Overall Quality Assurance and Review
Aims

Assuring accurate and safe delivery of radiotherapy to cancer patients through setting up a quality assurance/review system
Specific Learning Objectives

• To define Quality Assurance (QA), Quality Control (QC) and Quality Standards (QS) in Radiotherapy

• To describe the components of a comprehensive quality assurance programme

• To describe the details and importance of each component of QA programme

• To integrate QA and QC in daily practice

• To explain the benefits of implementing a comprehensive QA program

• To design forms to be used for routine quality control activities
Quality Assurance (QA)

Defined as:

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality

ISO 9000:1994
Quality Control (QC)

QC is one part of overall quality assurance and is defined as:

A regulatory process through which the actual quality performance is:
- Measured
- Compared with existing standards
Quality Standards (QS)

The set of accepted criteria against which the quality of the activity in question can be assessed

e.g. guidelines from WHO, ESTRO, AAPM, IAEA, etc.
QA in General

- The **ISO 9000** family of standards is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product. The standards are published by ISO, the **International Organization for Standardization**, and available through National standards bodies.

The slide illustrates the fact that ISO standards are often incorporated into national standards - this makes them legally binding locally. (http://en.wikipedia.org/wiki/ISO_9000)
QA in General

- ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which the family of standards is based. ISO 9001 deals with the requirements that organizations wishing to meet the standard have to fulfil.
- They are highly successful in manufacturing industry because they do improve productivity and avoid costly mistakes.

The slide illustrates the fact that ISO standards are often incorporated into national standards - this makes them legally binding locally.
Quality Assurance in radiotherapy

• All procedures that ensure
  – consistency of the delivered dose with the radiotherapy prescription
  – safe and effective treatment
• This includes
  – Optimal Dose to target volume
  – Minimal dose to normal tissue
  – Minimal exposure of personnel
  – Vigilant clinical assessment
  – Complete documentation, etc.
Good QA systems in radiotherapy

- Improve work practices
- Monitor risk
- Help to prevent major accidents
- Encourage vigilance
- Take note of lessons learned

The second message - while obvious - is important. The cost of a major accident exceeds the cost to instigate a good QA system by far.
A Comprehensive Quality Assurance Program

• The details of such a program are often captured in a “Code of Practice”
  – “Quality Assurance in Radiotherapy”, WHO, 1988
Components of a Comprehensive QA Program

- Quality Assurance Committee
- Policies and Procedures Manual
- Quality Assurance team
- Quality audits
- Appropriate Resources

These points are discussed in more detail in the following slides
QA Committee Members

- Must represent the many disciplines within the department
- Should be chaired by the Head of Department
- At a minimum, the committee members must include at least a radiation oncologist, a medical physicist and a radiotherapy technologist. Other professional groups like nursing, dosimetrists and an engineer responsible for service and maintenance, can be added as relevant.
- Must be appointed and supported by senior management
- Must have sufficient depth of experience to understand the implications of the process
- Must have the authority and access to the resources that are needed to initiate and support the QA process

An important slide - the lecturer should take some time to take the participants through it.
Policies and Procedures Manual

The manual should include:

- Clear and concise statements of all the policies & procedures carried out in the Department
- Define the action levels
- Be reviewed (typically) yearly
- Be updated as procedures change
- Be used for orientation of new staff
Policies and Procedures Manual

- As a minimum, sections should exist for
  - Administrative procedures including the roles and responsibilities of each profession
  - Pertinent national regulations and licenses
  - Clinical procedures and protocols
  - Treatment planning and delivery procedures and protocols
  - Physics and technical procedures
  - Radiation safety
  - Emergency procedures
Policies and Procedures Manual

- It must be “signed off” by the Head of Department and appropriate section heads.
- It is important that all the staff have “ownership” to the manual.
- It should reflect the opinions of all and be agreed to by all.
- A list of all copies of the Manual and their location must be kept to ensure that each copy is updated.
Policies and Procedures Manual

• Ownership of working procedure is essential.
• It is obtained by involving as many staff as possible in drafting the details of the procedures
• Periodic review should be carried out by the same staff
Quality Assurance Team

- Includes all disciplines
- Well defined responsibility and reporting structure
- Each member of the team must
  - Know his/her responsibilities
  - Be trained to perform them
  - Know what actions are to be taken should a test or action be outside the preset “action levels”

The lecturer should point out that the QA team is different from the QA committee. The QA team is responsible for performing the QA activities.
<table>
<thead>
<tr>
<th>Area of responsibility</th>
<th>Doctor</th>
<th>Head Technician</th>
<th>Physicist</th>
<th>Secretary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>●</td>
<td>○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td>○</td>
<td>○</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Availability of Technicians</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock</td>
<td></td>
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<td></td>
<td>●</td>
</tr>
</tbody>
</table>
Quality Audit

A systematic and independent examination and evaluation to determine:

- whether quality of activities and results comply with planned arrangements
- whether the arrangements are implemented effectively and are suitable to achieve the objectives.”

“Quality assurance in radiotherapy.”, Radiother. Oncol., 1995

Do we do what we say we do?

Internal audit

- Carried out by staff members in the department who are appointed to:
  - Review results of all QC
  - Verify QC are effectively carried out at prescribed intervals
  - Verify results of QC are in line with tolerances and action levels
  - Identify trends for deviations
  - Propose improvements in QC technique
External Quality Audit

- Ideally performed by someone outside of the organisation (but with the same professional background): Peer review
- Examples
  - IAEA/WHO TLD programme for check of dose in radiotherapy units
  - QUATRO by IAEA
  - EQUAL programme for Europe
  - Audits as part of participation in clinical trials (eg RPC audit for RTOG)

The first two examples are dose verification services.
The calibration of a radiation beam is checked using TLDs.
More details on this are provided in part X lecture 2 of the course.
Radiological Physics Center Audits

Graph showing frequency distribution of 1371 Photons and 2010 Electrons.

- Mean and Standard Deviation:
  - Photons: Mean 1.006, S.D. 1.7%
  - Electrons: Mean 1.005, S.D. 2.1%

- Outside Plot Range:
  - Photons: 1.11, 1.13
  - Electrons: 0.84, 1.13, 1.33, 1.49

Visit after 04/15/84

RPC / INSTITUTION
QUATRO: comprehensive RT audit
QUATRO medical physics kit

IAEA dosimetry travel kit used for expert missions to radiotherapy hospitals
This is an interesting article which is mentioned as it focuses on the point that QA is not just required for hardware but also for information flow.

The complexity of the information flow chain in radiotherapy can be enormous (in particular in advanced treatment such as IMRT). It is essential to ensure that all transmission of information is accurate. Record and verify systems (such as Varis or Impac) are useful in this context.
QA should ensure every step in the treatment chain...

The treatment chain in radiotherapy

- Eg: Hand calculation of treatment time
- Eg: Check source activity
Explained more in the next slide

Verification - as test of a large part of a chain at once - is an additional QA check suitable for audits. It does NOT replace QA activities for individual steps.
The lecturer can point out that it is beyond the scope of the course to introduce any of the QA protocols in much detail. Here, the general ideas shall be dealt with, the protocols shown here provide guidance on the set-up of a QA program which must be specific for the circumstances a radiotherapy department is in. The references shown are:


Not shown but equally important is:


Participants should have access to all of them.
Documentation

- Internal
  - procedures
  - QA
  - forms
- External
  - reports
  - audits
  - publications
Treatment records

- Must contain all relevant information
- Should be compatible with international standards (e.g. ICRU reports 38, 50, 58, 62, 83)
- Can be in electronic format but should provide for electronic signatures according to local procedures.
The lecturer must point out that the activities suggested on the following slides are suggestions only. The same applies for the practical exercises. They must be modified and agreed upon locally.
These checks are usually quickly done.

The picture shows a device for daily output consistency checks - it is based on a sealed ionization chamber (no temperature/pressure correction necessary) and features a large read-out which can be seen through the patient monitoring video system.
QC - Weekly

- Check of source positioning (cobalt 60)
- Couch movements (lateral, vertical, longitudinal, rotation)
- Other interlocks

The couch movements are often used for patient positioning eg when lining up the patient to an anatomical landmark or tattoo and then shifting the patient x cm longitudinally.
Example for weekly QC summary

From Constantinou 1992

Part of handout slides - the participants are encouraged to produce their own chart in a practical exercise.
Both % depth dose and flatness symmetry can verify the radiation energy. Flatness is usually a rather sensitive test as the flattening filter is energy sensitive.
QC - Monthly

- Safety interlocks
  - emergency
  - wedge etc
- Light/ radiation field coincidence
- Scales
- Isocentre position

Shown is a tool for cross hair alignment checks
QC - Monthly

- Field size indicators
- Jaw symmetry
- Latching of wedges, trays etc.
- Wedge position (factors etc.)

Shown is a tool to verify field size and distance indicators.
QC - Annual

- Dosimetry
- Safety
- Mechanical

*These checks are a scaled down version of the commissioning checks. It is a major QA exercise and is intended to validate the unit for another twelve months. These tests are also done after catastrophic failures.*
How to decide on frequency for tests?

- Likelihood of failure
- Severity of the consequences if something goes wrong
- Ease of the test - resources required

*This depends on local circumstances!!!*
In particular for a badly performing unit, or a unit which has failed often on previous tests, one may need to spend considerably longer time.

The picture is just an illustration.
The form shown is a good example - it is clearly laid out and uses graphics. A brief graphical description of the test (cross hair centre variation with gantry position) is shown.

Most importantly, the ‘bottom line’ is: Action required?
Forms are useful for all tests

C. Safety System Function
1. Emergency Off Switches
   All emergency off buttons function correctly?

<table>
<thead>
<tr>
<th>Location</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Console</td>
<td>ok/needs repair</td>
</tr>
<tr>
<td>Couch right side</td>
<td>ok/needs repair</td>
</tr>
<tr>
<td>Couch left side</td>
<td>ok/needs repair</td>
</tr>
<tr>
<td></td>
<td>ok/needs repair</td>
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<td></td>
<td>ok/needs repair</td>
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<td></td>
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</tr>
</tbody>
</table>

Simple ticks may be sufficient

Empty space for comments and drawings
Forms

- All these forms should be bound together (logbook) and should be easily available at the equipment
Action Levels

- Are quantitative
- Reflect the required outcome
- Are informed by the achievable outcome
- Must be unambiguous
- Should be easy to understand
Action Levels

- Not too tight - one must be realistic about what can be locally achieved
- Not too lax - one must identify unsatisfactory practice
- As the practice improves, the action levels may be tightened

Here one can ask for examples, e.g. can treatment continue without one of the laser positioning devices functioning?
QA of Simulator

• Appropriate sections from the QA activities for a treatment unit
• kVp and mAs calibration
• Image intensifier quality checks
• Automatic exposure control if applicable
• Film processor
The test tool shown has different sections:

The front section which is visible checks alignment and CT numbers for 4 test objects.

Other sections check spatial and contrast resolution.

The whole phantom is made from water equivalent material.
QA for Dosimetry Equipment

- Local standard
  - 2 - 5 yearly calibration
- Field instruments
  - yearly calibration
- Linearity
- Leakage
- Recombination

The illustration shows a PTW electrometer and a pin-point chamber.
Barometer can be checked against a meteorological station close - however, care must be taken that the correct units are used and appropriate corrections eg for altitude are applied.
Clinical QA

- QA extends to everyone - not just the technical aspects
- A good way to do this are ‘chart rounds’ or ‘grand rounds’
- Film review
- New patient planning conferences

Explained in more detail on the next slide. There can be more discussion here around the chart check protocols used by the participants.
Chart Rounds

• Regular review of patients
• Can be all patients or randomly selected patients
• Should include all patients with unexpected severe complications

By doing this chart rounds not only can improve clinical practice and help to develop good local protocols, it is also possible that the round pick up potential accidents.
Outcome Monitoring

• At the regional or national level: Cancer Registry (incidence and mortality)

• At the department level:
  – Serious adverse events registry
  – Survival of cancer patients
  – Morbidity and mortality conferences
Redundancy in the context of the second point means there should be a second piece of equipment which can perform the same (or at least a similar) function as the equipment in use. This allows cross checks and ensures the availability of a back-up.

The bottom line for many people - it is important to discuss costs/benefit also for QA. It is hoped that the following slides can be used to stimulate discussion amongst the participants.
QA Cost-Benefit

- Benefit of QA comes at a cost
- Are these the true shapes of curves?
- Balance between too little and too much
What do we get?

Yes, correct - lots of documentation. But there are other benefits...
The benefits of QA

- Benefits for the department
  - improved management system
  - improved communication
  - improved safety
  - less duplication and waste
- Benefits to patients
  - Better chance of safe and effective treatment
  - optimized procedure
  - re-assurance

Prevention of accidents is not mentioned here on purpose even if it is a very important outcome of QA. It would be excellent if the participants note this (prompted or un-prompted by the lecturer).

Accidents are covered in the last slides of the talk.
Additional benefits

• Credibility
• Potential to attract funding (and account for it…)
• Participation in clinical trials
• Regular updates and audits continue improvements
• Pride and confidence of staff
It should not be difficult to convince management about the need for QA. It helps everyone. Typically only the expenditures and resources necessary to perform it are a matter of discussion. This can be resolved by a scientific approach which assesses QA needs and resources and prioritize the activities needed.
But-Beware the Administration “Tick in the Box” syndrome!

• Administration may agree with QA
• They may even insist upon it
• Without education they will not understand what that really means in our environment
• Many administrators equate QA with an “audit”
• Some simply require the right boxes get ticked so they can be seen to have done their job - this is not enough...
What do we risk without a Quality Assurance Program?

• Exeter, UK
  – New cobalt 60 source installed
  – Over the next 5 months, 207 patients were overdosed by 25% due to an incorrect calibration

• Contributing factors
  – Calibration details not recorded
  – Little documentation or protocols
What do we risk without a Quality Assurance Program?

• Exeter: Contributing factors (cont.)
  – Reduced staffing levels (money)
  – No independent check of calculations
  – No independent check calibration

• It was detected during a nation wide survey (not clinically)!
The last two points are important: openness must be encouraged. Any problem becomes worse if it is not addressed.
Summary

- Quality assurance is an essential part of radiotherapy
- It affects all aspects including the radiation protection program
- There are many different standards and guidelines for specific QA activities - it requires a qualified expert to choose the most appropriate for a particular center
- QA requires and encourages regular external audits
- QA is a continuous process - it is aimed at achieving improvements not laying blame.

Other features could be added as required locally
Where to get more information


