERAPY

A project of the ESTRO Quality Assurance Committee sponsored by 'Europe against Cancer'

Writing party: J W H Leer, A L McKenzie, P Scalliet, D I Thwaites

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program



- A comprehensive quality system in radio-therapy is a management system that:

QA control

- Requires control of the system itself, including:
  - Responsibility for quality assurance and the quality system: quality management representatives.
  - Document control.
  - Procedures to ensure that the quality system is followed.
  - Ensuring that the status of all parts of the service is clear.
  - Reporting all non-conforming parts and taking corrective action.
  - Recording all quality activities.
  - Establishing regular review and audits of both the implementation of the quality system (quality system audit) and its effectiveness (quality audit).

12.2 MANAGING A QUALITY ASSURANCE PROGRAMME

12.2.2 Quality system/comprehensive QA program

- When starting a quality assurance (QA) program, the setup of a **QA team** or **QA committee** is the most important first step
- The QA team should reflect composition of the multidisciplinary radiotherapy team
- The quality assurance committee must be appointed by the department management/head of department with the authority to manage quality assurance

Membership and responsibilities of the QA team (QA committee)

QA Team (Committee)

Membership:

Radiation Oncologist(s)
Medical Physicist(s)
Radiation Therapist(s)
.....

Chair:

Physicist or
Radiation Oncologist

Responsibilities:

Patient safety
Personnel safety
Dosimetry instrumentation
Teletherapy equipment
Treatment planning
Treatment delivery
Treatment outcome
Quality audit

12.5 QUALITY AUDIT

12.5.1 Definition

Definition

- Quality audit is a systematic and independent examination to determine whether or not quality activities and results comply with planned arrangements and whether or not the arrangements are implemented effectively and are suitable to achieve the stated objectives

12.5 QUALITY AUDIT

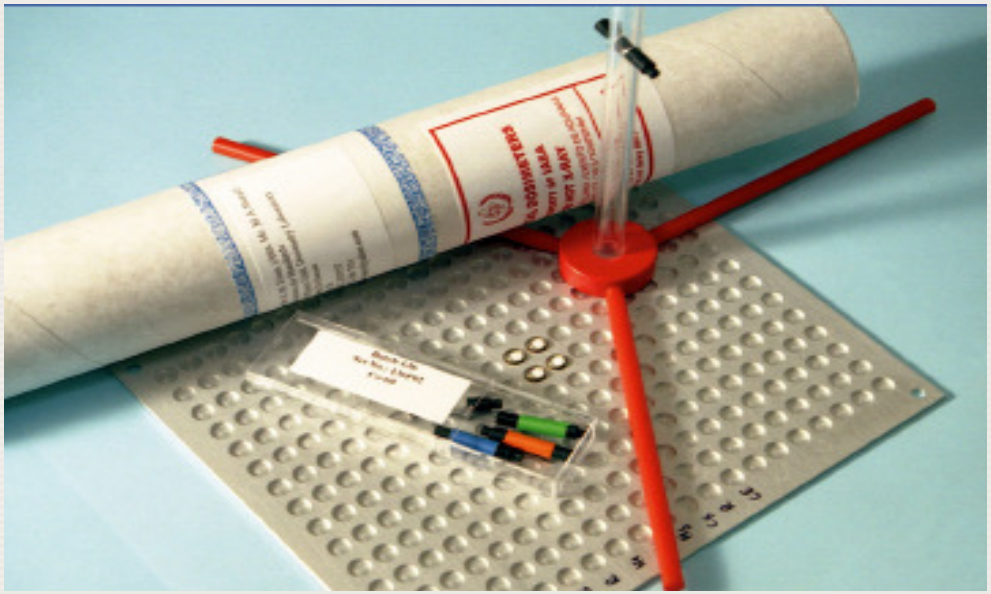
12.5.1 Definition: Parameters of quality audits

- **Quality audits:**
  - Should be regular and form part of a quality feedback loop to improve quality.
  - Can be mainly **procedural**, looking at QA procedures, protocols, QC programs, QC and QA results and records, etc.
  - Can be mainly **practical**, i.e. verify the effectiveness or performance of a quality system.
  - May be voluntary and co-operative, or may be regulatory (e.g., for accreditation of the department or hospital, for QS certification, etc.).

12.5 QUALITY AUDIT

12.5.2 Practical quality audit modalities

- A good example for an external audit is the simple but very effective dosimetry audit organized as postal audit with mailed dosimeters (usually TLD).
- These are generally organized by SSDL or agencies, such as the IAEA, Radiological Physics Center (RPC) in the U.S., ESTRO (EQUAL), national societies, national quality networks, etc.

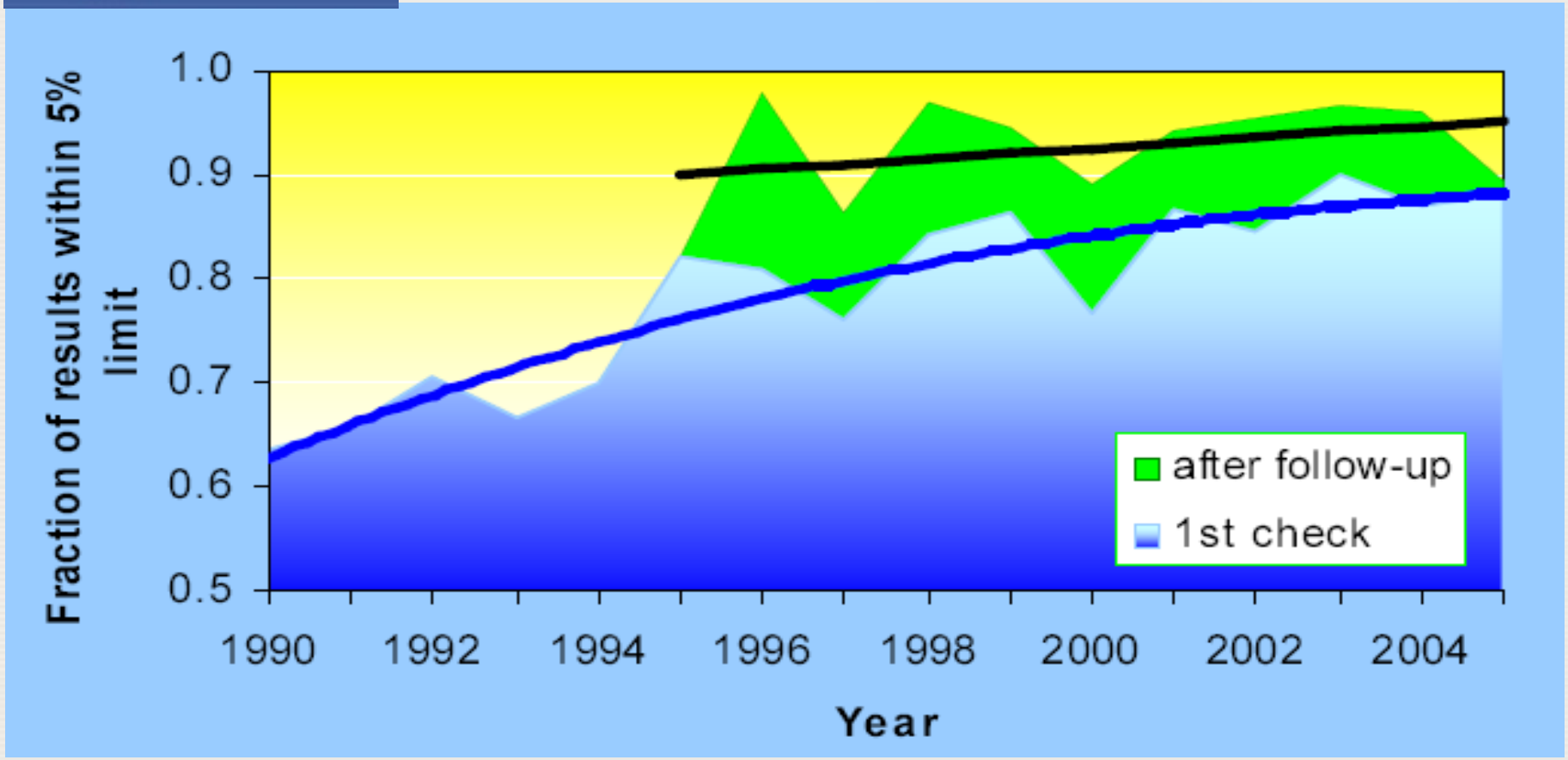


Material used in IAEA/WHO TLD audits

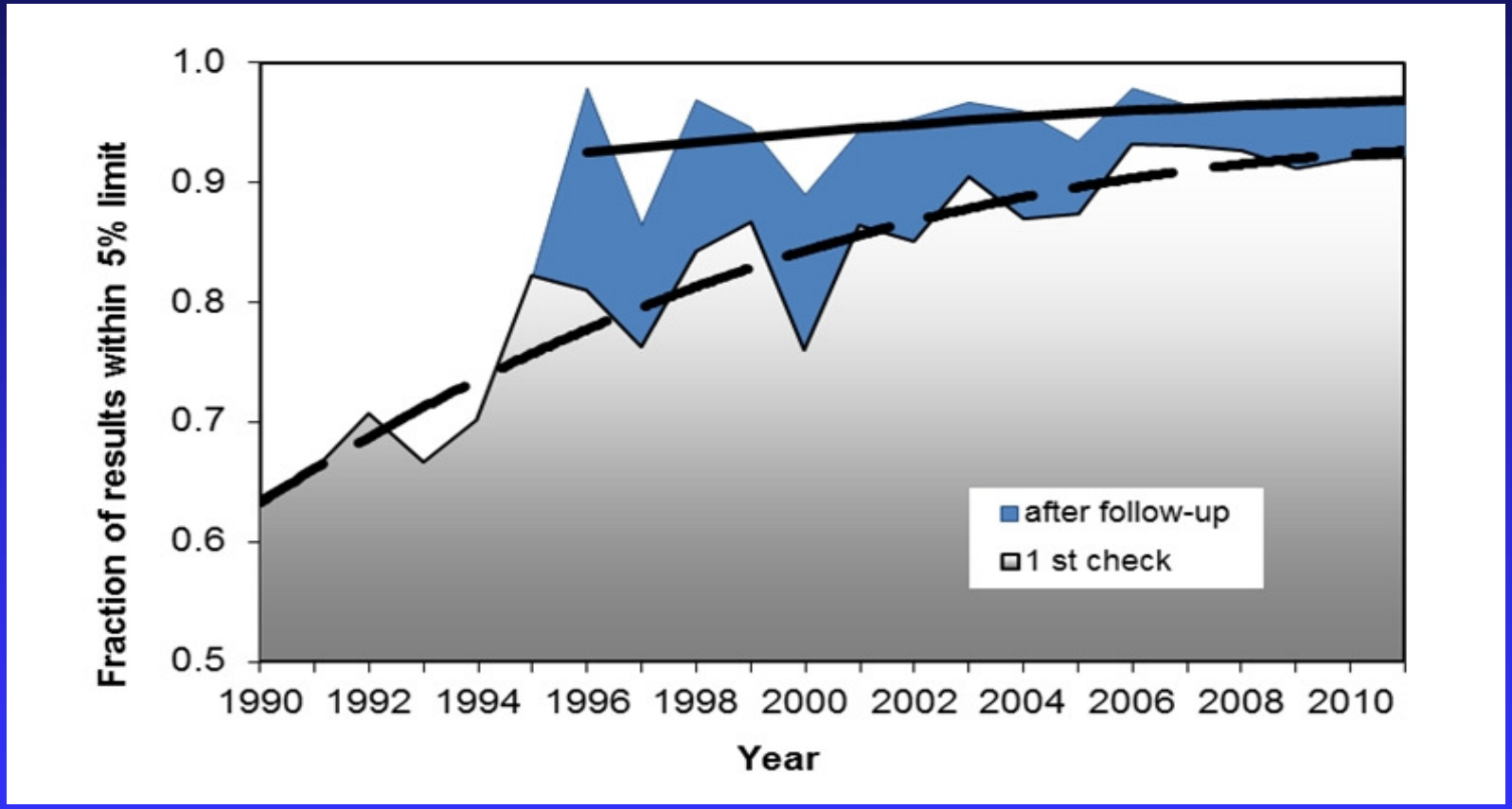
12.5 QUALITY AUDIT

12.5.2 Practical quality audit modalities

TLD results within the 5% limit



Fraction of TLD results within 5% acceptable limit in the IAEA / WHO TLD postal dose audit programme



(From the IAEA Report “Accuracy Requirements and Uncertainties in Radiation Therapy”)

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- The content of a quality audit visit must be pre-defined.
- It will depend on the purpose of the visit:
  - Is it a routine regular visit within a national or regional quality audit network?
  - Is it regulatory or co-operative between peer professionals?
  - Is it a visit following a possible misadministration?
  - Is it a visit following an observed higher-than-expected deviation in a mailed TLD audit program that the centre cannot explain?

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- Example of content of a comprehensive quality audit visit:

Check infrastructure

- equipment
- personnel
- patient load
- existence of policies and procedures
- quality assurance program in place
- quality improvement program in place
- radiation protection program in place
- data and records, etc.

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- Example of content of a comprehensive quality audit visit:

Check documentation

- content of policies and procedures
- QA program structure and management
- patient dosimetry procedures
- simulation procedures
- patient positioning, immobilization and treatment delivery procedures
- equipment acceptance and commissioning records
- dosimetry system records
- machine and treatment planning data
- QC program content
- tolerances and frequencies, QC and QA records of results and actions
- preventive maintenance program records and actions
- patient data records
- follow-up and outcome analysis etc.

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- Example of content of a comprehensive quality audit visit:

Carry out check measurements of

- beam calibration
- depth dose
- field size dependence
- wedge transmissions (with field size), tray, etc. factors
- electron cone factors
- electron gap corrections
- mechanical characteristics
- patient dosimetry
- dosimetry equipment comparison
- temperature and pressure measurement comparison, etc.

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- Example of content of a comprehensive quality audit visit:

Carry out check of training programs

- Academic program
- Clinical program
- Research
- Professional accreditation
- Continuous Professional Education

12.5 QUALITY AUDIT

12.5.3 What should be reviewed in a quality audit visit?

- Example of content of a comprehensive quality audit visit:

Carry out check measurements on other equipment

- simulator
- CT scanner, etc.

Assess treatment planning data and procedures.

Measure some planned distributions in phantoms.

Positive lessons to be learned from accidents in radiotherapy

Most analyses and reviews of radiotherapy accidents and incidents show that most of them are due to human errors rather than failure of equipment. Mistakes are mainly due to:

- lack of clear verification procedures
- lack of documentation
- poor communication
- lack of training

Therefore teaching and training of the personnel is important, as well as well documented working procedures

Key issues of good quality practice

Verification

Documentation

Communication

Training

Lack of training

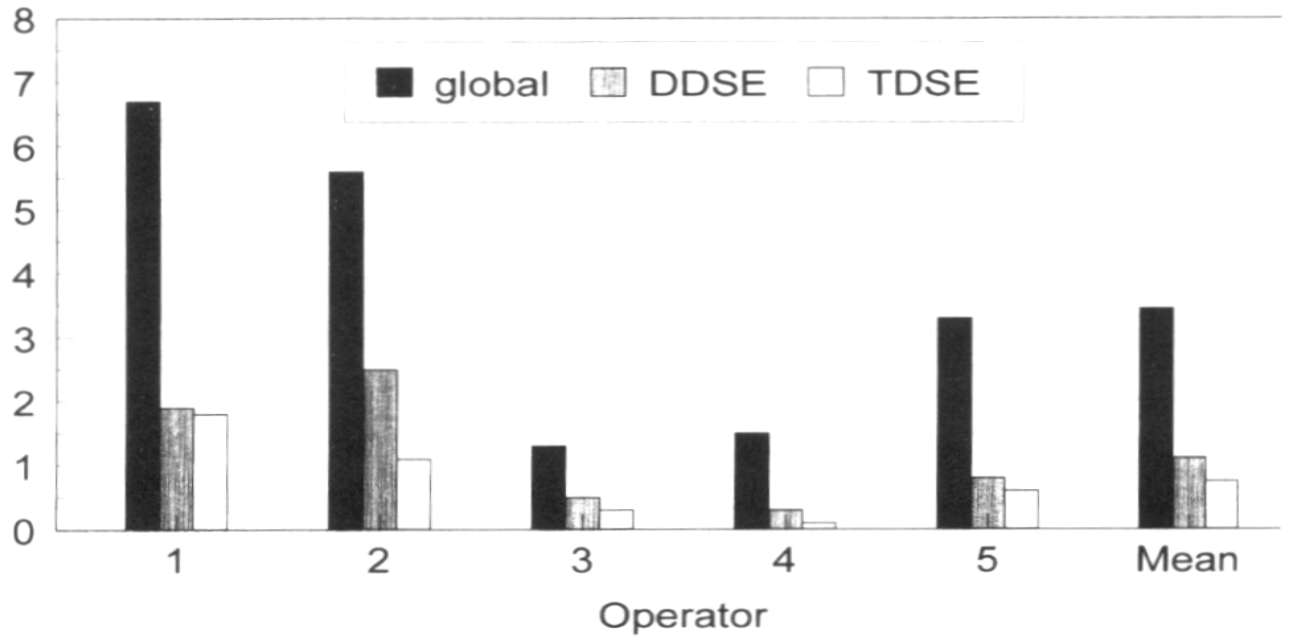


Fig. 1. The percentage rates of overall error, daily dose serious error (DDSE, >5% of the daily dose) and total dose serious error (TDSE, >5% of the total dose) are plotted for each operator. The error rates are strongly operator-dependent.

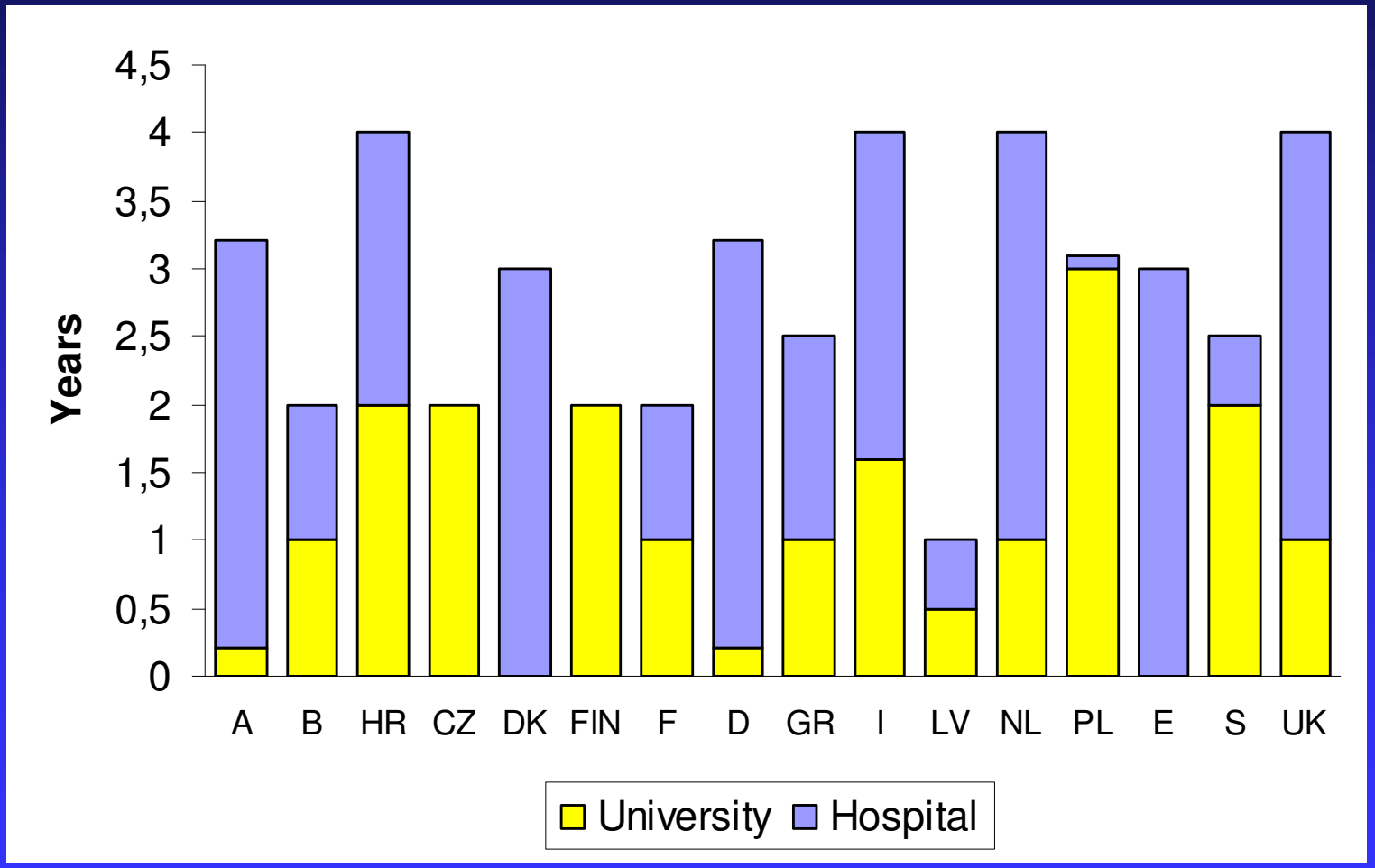
(Calandrino *et al.*, Radiother. Oncol. 45: 271-274, 1997)

Staff training, availability and dedication

- Replacement of proper training with a short briefing or demonstration should be avoided, because important safety implications of new techniques cannot be fully appreciated from a short briefing

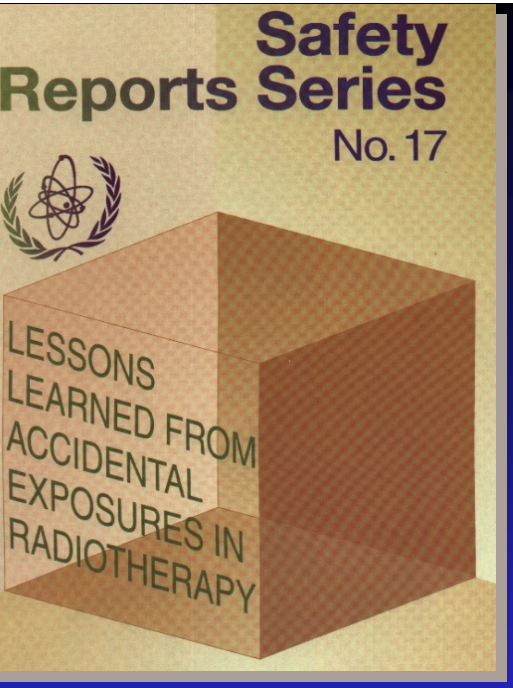
- Certain safety-critical tasks, such as calibration, beam characterization, complex treatment planning and pre-treatment verification, require a substantial increase in staff allocation

Training programmes in EU

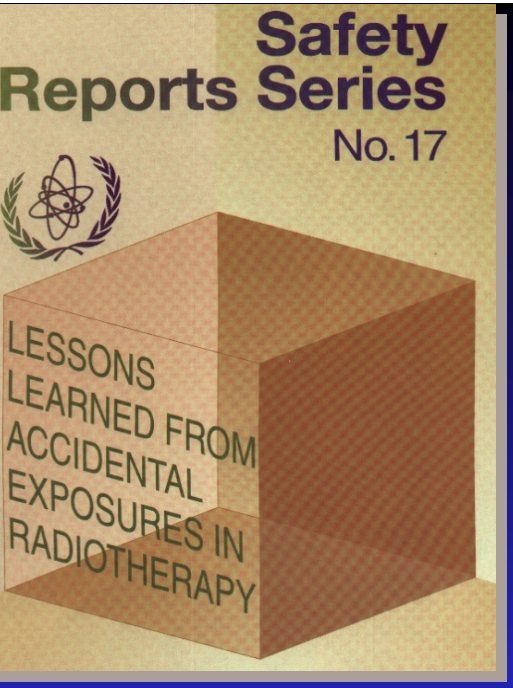


There are lots of safety issues in a radiotherapy department!

John Humm, MSKCC

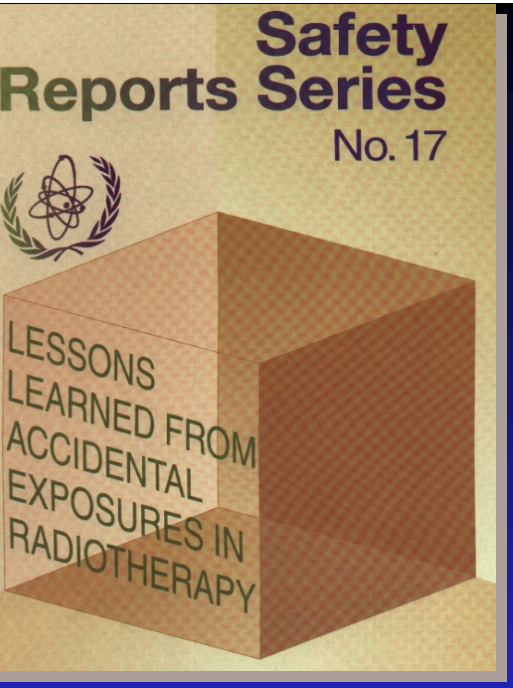


Given all the bad things that can happen in radiotherapy we must do much more QA



Given all the bad things that can happen in radiotherapy we must do much more QA

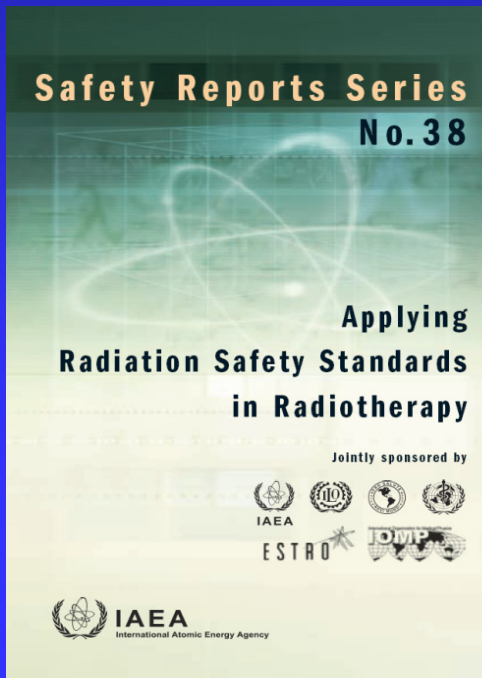
NO !



Given all the bad things that can happen in radiotherapy we must do much more QA

NO !

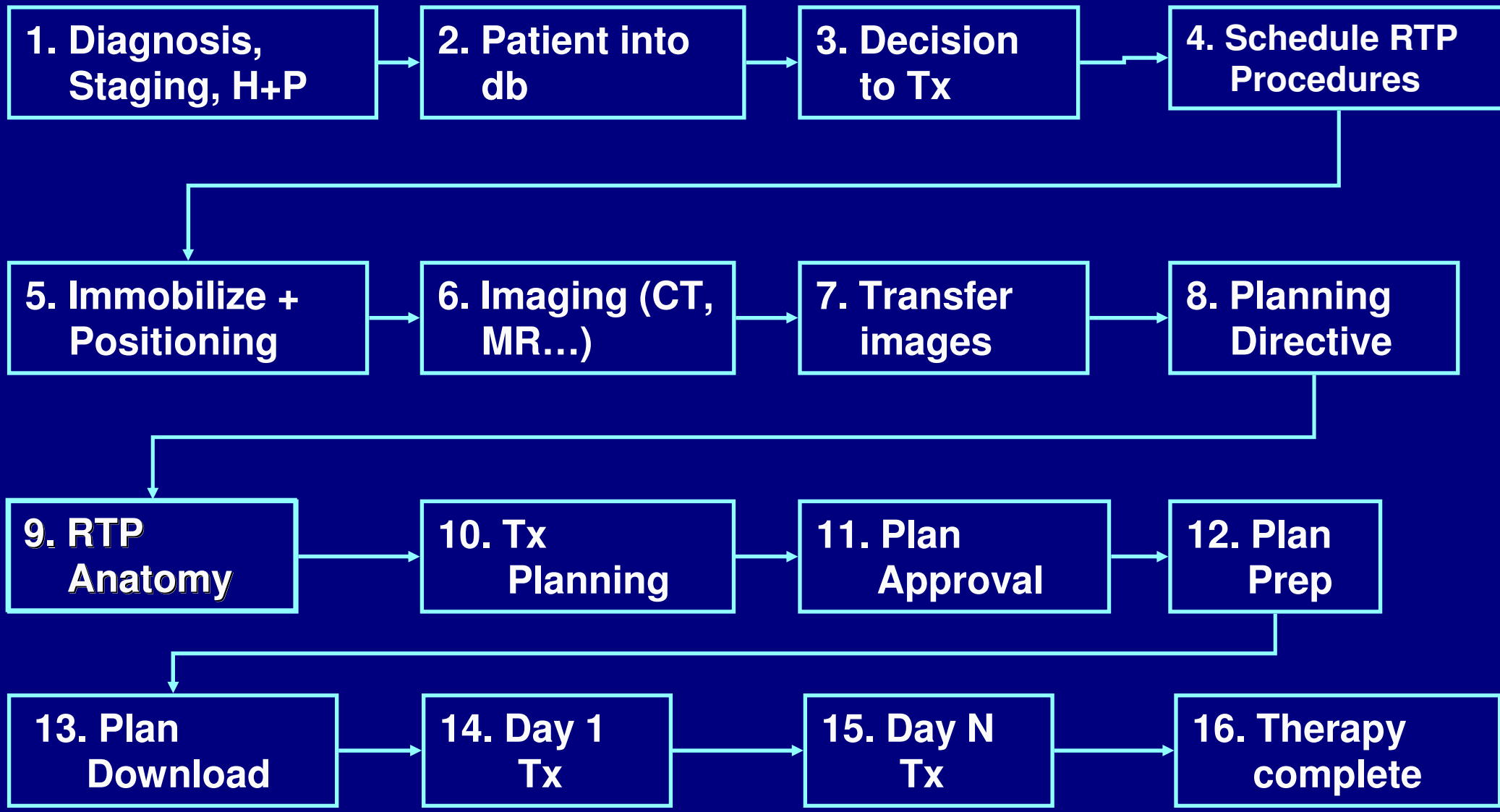
We must evaluate the problems, risks, and processes, then prioritize our efforts so we spend our QA efforts on the most frequent, severe, and risky problems



Process-Oriented Risk-Aware Quality Methods
AAPM Task Group-100

1. Map the process to be studied
2. Analyze how the process can fail, and what the effects of the failures will be: [FMEA: Failure modes and effects analysis]
3. Once all the failure modes and effects are identified, map how the faults propagate: [FTA: Fault tree analysis]
4. Find efficient ways to minimize propagation of errors through the process: [QM, QA, QC]

1. Map the Process



2. FMEA: Failure Modes and Effects Analysis

2.1. Failure Modes

- Identify the possible failure modes
- Identify the potential causes of each failure
- Identify the possible effects of each failure
  - Causes include patient inconvenience, overdose, injury, wrong location, etc...

2. FMEA: Failure Modes and Effects Analysis

2.2. For each failure mode:

Estimate the probability of Occurrence (O), the Severity (S), and the lack of Detectability (D)

Rank	Occurrence (O)	
	Qualitative	Frequency
1	Failure unlikely	1/10,000
2		2/10,000
3	Relatively few failures	5/10,000
4		1/1,000
5		<0.2%
6	Occasional failures	<0.5%
7		<1%
8	Repeated failures	<2%
9		<5%
10	Failures inevitable	>5%

Rank	Severity(S)	
	Qualitative	Categorization
1	No effect	
2	Inconvenience	Inconvenience
3		
4	Minor dosimetric error	Suboptimal plan or treatment
5	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume
6		
7	Potentially serious toxicity or tumor underdose	
8		
9	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distrib, location or volume
10	Catastrophic	

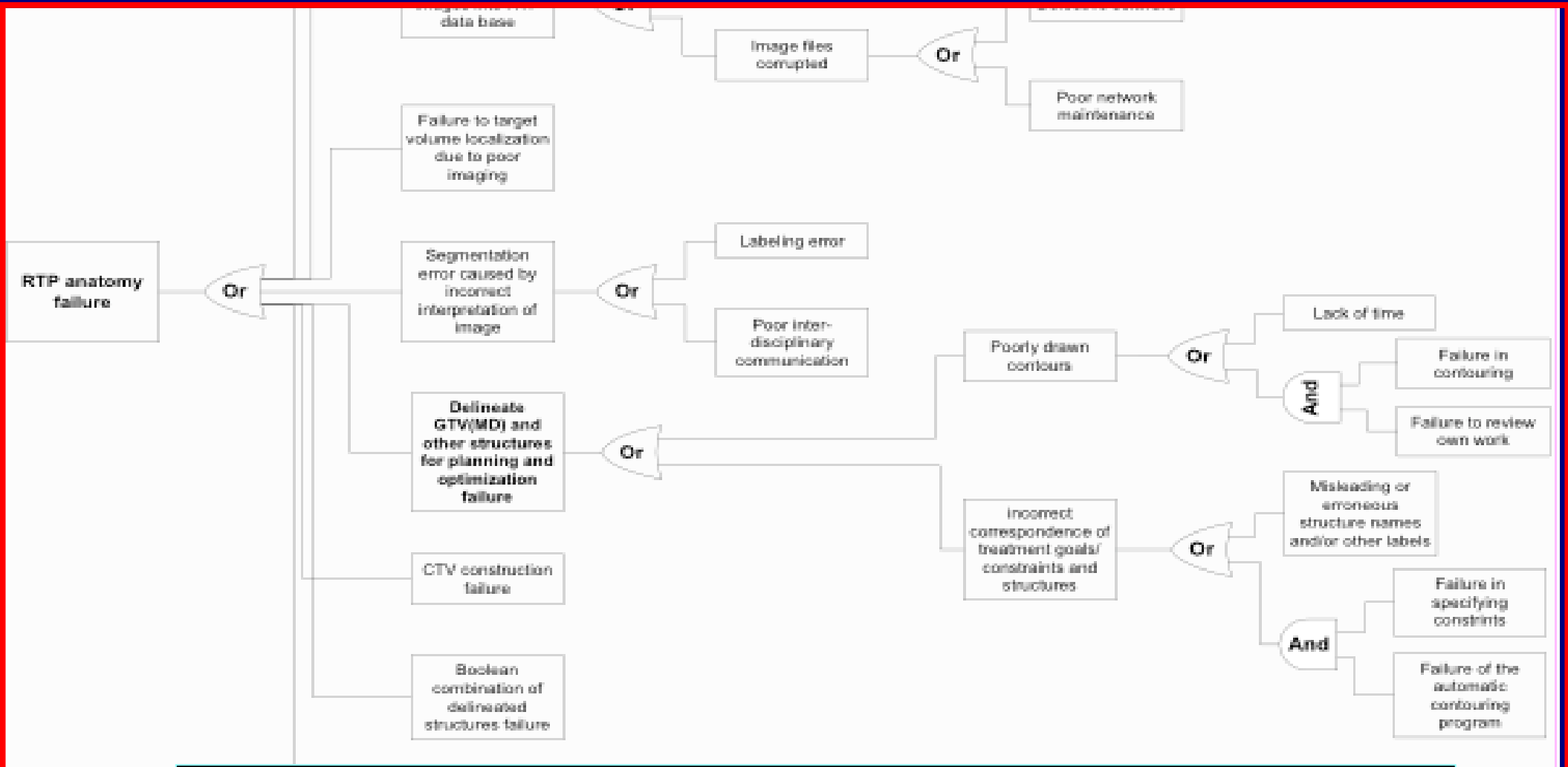
Rank	Un-Detectability (D)
	Estimated probability of failure going undetected (in %)
1	0.01
2	0.2
3	0.5
4	1.0
5	2.0
6	5.0
7	10
8	15
9	20
10	>20

2. FMEA: Failure Modes and Effects Analysis

2.3. Priority for mitigation:

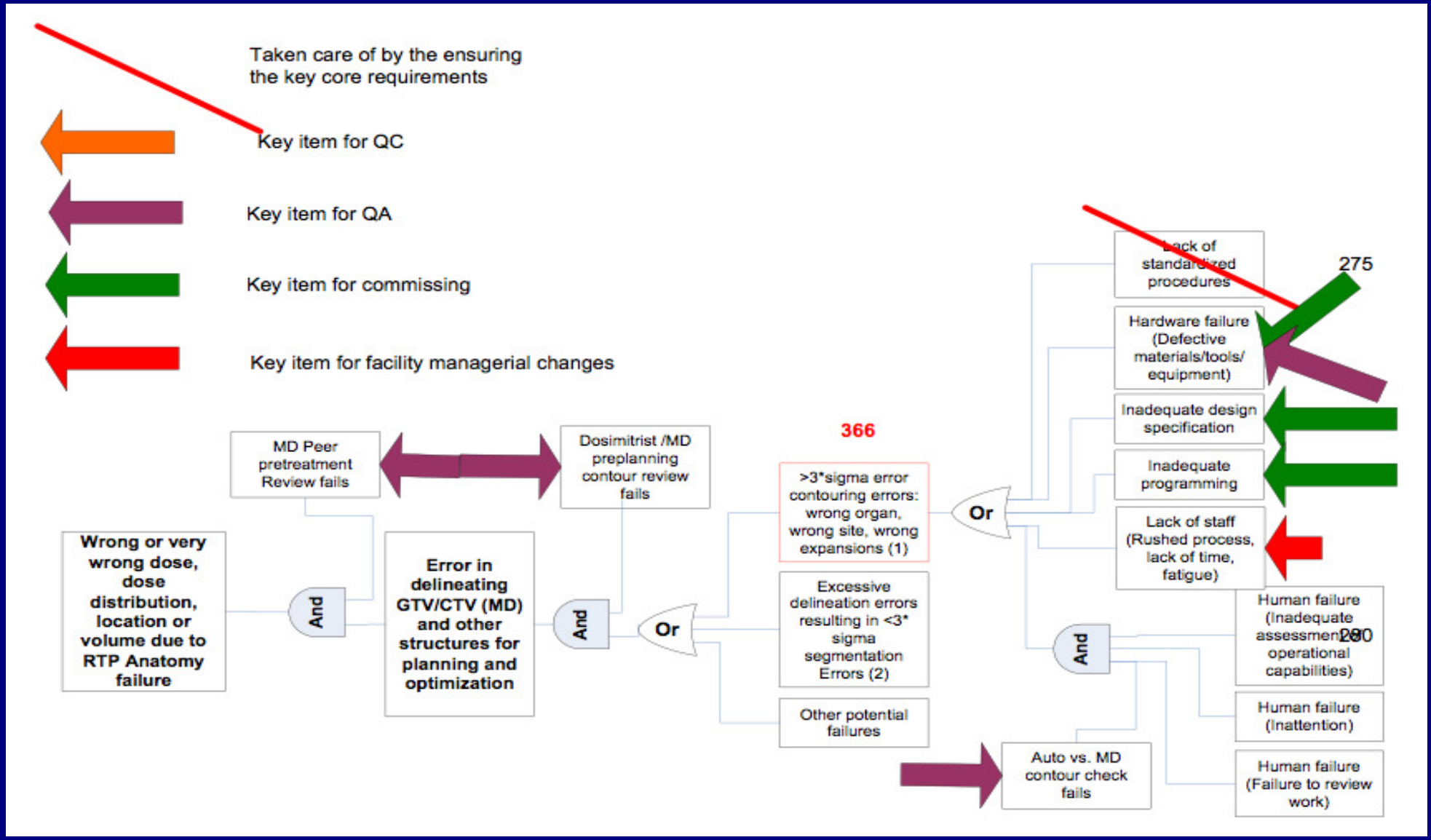
- use product O x S x D = RPN
- severity
- or some combination

3. FTA: Fault Tree Analysis



Start with the failures, and work backwards thru the process steps to see how faults propagate

4. Design QA/QC/Process to avoid propogation of errors



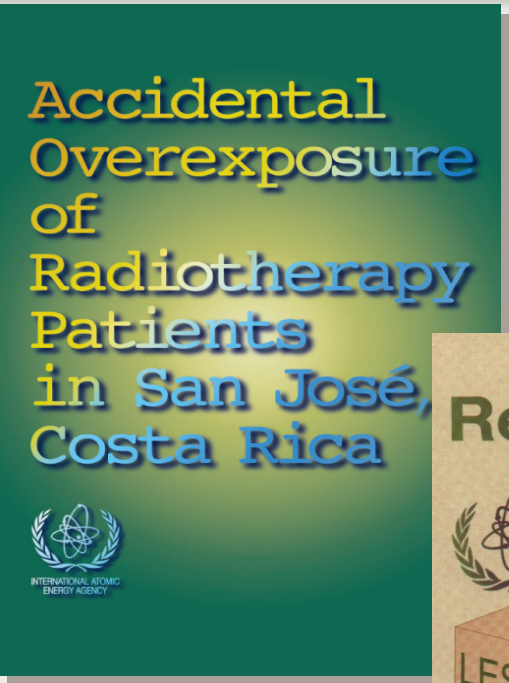
Process-Oriented Risk-Aware Quality Methods

Keys to Success

- Create multidisciplinary team
- Attack specific process
- Define and control appropriate scope
- Careful choice of prioritization scheme
- Accept (and take to heart) that QA is not a "technical matter" and that quality is dependent on everyone in the team, not just the people "doing QA"

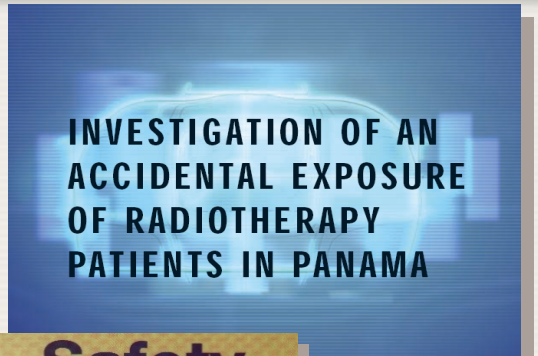
To ensure patient safety we need

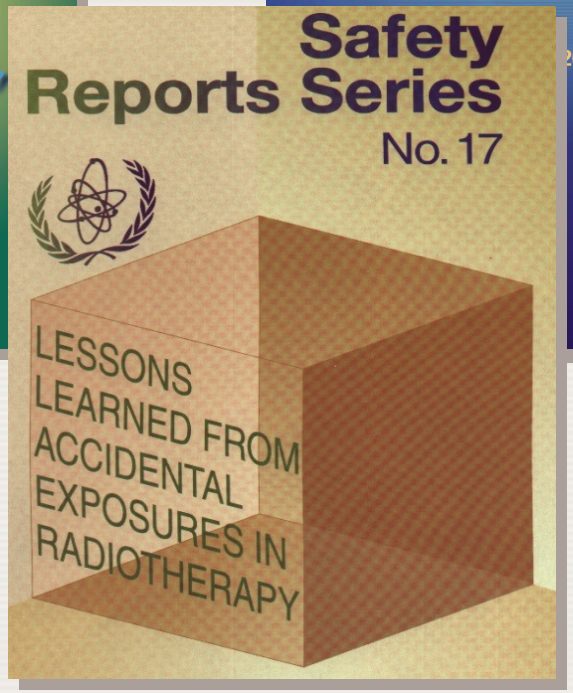
Relevant IAEA Publications



1998

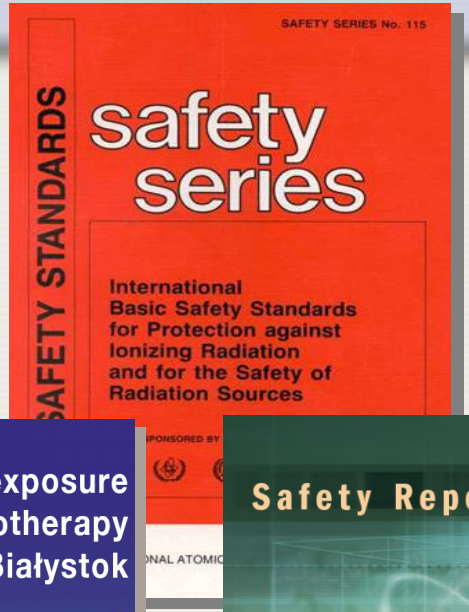
2001

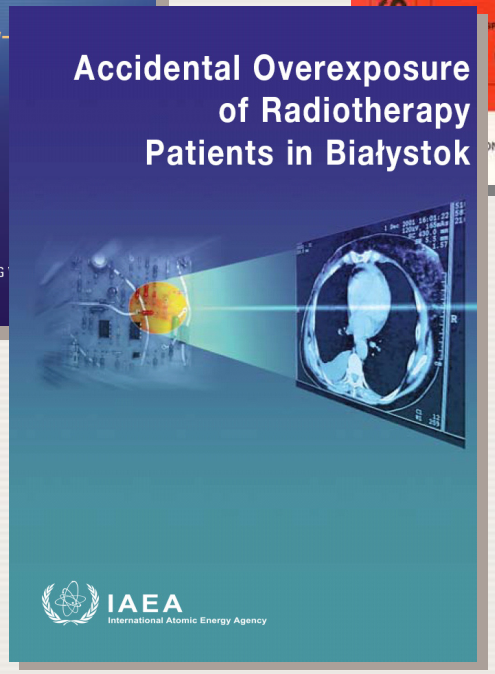


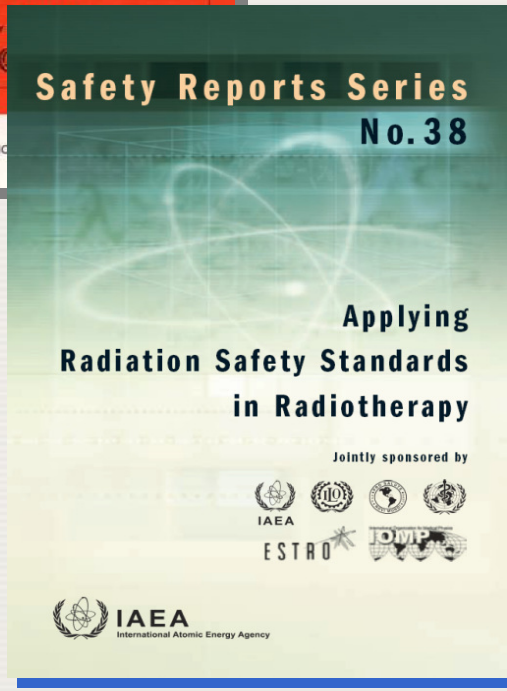


2000

2004







2006

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Thank you for your attention!