Quality Assurance Program in Radiotherapy

Prof. Golam Abu Zakaria
Klinikum Oberberg
Gummersbach Hospital
Department of Medical Radiation Physics
Academic Teaching Hospital of the University of Cologne
51643 Gummersbach, Germany
Email: GolamAbu.Zakaria@klinikum-oberberg.de

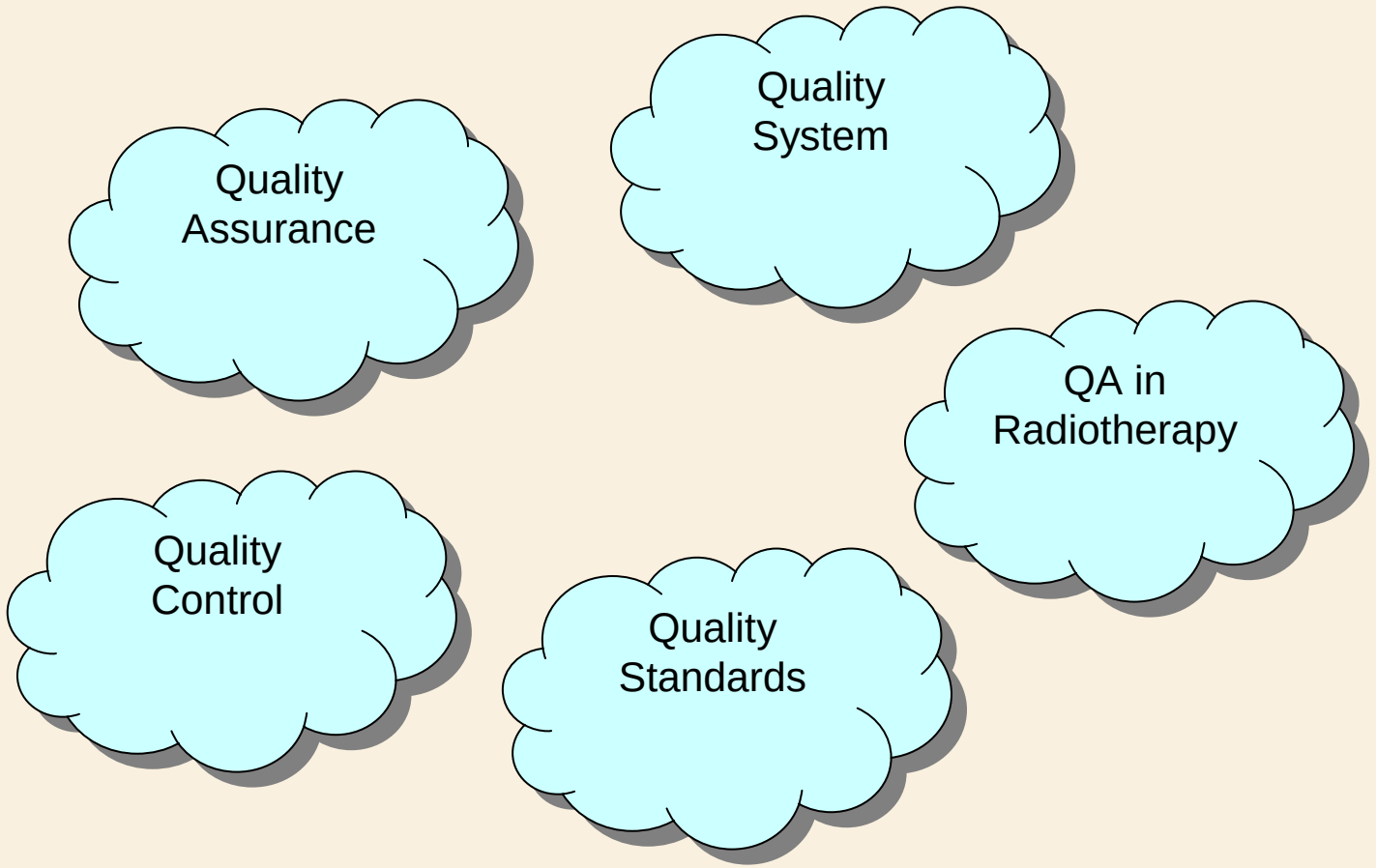
Content:

1. Definitions
2. The need for Quality Assurance (QA) in Radiotherapy
3. Requirements on Accuracy in Radiotherapy
4. Accidents in Radiotherapy
5. Legal and other Aspects
6. Management of Quality Assurance Program
7. Construction of a Quality System

1 Definitions

1.1 Quality Assurance (QA)

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



1 Definitions

1.1 Quality Assurance (QA)

- "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.

1 Definitions

1.2 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.

1 Definitions

1.3 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 a **part of quality system management**.
- 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.

1 Definitions

1.4 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.

1 Definitions

1.5 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

1 Definitions

1.6 Quality Standards in Radiotherapy

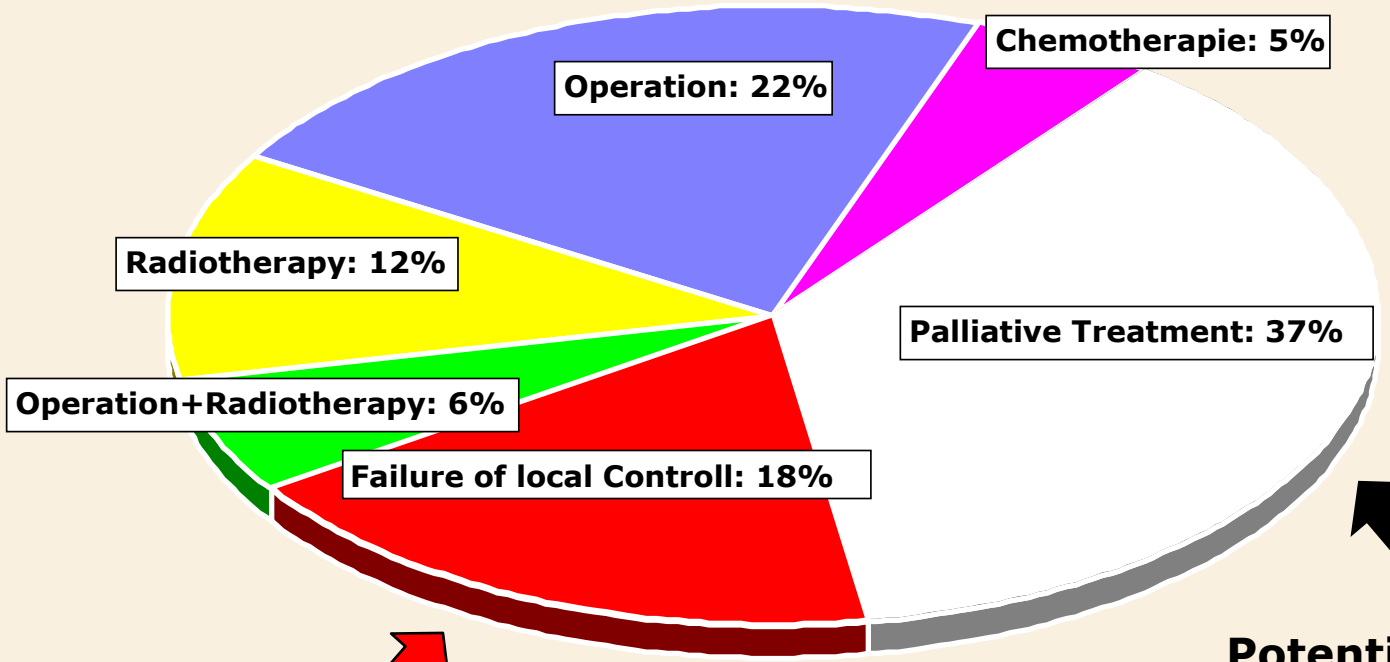
- Various national or international organizations have issued recommendations for standards in radiotherapy:
  - World Health Organization (WHO) in 1988,
  - AAPM in 1994,
  - European Society for Therapeutic Radiation Oncology (ESTRO) in 1995 and 1998
  - Clinical Oncology Information Network (COIN) in 1999
    - Where recommended standards are not available, **local standards need to be developed**, based on a local assessment of requirements.

2 The need for QA in Radiotherapy

2.1 Level of Cancer Treatment in Germany

Localized tumors: 58%

Metastatic tumors: 42%



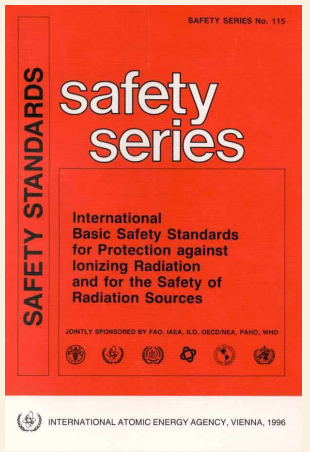
Potential for further improvements by therapy

Potential for further improvements by diagnosis

2 The need for QA in Radiotherapy

2.2 Basic Safety Standards of IAEA

1) You must establish a QA program!



- This follows directly from the Basic Safety Series of IAEA.

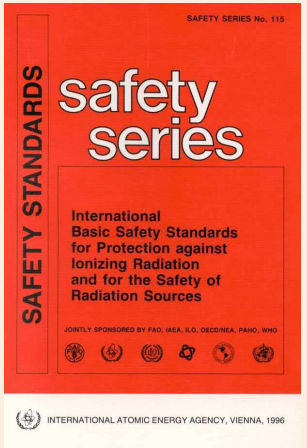
  Appendix II.22. says:

  “Registrants and licensees, in addition to applying the relevant requirements for quality assurance specified elsewhere in the Standards, shall establish a **comprehensive quality assurance program for medical exposures** with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the WHO and the PAHO.”

2 The need for QA in Radiotherapy

2.2 Basic Safety Standards of IAEA

1) You must establish a QA program!



- BSS appendix II.23 says:
  "Quality assurance programs
  for medical exposures shall include:
  (a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
  (b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment; …"

2 The need for QA in Radiotherapy

2.3 The best Treatment

2) It helps to provide "the best treatment"

- It is a characteristic feature of the modern radiotherapy process that this process is a multi-disciplinary process.
- Therefore, it is extremely important that
  - the radiation therapist **cooperates** with specialists in the various disciplines **in a close and effective manner**, and
  - the various **procedures** (related to the patient and that related to the technical aspects of radiotherapy) **will be subjected to careful quality control**.
- The establishment and use of a comprehensive quality system is an adequate measure to meet these requirements.

2 The need for QA in Radiotherapy

2.4 More Objectives

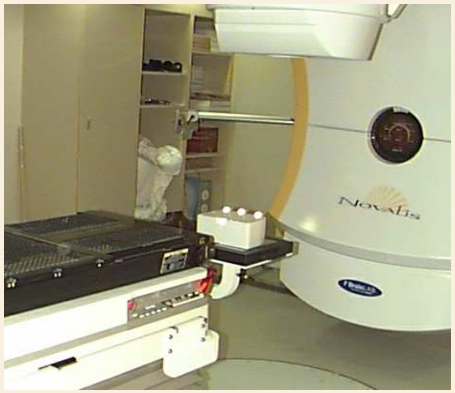
3) It provides measures to approach to the following objectives:

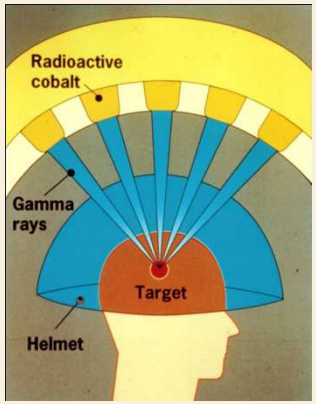
- **Reduction of uncertainties and errors** (in dosimetry, treatment planning, equipment performance, treatment delivery, etc.)
- **Reduction of the likelihood of accidents and errors** occurring as well as increase of the probability that they will be recognized and rectified sooner
- **Providing reliable inter-comparison of results** among different radiotherapy centers
- **Full exploitation of improved technology** and more complex treatments in modern radiotherapy

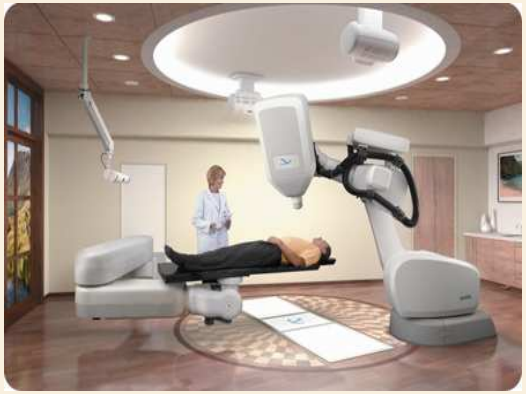
2 The need for QA in Radiotherapy

2.5 Complex Treatments in modern Radiotherapy

- Radiotherapy is a multidisciplinary specialty, involving complex equipment and procedures.





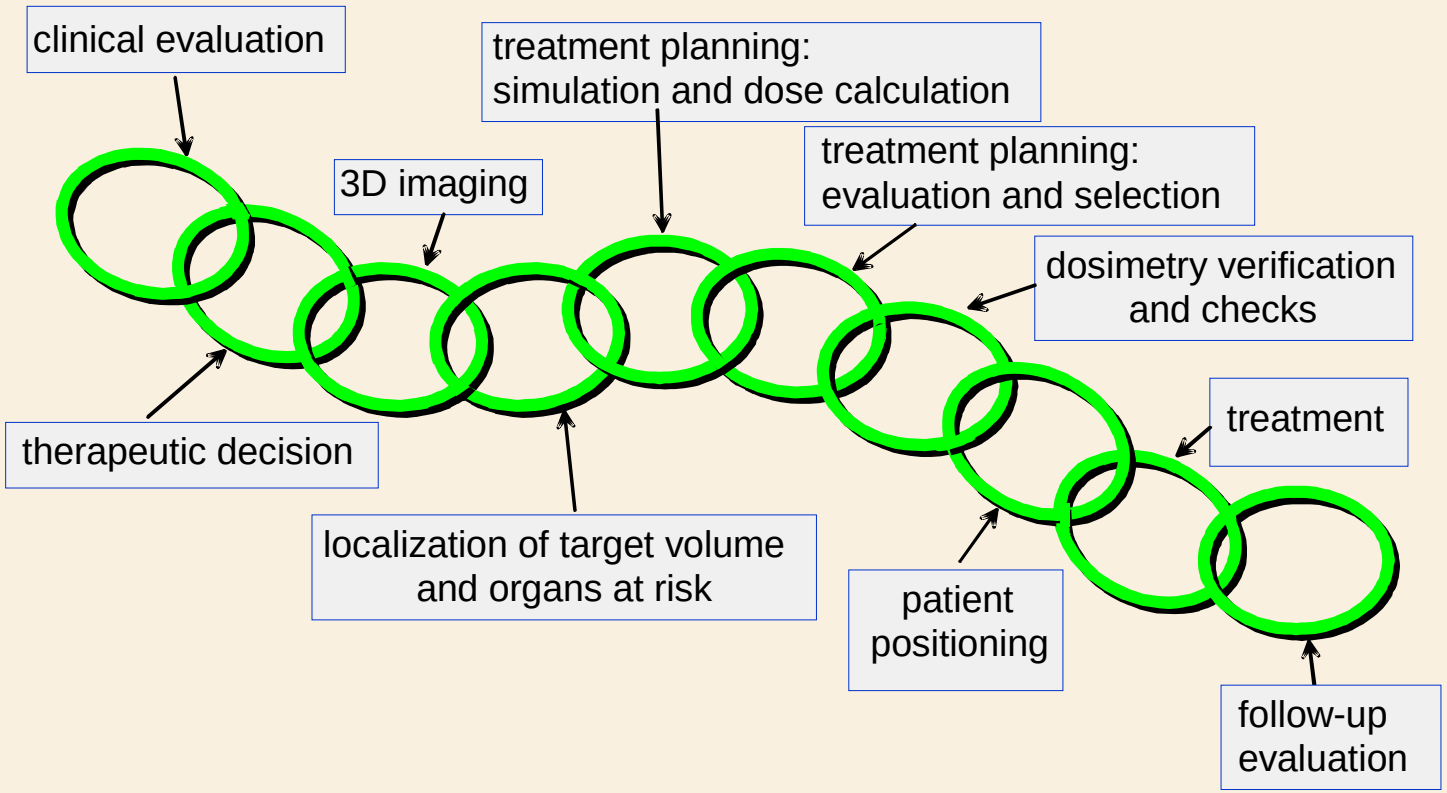


2 The need for QA in Radiotherapy

2.5 Complex Treatments in modern Radiotherapy

(The Radiotherapy Chain)

- A characteristic feature of modern radiotherapy is a **multi-disciplinary approach**, consisting of and usage of many complex devices and procedures.



3 Requirements on Accuracy in Radiotherapy

3.1 Requirements on accuracy in radiotherapy

- Many QC procedures and tests in QA program for equipment are directly related to the clinical requirements on accuracy in radiotherapy:
  - Which accuracy is required on the **absolute absorbed dose**?
  - Which accuracy is required on the **spatial distribution** of dose (geometrical accuracy of treatment unit, patient positioning etc.)?

3 Requirements on Accuracy in Radiotherapy

3.2 Dose delivery Accuracy

- The ICRU Report No. 24 (1976) concludes:

An uncertainty of 5% is tolerable in the delivery of absorbed dose to the target volume

- This value is generally interpreted to represent a confidence level of 1.5 - 2 times the standard deviation.

- Currently, the recommended accuracy of dose delivery is generally 5 - 7% at the 95% confidence level.

3 Requirements on Accuracy in Radiotherapy

3.2 Dose delivery Accuracy

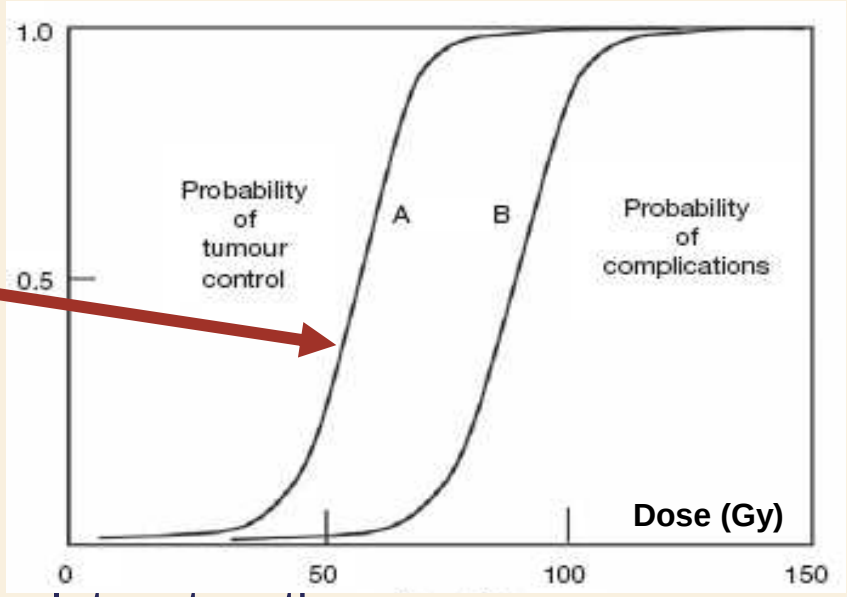
- **Geometric uncertainty**, for example systematic errors on the field position, block position, etc., relative to target volumes or organs at risk, **also leads to dose problems:**
  - either **underdosing of the required volume** (decreasing the TCP)
  - or **overdosing of nearby structures** (increasing the NTCP).

- Figures of 5–10 mm (95% confidence level) are usually given on the tolerable **geometric uncertainty**.

3 Requirements on Accuracy in Radiotherapy

3.2 Dose delivery Accuracy

- The steepness of a given TCP or NTCP curve defines the change in response expected for a given change in delivered dose.



- Thus uncertainties in delivered dose translate into either reductions in the TCP or increases in the NTCP, both of which worsen the clinical outcome.

4 Accidents in Radiotherapy

- Generally speaking, treatment of a disease with radiotherapy represents a **twofold risk for the patient**:
  - Firstly, and primarily, there is the **potential failure to control** the initial disease, which, when it is malignant, is eventually lethal to the patient;
  - Secondly, there is the **risk to normal tissue** from increased exposure to radiation.
- Thus in radiotherapy an accident or a misadministration is **significant** if it results **in either an underdose or an overdose**, whereas in conventional radiation protection only overdoses are generally of concern.

4 Accidents in Radiotherapy

- From the general aim of an accuracy approaching 5% (95% confidence level), a **definition for an accidental exposure** can be derived:

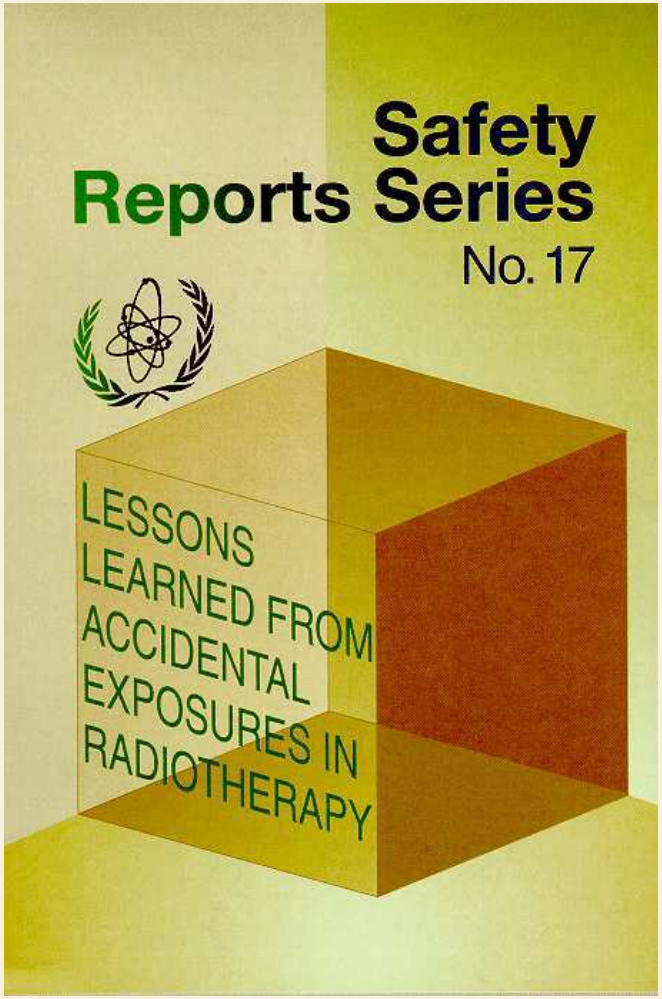
A generally accepted limit is about twice the accuracy requirement, i.e. a 10% difference should be taken as an accidental exposure

- In addition, from clinical observations of outcome and of normal tissue reactions, there is good evidence that differences of 10% in dose are detectable in normal clinical practice.

4 Accidents in Radiotherapy

- IAEA has analyzed a series of accidental exposures in radiotherapy to draw lessons in methods for prevention of such occurrences.

- Criteria for classifying them:
  - Direct causes of misadministrations
  - Contributing factors
  - Preventability of misadministration
  - Classification of potential hazard.



4 Accidents in Radiotherapy

Examples of the direct causes of misadministrations

Cause	Number	Cause	Number
Calculation error of time or dose	15	Human error during simulation	2
Inadequate review of patient chart	9	Decommissioning of teletherapy source error	2
Error in anatomical area to be treated	8	Error in commissioning of TPS	2
Error in identifying the correct patient	4	Technologist misread the treatment time or MU	2
Error involving lack of/or misuse of a wedge	4	Malfunction of accelerator	1
Error in calibration of cobalt-60 source	3	Treatment unit mechanical failure	1
Transcription error of prescribed dose	3	Accelerator software error	1
		Wrong repair followed by human error	1

5 Legal and other Aspects

5.1 German Legislations

In addition to these reasonable recommendations and quite practical reasons, there are also **crucial legal** regulations.

Because they are normally subjected to national laws, the following two examples refer to German legislative.

The first example is taken from the German Social Security Statutes 5 (= Sozialgesetzbuch 5).

The second example is taken from the German Radiation Protection Act (= Strahlenschutzverordnung)

5 Legal and other Aspects

5.2 German Social Security Statutes 5

SGB V - Gesetzliche Krankenversicherung –
VIERTES KAPITEL
Beziehungen der Krankenkassen zu den Leistungserbringern
Neunter Abschnitt: Sicherung der Qualität der Leistungserbringung
§ 135a: Verpflichtung zur Qualitätssicherung

(1) Die Leistungserbringer sind zur Sicherung und Weiterentwicklung der Qualität der

Service organizations are obliged to maintain and develop the quality of their service

(2) Vertragsärzte, medizinische Versorgungszentren, zugelassene Krankenhäuser, Erbringer von Vorsorgeleistungen oder Rehabilitations-maßnahmen und Einrichtungen, ..., sind nach Maßgabe der §§ 136a, 136b, 137 und 137d verpflichtet,
1. sich an einrichtungsübergreifenden Maßnahmen der Qualitätssicherung zu beteiligen, die insbesondere zum Ziel haben, die Ergebnisqualität zu verbessern
2.

Hosptitals have to implement a quality management system

Bundesgesetzblatt
Teil I G 5702

Ausgegeben zu Bonn am 26. Juli 2001 Nr. 38

Verordnung über den Schutz vor Schäden durch ionisierende Strahlen (Strahlenschutzverordnung – StrlSchV)

§ 83
Quality Maintenance for medical applications of radiation

Qualitätssicherung bei der medizinischen Strahlenanwendung

5 Legal and other Aspects

5.4 EFOMP Policy Statements and Documents

In Europe, further legal argumentation can be taken from EFOMP policy statements and documents.

The European Federation of Organisations for Medical Physics (EFOMP) has issued in 2011 a document on

CORE CURRICULUM FOR MEDICAL PHYSICISTS IN RADIOTHERAPY

The following recommendation on the competence to be acquired by a Qualified Medical Physicist is taken from that.

5 Legal and other Aspects

5.4 EFOMP Policy Statements and Documents

6. Principles of quality management

Short description:

Quality management requires an organisational structure (quality system) wherein responsibilities, procedures, processes and resources are clearly defined. It should be supported by the department management in order to work effectively and should be as comprehensive as is required to meet the overall quality objectives. It must have a clear definition of its scope and of all the quality standards to be met and requires collaboration between all members of the radiotherapy team. The quality system must incorporate compliance with all the requirements of national legislation, accreditation, etc. and requires the development of a formal quality assurance program that details the quality assurance policies and procedures, quality control tests, frequencies, tolerances, action criteria, required records and personnel.

Competences:

- ability to participate in quality management and facilitate quality improvement;
- ability to define quality objectives;
- ability to measure effective quality performance;
- ability to improve effective quality performance;
- ability to define control tests, frequencies, tolerances, action criteria, records and personnel;
- ability to assess the national legislation, accreditation requirements.

Core curriculum items:

- meaning of quality, quality assurance and quality control;
- quality standards;
- assessment of quality;
- quality management systems, records, audit and improvement of quality.

6 Managing a Quality Assurance Program

6.1 General

- It must be understood that the **required quality system is essentially a total management system**.
  - for the total organization
  - for the total radiation therapy process
- The total radiation therapy process includes:
  - clinical radiation oncology service
  - supportive care services (nursing, dietetic, social, etc.)
  - all issues related to radiation treatment
    - radiation therapists
    - physical QA by physicists
    - engineering maintenance
    - management

6 Managing a Quality Assurance Program

6.2 Recommendations Documents

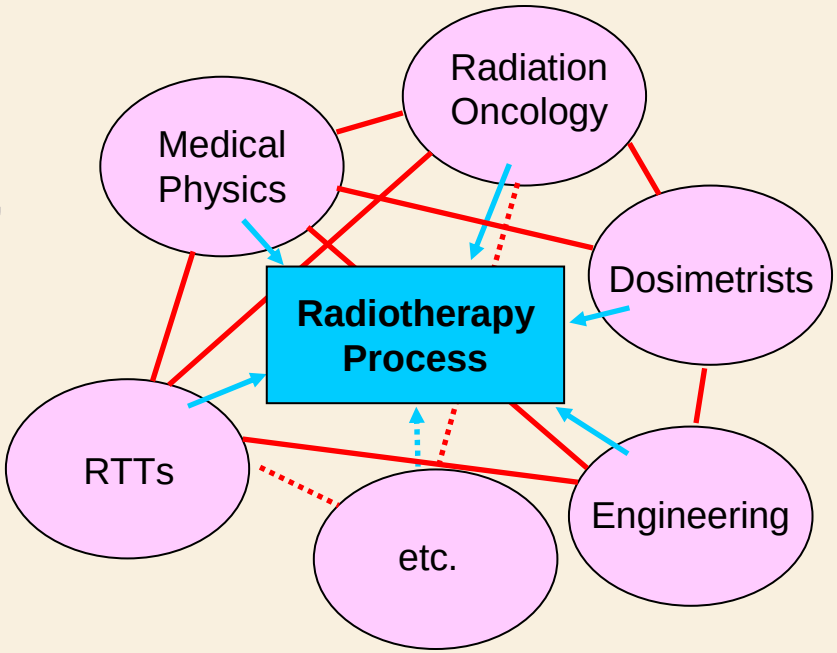
- A number of organizations and publications have given background discussion and recommendations on the structure and management of a quality assurance program in radiotherapy or radiotherapy physics:

  - WHO in 1988,
  - AAPM in 1994,
  - ESTRO in 1995 and 1998,
  - IPEM in 1999,
  - Van Dyk and Purdy in 1999,
  - McKenzie et al. in 2000.

6 Managing a Quality Assurance Program

6.3 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.



6 Managing a Quality Assurance Program

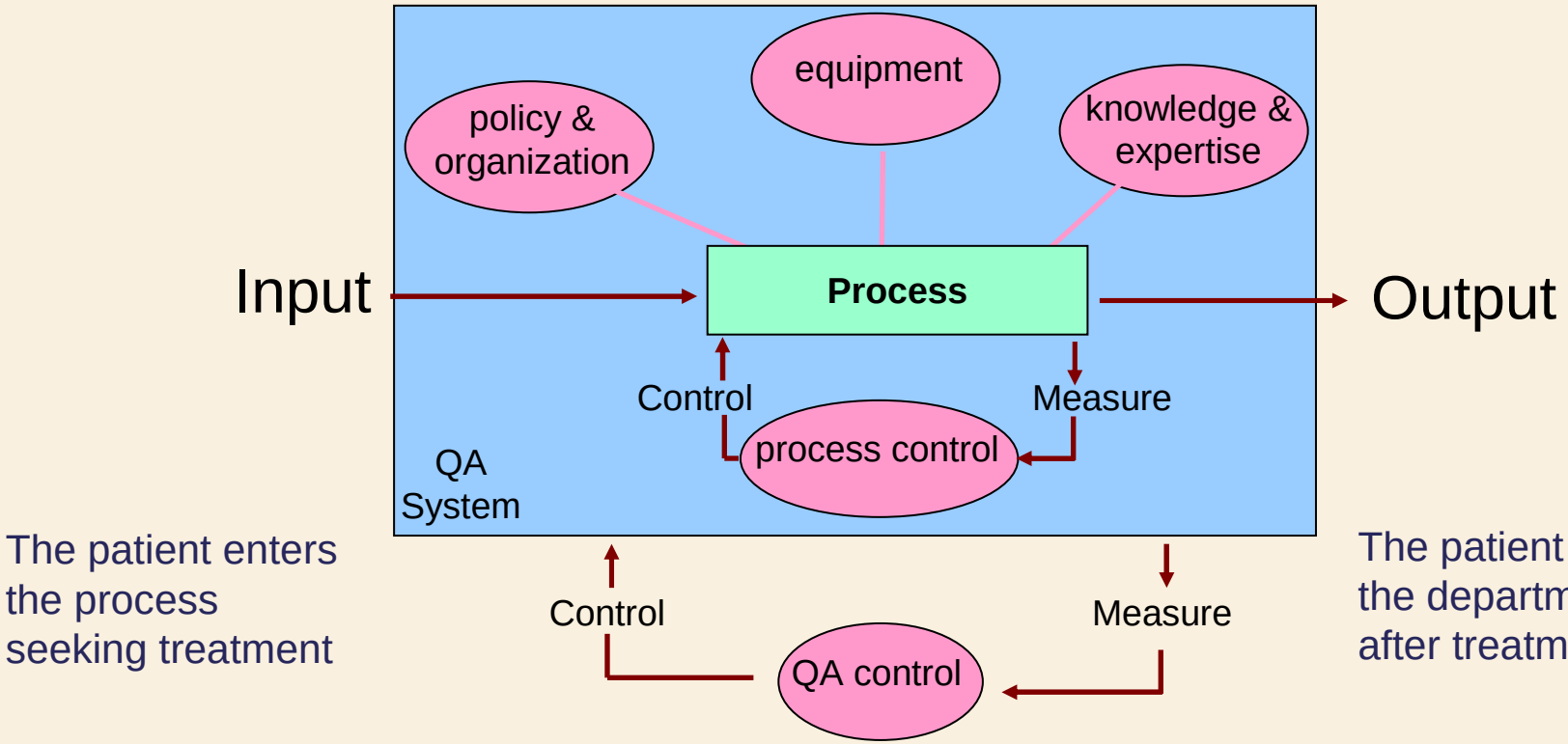
6.4 Quality System / Comprehensive QA Program

- It is now widely appreciated that the concept of a QA (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.

6 Managing a Quality Assurance Program

6.5 Quality System / Comprehensive QA Program



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.

6 Managing a Quality Assurance Program

6.5 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.

6 Managing a Quality Assurance Program

6.6 ESTRO Booklet 4:

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

7 Construction of a Quality System

In the following we will concentrate on this document.

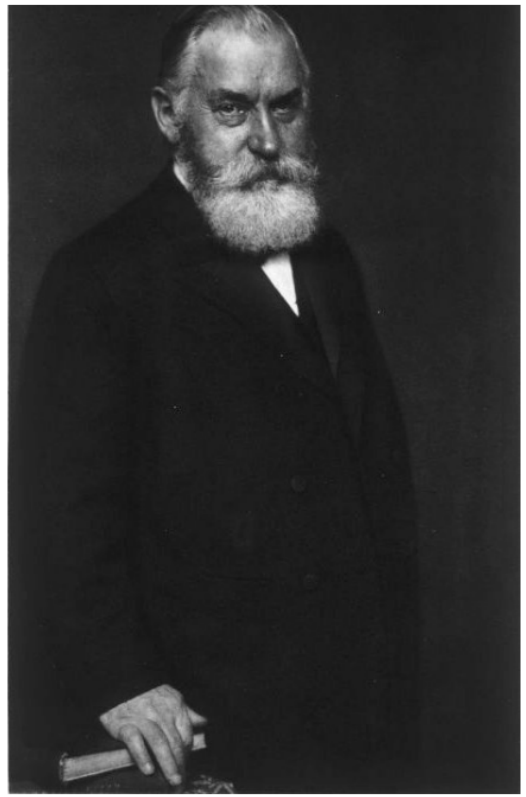
Important arguments always are:

1. We have to implement a quality system.
2. However, we are free to implement any system which appears appropriate for us.
3. This means: In principle we could develop any system.
4. In order to save time and to avoid mistakes, however, it is highly advisable to make use of existing models such as the ESTRO booklet No 4:

PRACTICAL GUIDELINES FOR THE IMPLEMENTATION OF A QUALITY SYSTEM IN RADIOTHERAPY

7 Construction of a Quality System

1) Role of the Head of Department



It is essential - as the **very first step** - that the Head of Department and the management of the institution whole-heartedly support the project.

He / They must be absolutely convinced of the benefit which everyone in the department will find in working in an optimally organized structure.

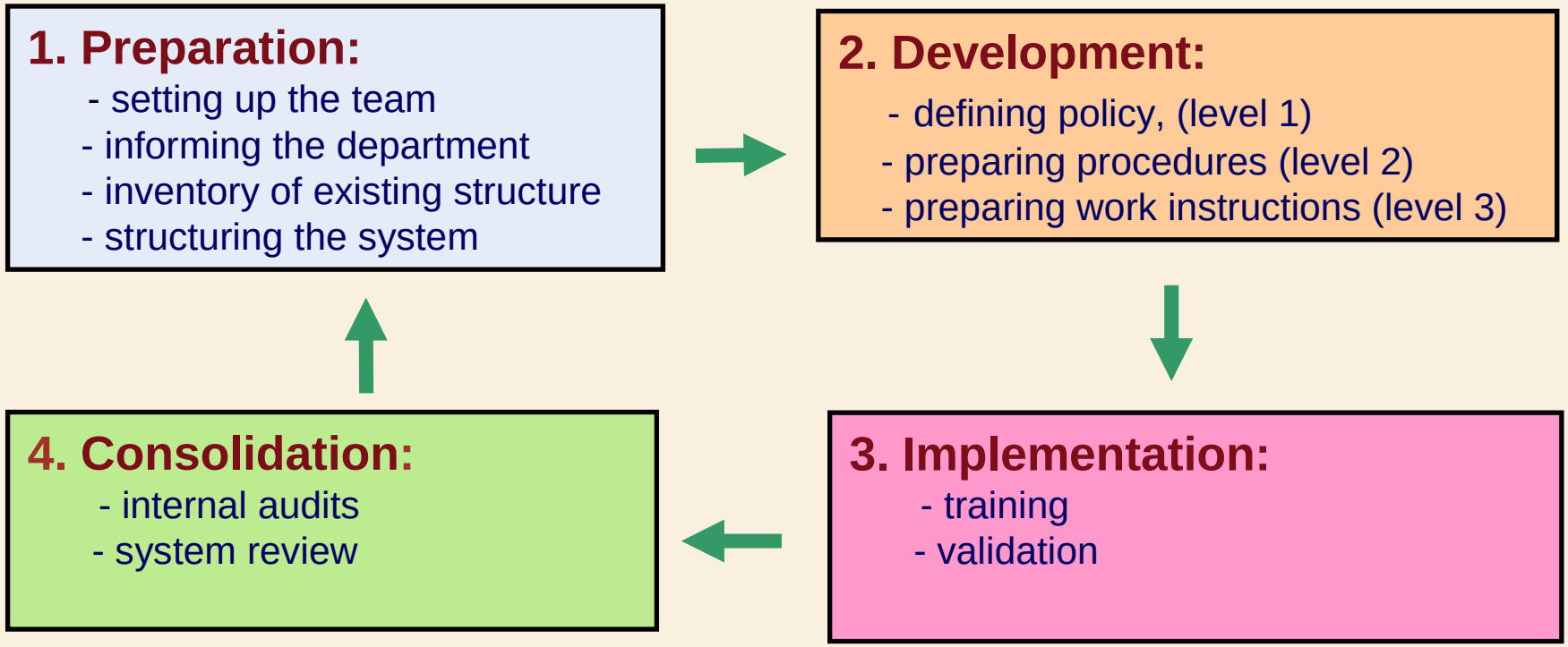
If the Head of Department is not firmly and obviously committed to supporting the quality project and the quality team, the QM project will not gain momentum.

Vincenz Czerny (1842 - 1916) German Oncologist in Heidelberg

7 Construction of a Quality System

2) Implementation steps of a quality project

A quality project will usually progress through four consecutive periods:



7 Construction of a Quality System

Step 1: **Preparation**

Important aspects are:

a) Involving and informing the department
b) The project team
c) Detailed Preparation, planning
d) Setting up priorities

7 Construction of a Quality System

a) Involving and informing the department

Each member should feel as an important part hare of the QMS.

b) The project team

A project **team** is most appropriate to control the entire QM implementation process.

It **must** be appointed by the Head of the Department, taking care that all groups of personnel are appropriately represented.

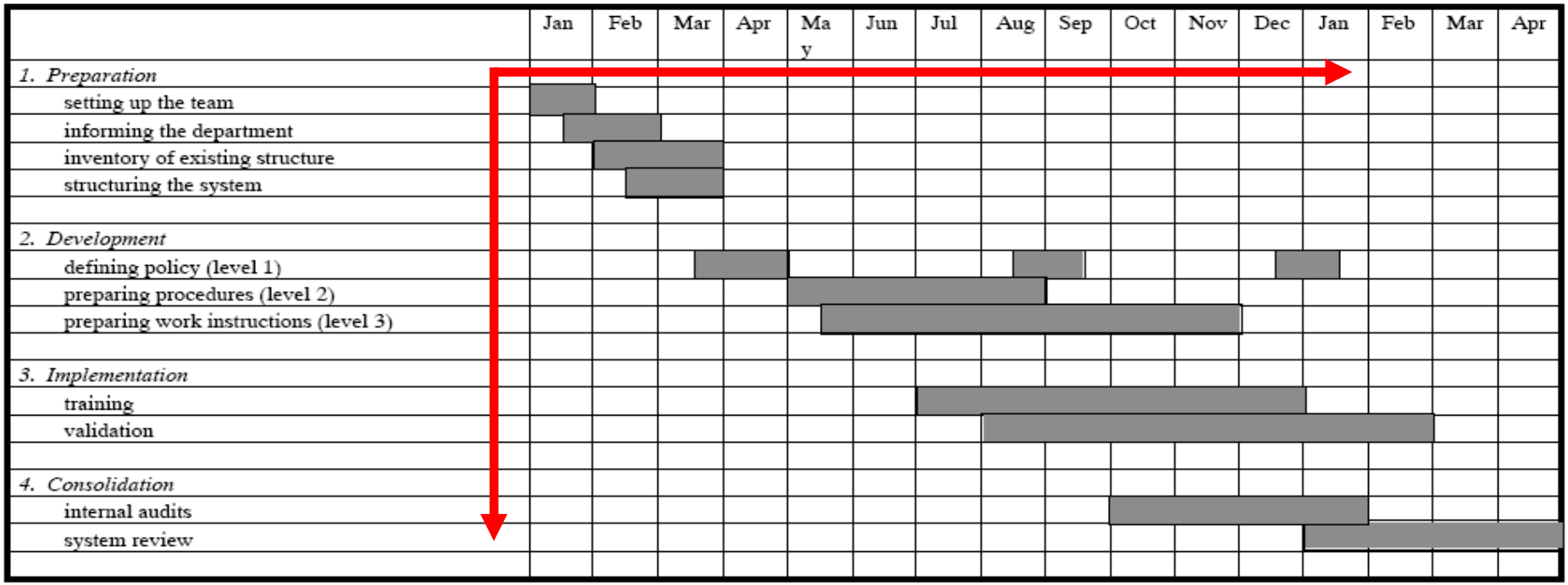
The Head of Department would not usually be a team member, so that he can be detached in judging the team's recommendations.

However he must show steady interest in the progress of the project. Disinterest will kill the project through undermining the motivation of the quality officers.

7 Construction of a Quality System

c) Detailed Preparation, Planning

Careful planning must be carried out, covering the different phases of the project.
It may typically last several years:

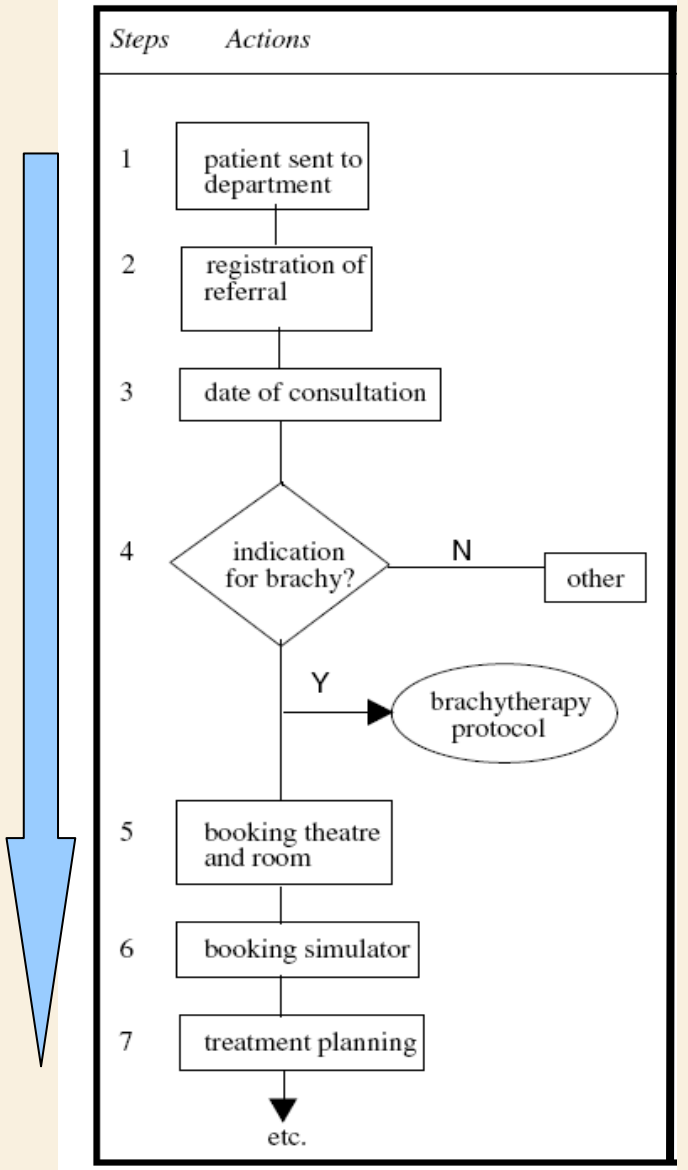


7 Construction of a Quality System

d) **Setting up priorities**

The following method based on a **workflow** analysis can be used to define priorities

(Example from Brachytherapy)

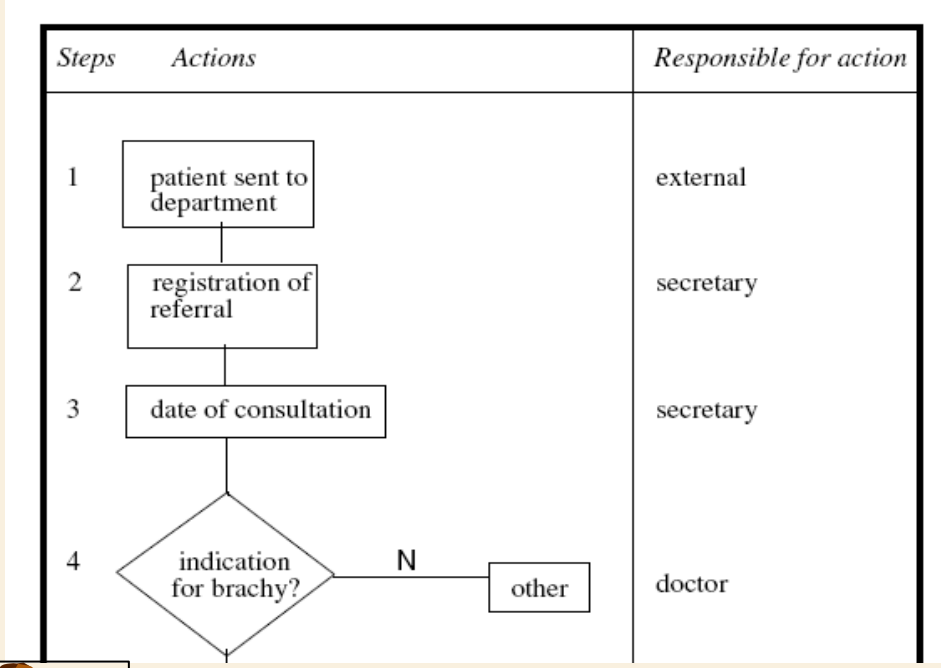


7 Construction of a Quality System

1) to 3) is the referral of the patient to the radiation oncology department by a clinician outside the department.

This involves recording initial information, *etc*, which may be identified as a separate step if appropriate.

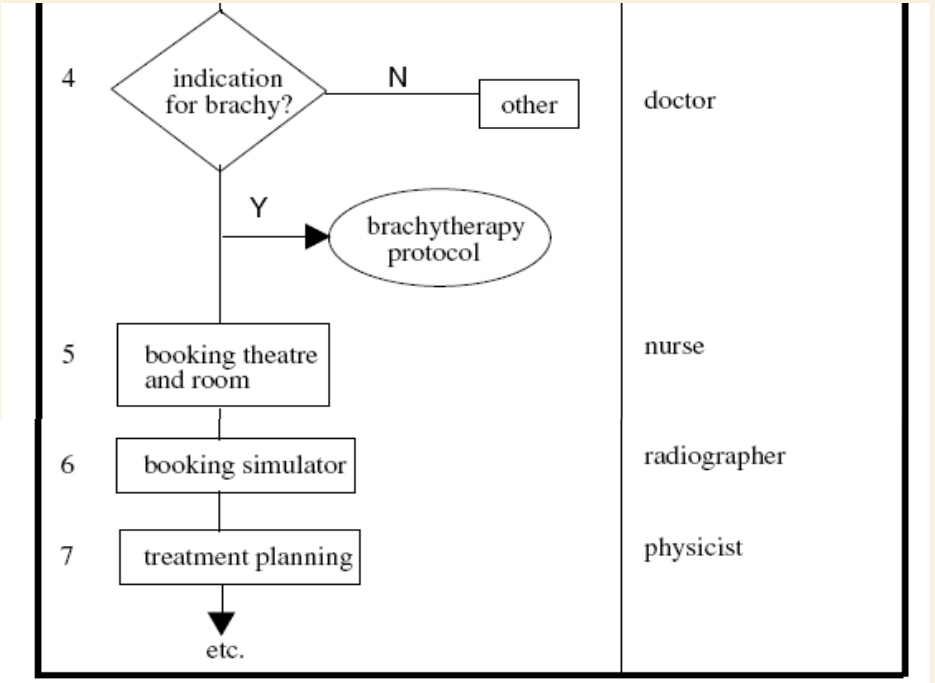
4) is the decision to prescribe brachytherapy and the initial prescription itself;
the responsible person
is the radiation oncologist.



7 Construction of a Quality System

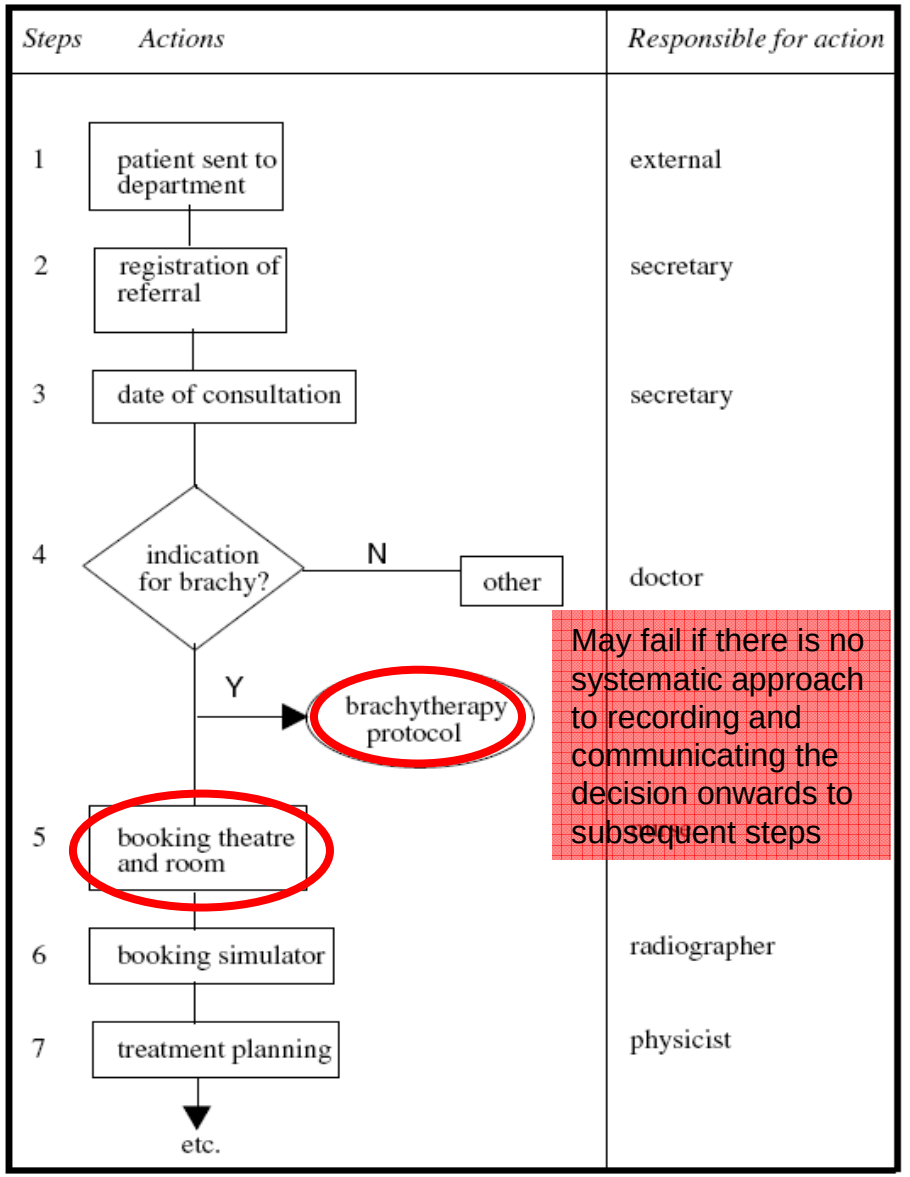
5) is the entry of the patient into the booking system (for theatre time, bed space, *etc*); again responsibility lies with a clinician.

6) and 7) is the initial planning of the treatment, to decide sources required, time course, *etc*; this is the responsibility of the clinician and will involve physics personnel in calculation, source ordering, *etc*; and so on.



7 Construction of a Quality System

At each step, a description of the problems and actual - or potential - quality failures should be written, if any are identified.



May fail if sources are not ordered in time to mesh in with later steps

May fail if there is no systematic approach to recording and communicating the decision onwards to subsequent steps

7 Construction of a Quality System

Each of these problems can be assigned an index of significance (or criticality), with a value between 1 and 10, by each group of personnel involved in the particular step.

The index value is given according to how critical the failure may be and to how often it happens or is likely to happen.

Steps	***Problems***	***Criticality index***
5	Booking of operating theatre and of room is not co-ordinated	8
6	Date and hour of simulation are not planned appropriately	8
7	Details of dosimetry are not communicated to nursing staff for planning of hospitalisation	2

7 Construction of a Quality System

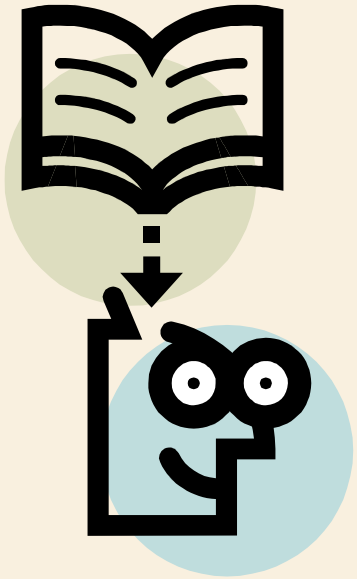
Step 2: **Development of a QM system**

Important aspects are:

a) The quality manual
b) Working in the three hierarchical levels of the QM system

7 Construction of a Quality System

a) The quality manual



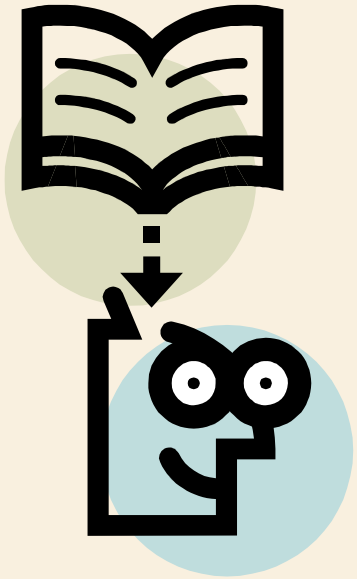
Basically, the quality manual will answer two questions for each step in the RT process:
- what is the standard required
 (as a particular example: what tolerances are
 required on treatment unit positioning precision)
- and how to meet this requirement.

Generally agreed standards may already in existence for a number of areas. In other areas, agreed standards still need to be developed.

Finally, some standards will be internal to a given department (*example:* waiting time before treatment) and will have to be developed locally.

7 Construction of a Quality System

a) The quality manual



The Quality Manual

is the central part of any QM implementation:

- **fixation of standards & methods**
- **compliance with standards**

7 Construction of a Quality System

b) There are three hierarchical levels of a QM system

Level 1 reflects the quality management policy of the department (objectives, strategies to meet these objectives, responsibilities, supervision of all functions having an impact on quality).

Level 2 describes all required **managing documents** on actions needed to be formally organised. These documents must contain:

- a definition of the scope of the procedure (what it covers and is about),
- of the respective responsibilities of those involved (who is responsible for doing what, who is in charge of which areas)
- outline of the practical actions to be undertaken (what is to be done).

At Level 3 the real work instructions are explained in detail.

7 Construction of a Quality System

Step 3: **Implementation**

Important aspects are:

a) Training
b) Validation process

7 Construction of a Quality System

a) Training

- There are a few general tips:
  - Implement short, but repeated, training sessions;
  - Execute training internal to the department (rather than by external professionals);
  - Training should be initially oriented towards very practical subjects, before addressing wider principles;

- Initial reactions of personnel will be tempered by the fact that the first result of implementing a quality system is that people will have to change some (a few, or a lot) of their habits.

- This may mean: There is an element of loss of comfort which must be taken into account.

- Persuasion and repeated demonstration of small improvements is the best way to obtain acceptance of the majority to the system.

7 Construction of a Quality System

b) Validation process

- The objective of this phase is to test the new procedures, as to their appropriateness and feasibility.
- Advice from the users is important and must be used as a source of improvement. Any suggested improvements at this stage must be carried out rapidly.
- Care should be taken that any inefficient or unaccepted procedures are not left unchanged, as they will act as sources of generalised de-motivation towards, and criticism of, the whole approach.
- The Head of Department must be involved and openly interested during this phase.

7 Construction of a Quality System

Step 4: **Consolidation**

Important aspects are:

a) Internal audits
b) System review and external audits.

7 Construction of a Quality System

a) Internal audits

- Internal audits constitute a good way to consolidate the quality system.
- These audits must be presented to the department for what they are; ie. not a policing operation, but rather a test for possible improvements.
- The first question that arises when a procedure is not followed appropriately is why do people not follow or use it. Indeed, looking for errors or deviations does not mean looking for the guilty, but rather looking to change things in the system that do not work properly.
- Internal audit must be an important source of improvements, not of additional stress.

7 Construction of a Quality System

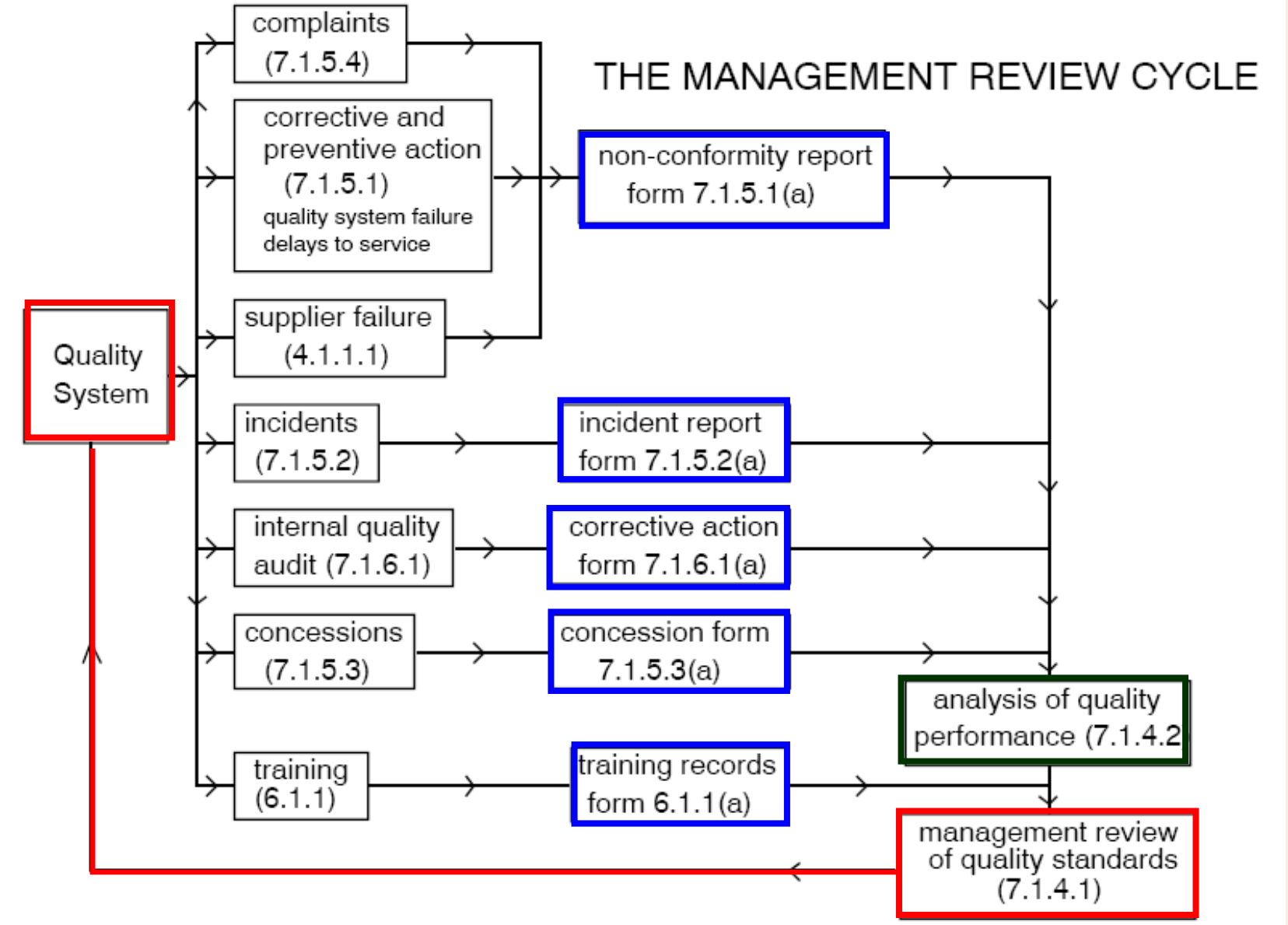
b) System review

The department and the effectiveness of every part of the quality system must be analyzed by reviewing its performance since prior QM meetings and implementations …

and corrective action is then fed back into the quality system.

This cycle of Management Review is summarized in the next slide

7 Construction of a Quality System



Summary

(1) A QM system can be implemented according to the ESTRO booklet No 4: PRACTICAL GUIDELINES FOR THE IMPLEMENTATION OF A QUALITY SYSTEM IN RADIOTHERAPY.

(2) Key message of this recommendation are:
Construct and formalize a quality system which is sensible, practical, economical and reactive.
Convince the department of the need for a quality system (communicate, seek participation).
Respect the initial planning and timing; encourage confidence of the personnel in the quality system; listen to comments of personnel on it; encourage participation in it, and development of it.

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