

## CHAPTER 12.

### **QUALITY ASSURANCE OF EXTERNAL BEAM RADIOTHERAPY**

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#### **12.1. INTRODUCTION**

##### **12.1.1. Definitions**

*Quality Assurance (QA):* All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO 9000:1994). As such it is wide-ranging, covering **all** relevant procedures, activities and actions and therefore all groups of staff involved in the process under consideration.

*QA in radiotherapy:* All procedures that ensure consistency of the medical prescription and safe fulfilment of that prescription, as regards dose to the target volume together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment (WHO 1988). Again it must be stressed that QA in radiotherapy is concerned with **all** aspects of the radiotherapy process and should involve all groups of staff in a co-operative approach, since quality activities are interdependent.

*Quality Control (QC):* The regulatory process through which the actual quality performance is measured, compared with existing standards, and finally the actions necessary to keep or regain conformance with the standards (ISO 9000 (1994)). QC is one part of overall QA. It is concerned with operational techniques and activities used:

- (i) To check that quality requirements are met
- (ii) To adjust and correct performance, if the requirements are found not to have been met.

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*Quality Standards:* The set of accepted criteria against which the quality of the activity in question can be assessed. There are various agreed standards recommended for radiotherapy (*e.g.*, WHO (1988); AAPM (1994); ESTRO (1995); COIN (1999)) or for parts of the radiotherapy process (*e.g.*, Brahme *et al.* (1988); IEC (1989); AAPM (1994); IPEM (1999)). Where recommended standards are not available, then local standards need to be developed, based on a local assessment of requirements (ESTRO (1998)).

### **12.1.2. The need for QA in radiotherapy**

An assessment of clinical requirements in radiotherapy indicates that a high accuracy is necessary to produce the desired result of tumour control rates as high as possible, consistent with maintaining complication rates within acceptable levels. The QA procedures in radiotherapy can be characterized as follows:

- QA reduces uncertainties and errors in dosimetry, treatment planning, equipment performance, treatment delivery, etc., thereby improving dosimetric and geometric accuracy and precision of dose delivery. This improves radiotherapy results (treatment outcomes), raising tumour control rates as well as reducing complication and recurrence rates.
- QA not only reduces the likelihood of accidents and errors occurring, it also increases the probability that they will be recognised and rectified sooner, if they do occur, thereby reducing their consequences for patient treatment. This is the case not only for larger incidents but also for the higher probability minor incidents (ESTRO 1998).
- QA allows a reliable inter-comparison of results among different radiotherapy centres, ensuring a more uniform and accurate dosimetry and treatment delivery. This is necessary for clinical trials and also for sharing clinical radiotherapy experience and transferring it between centres.
- Improved technology and more complex treatments in modern radiotherapy can only be fully exploited provided a high level of accuracy and consistency is achieved.

The objective of patient safety is to ensure that exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume. This forms part of the objective of the treatment itself. The measures to ensure quality of a radiotherapy treatment inherently provide for patient safety and for the avoidance of accidental exposure. Therefore patient safety is automatically integrated with the quality assurance of the radiotherapy treatments.

### **12.1.3. Requirements on accuracy in radiotherapy**

- Definitions of accuracy and precision as applied in a radiotherapy context can be found in various publications, as well as discussions of dosimetric and geometric uncertainty requirements, *e.g.*, Dutreix (1984), Mijnheer *et al.* (1987), Dobbs and Thwaites (1999), Van Dyk (1999).

- In modern statistical analysis, uncertainties are classified as either *type A* meaning that they have been assessed by statistical means or *type B* meaning that they have been assessed by some other means. In earlier textbooks and still in common practice, uncertainties are frequently described as random (*a posteriori*) or systematic (*a priori*).
- Random uncertainties can be assessed by repeated observations or measurements and can be expressed as the standard deviation (sd) of their random distribution. The underlying distribution is frequently unknown but for the Gaussian distribution, 68% of occurrences are within 1 sd of the mean). The 95% confidence level (cl) or confidence interval is frequently taken to be approximately equivalent to 2 sd.
- Systematic uncertainties, on the other hand, can only be assessed by an analysis of the process. Possible distributions may well be very different. However, it may be possible to estimate the effective sd, within which the correct value is expected to lie in around 70% of cases.
- Irrespective of how uncertainties are assessed, the uncertainties at different steps are usually combined in quadrature to estimate overall values. For example, if two steps are involved and the uncertainty on each is estimated to be 5%, then the combined uncertainty is approximately 7%.

The clinical requirements for accuracy are based on evidence from dose-response (dose-effect) curves for tumour control probability (*TCP*) and normal tissue complication probability (*NTCP*). Both of these need careful consideration in designing radiotherapy treatments for good clinical outcome.

The steepness of a given *TCP* or *NTCP* curve against dose defines the change in response expected for a given change in delivered dose. Thus, uncertainties in delivered dose translate into either reductions in *TCP* or increases in *NTCP*, both of which worsen the clinical outcome. The accuracy requirements are defined by the most critical curves, *i.e.*, very steeply responding tumours and normal tissues.

From a consideration of the available evidence on clinical data, various recommendations have been made about required accuracy in radiotherapy:

- The ICRU (Report 24, 1976) reviewed *TCP* data and concluded that an uncertainty of 5% is required in the delivery of absorbed dose to the target volume. This has been widely quoted as a standard; however, it was not stated explicitly what confidence level this represented. It is generally interpreted as 1.5 sd or 2 sd and this assumption has been broadly supported by more recent assessments. For example, Mijnheer et al. (1987), considering *NTCP*, and Brahme et al. (1988), considering the effect of dose variations on *TCP*, recommend an uncertainty of 3 to 3.5% (1sd), *i.e.*, 6% or 7% at the 95% cl. In general, the smallest of these numbers (5% as the 95% cl) might be applicable to the simplest situations, with the minimum number of parameters involved, whilst the larger figure (7%) is more realistic for practical clinical radiotherapy when more complex treatment situations and patient factors are considered.

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- Geometric uncertainty, *e.g.*, systematic errors on field position, block position, etc., relative to target volumes or organs at risk also lead to dose problems, either underdosing of the required volume (decreasing the *TCP*) or overdosing of nearby structures (increasing the *NTCP*). Consideration of these effects has led to recommendations on geometric (or spatial) uncertainty of between 5 and 10 mm (at the 95% cl). The figure of 5 mm is generally applied to the overall equipment-related mechanical/geometric problems, whilst larger figures (typically 8 mm or 10 mm) are used to indicate overall spatial accuracy including representative contributions for problems related to the patient and to clinical set-up. The latter factors obviously depend on the site involved, the method of immobilisation and the treatment techniques employed.

Thus, the recommended accuracy on dose delivery is generally 5% to 7% (95% cl), depending on the factors intended to be included. On spatial accuracy, figures of 5 mm to 10 mm (95% cl) are usually given, depending on the factors intended to be included. These are general requirements for routine clinical practice.

In some specialist applications better accuracy might be demanded, requiring an increased QA effort, for example, if doses are escalated above normal values (*e.g.*, high dose conformal radiotherapy), or smaller geometric tolerances are required (*e.g.*, stereotactic radiotherapy).

These recommendations are for the end-point of the radiotherapy process, *i.e.*, for treatment as delivered to the patient. Therefore, on each of the steps that contribute to the final accuracy correspondingly smaller values are required, such that when all are combined the overall accuracy is met. Many analyses have shown that this is not easy to achieve. The aim of a QA programme is to maintain each individual step within an acceptable tolerance. Very careful attention is required at all levels and for each process and sub-stage within each process. The more complex the treatment technique, the more stages, sub-stages, parameters and factors are involved and correspondingly more complex QA is required.

### 12.1.4. Accidents in radiotherapy

Treatment of disease with radiation therapy represents a two-fold risk for the patient:

- Firstly and mainly, 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 (and in radiation protection legislation and protocols) only overdoses are generally of concern.

When is a difference between prescribed and delivered dose considered to be at the level of an accident or a misadministration in external beam radiotherapy?

- From the general aim for an accuracy approaching 5% (95% cl), about twice this seems to be an accepted limit for the definition of an accidental exposure, *i.e.*, a 10% difference.

- For example, in several jurisdictions, levels are set for reporting to regulatory authorities, if equipment malfunctions are discovered which would lead to a 10% difference in a whole treatment or 20% in a single fraction.
- 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. Additional dose applied incidentally outside the proposed target volume may lead to increased complications.

The *International Atomic Energy Agency* (IAEA-2000) has analysed a series of accidental exposures in radiotherapy to draw lessons in methods for prevention of such occurrences. Criteria for classifying radiological accidents include:

- Direct causes of mis-administrations.
- Contributing factors.
- Preventability of misadministration.
- Classification of potential hazard.

From the incidents catalogued and analysed in the IAEA report, some examples of the direct causes of misadministrations in external beam radiotherapy include:

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

These incidents are representative of typical causes. Recording, categorising and analysing differences in delivered and prescribed doses in radiotherapy can be carried out at many levels. The above list gives one example for the relatively small number of events reported, where large differences are involved, *i.e.*, misadministrations.

Other evaluations have been reported from the results of *in-vivo* dosimetry programmes or other audits of radiotherapy practice, where smaller deviations, or ‘near-misses’, have been analysed. Similar lists of causes with similar relative frequencies have been observed. In any wide-ranging analysis of such events, at whatever level, a number of general observations can be made:

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- Errors may occur at any stage of the process and by every staff group involved. Particularly critical areas are interfaces between staff groups, or between processes, where information is passed across the interface.
- Most of the immediate causes of accidental exposure are also related to the lack of an adequate QA programme or a failure in its application.
- General human causes of errors include complacency, inattention, lack of knowledge, overconfidence, pressures on time, lack of resources, failures in communication, etc.

Human error will always occur in any organisation and any activity. However, one aim of the existence of a comprehensive, systematic and consistently applied QA programme is to minimise the number of occurrences and to identify them at the earliest possible opportunity, thereby minimising their consequences.

### **12.2. MANAGING A QUALITY ASSURANCE (QA) PROGRAMME**

A number of organisations and other publications have given background discussion and recommendations on the structure and management of a QA programme, or Quality System Management, in radiotherapy or radiotherapy physics, *e.g.*, WHO (1988); AAPM (1994); ESTRO (1995, 1998); IPEM (1999); Van Dyk and Purdy (1999); McKenzie *et al.* (2000).

#### **12.2.1. Multidisciplinary radiotherapy team**

- Radiotherapy is a process of increasing complexity involving many groups of professionals.
- 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 QA roles, are inter-dependent, requiring close cooperation.
- Each staff member must have qualifications (education, training and experience) appropriate to their role and responsibility and have access to appropriate opportunities for continuing education and development.

The exact roles and responsibilities or their exact interfaces or overlaps (and possibly also the terminology for different staff groups) may depend on:

- National guidelines, legislation, etc.
- Systems of accreditation, certification, licensing or registration, although such schemes may not exist for all the different groups in all countries.
- Local departmental structures and practice.

The following list of radiotherapy team members is based on WHO (1988), AAPM (1994) and ESTRO (1995), with modifications to reflect national variations:

- ***Radiation oncologist*** (in some systems referred to as radiotherapist or clinical oncologist) is almost always specialty-certified (or accredited) by recognized national boards and is at least responsible for:
  - Consultation;
  - Dose prescription;
  - On-treatment supervision and evaluation;
  - Treatment summary report;
  - Follow-up monitoring and evaluation of treatment outcome and morbidity.
- ***Medical physicist*** (or radiation oncology physicist, radiotherapy physicist, clinical physicist) is in many countries certified by a recognized national board and is generally responsible for:
  - Specification, acceptance, commissioning, calibration and QA of all radiotherapy equipment.
  - Radiation measurement of beam data.
  - Calculation procedures for determination and verification of patient doses;
  - Physics content of treatment planning and patient treatment plans.
  - Supervision of therapy equipment maintenance, safety and performance;
  - Establishment and review of QA procedures.
  - Radiation safety and radiation protection in the radiotherapy department.
- ***Radiotherapy technologist*** (in some systems referred to as radiation therapist, therapy radiographer, radiation therapy technologist, radiotherapy nurse) is in many countries certified by recognized national boards and is responsible for:
  - Clinical operation of simulators, CT scanners, treatment units, etc.;
  - Accurate patient setup and delivery of a planned course of radiation therapy prescribed by a radiation oncologist;
  - Documenting treatment and observing the clinical progress of the patient and any signs of complication.

Radiotherapy technologists may also often be involved in:

- Undertaking daily QA of treatment equipment in accordance with physics QA procedures and protocols;
- Treatment planning;
- Construction of immobilisation devices, etc.

In many countries, but by no means all, radiotherapy technologists constitute an independent professional group, distinct from general nursing staff.

- ***Dosimetrist*** (in many systems there is no separate group of dosimetrists and these functions are carried out variously by physicists, medical physics technicians or technologists, radiation dosimetry technicians or technologists, radiotherapy technologists, or therapy radiographers).

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The specific responsibilities of staff operating in this role include:

- Accurate patient data acquisition;
- Radiotherapy treatment planning;
- Dose calculation;
- Patient measurements.

Dosimetrists may be involved in machine calibrations and regular equipment QA under the supervision of a medical physicist; and may construct immobilisation and other treatment devices. In jurisdictions where the distinct profession of dosimetrist exists, dosimetrists may be certified by recognized national boards.

- *Engineering technologists* (in some systems medical physics technicians or technologists, clinical technologists, service technicians, electronic engineers or electronic technicians) have specialised expertise in electrical and mechanical maintenance of radiotherapy equipment. Their services may be “in-house” or via a service contract for equipment maintenance. They will also provide a design and build capability for specialised patient-related devices and are usually supervised by medical physicists.

### 12.2.2. Quality system/comprehensive QA programme

*Quality system* (QS): the organisational structure, responsibilities, procedures, processes and resources for implementing quality management. A quality system in radiotherapy is a management system that:

- Should be supported by department management to work effectively.
- May be formally accredited, *e.g.*, to ISO 9000.
- Should be as comprehensive as is required to meet the overall quality objectives.
- Must have a clear definition of its scope and all the quality standards to be met.
- Must be consistent in standards for different areas of the programme.
- Requires collaboration between all members of the radiotherapy team.
- Must incorporate compliance with all requirements of national legislation, accreditation, etc.
- Requires the development of a formal written QA programme which details QA policies and procedures, QC tests, frequencies, tolerances, action criteria, required records and personnel.
- Must be regularly reviewed as to operation and improvement. To this end, it requires a QA committee (QAC), which should represent all the different disciplines within radiation oncology.
- Requires control of the system itself, including:
  - Responsibility for QA and the QS: Quality Management Representatives.
  - Document control.
  - Procedures to ensure the QS is followed.
  - Ensuring 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 QS (QS audit) and its effectiveness (quality audit).



The QA committee must be appointed by department management/Head of Department with authority to manage QA and should:

- Involve the heads of all the relevant groups in the department (*e.g.*, radiation oncology, medical physics, radiation therapists, maintenance, nurses, etc.) or their nominees.
- Establish and support the QA team.
- Assist the entire radiation oncology staff to apply QA recommendations and standards to the local situation.
- Approve QA policies and procedures and the assignment of QA responsibilities in the department.
- Establish its own remit, meeting frequency, reporting routes and accountability
- Monitor and audit the QA programme to assure that each component is being performed appropriately and is documented and that feedback from this process is used to improve the QS and to improve quality generally.
- Regularly review the operation and progress of the QA system, and maintain records of this process and of all its own meetings, decisions and recommendations.
- Investigate and review all non-conformances, with feedback into the system.
- Review and recommend improvements in QA procedures, documentation, etc.

The comprehensive QA team:

- Is responsible for performing QA related tasks.
- Is an integrated team from all groups, including radiation oncologists, medical physicists, radiotherapy technologists, dosimetrists, health physicists, nurses, service engineers, data entry managers, administration staff, etc., as all areas of the process should be covered.

Each member should be clear on his/her responsibilities and be adequately trained to perform them, and should also know which actions are to be taken, if any result is observed outside the limits of established acceptable criteria. A sub-group of the team can be trained to act as internal auditors of the QS.

Increasingly, international bodies, such as the IAEA (1997), recommend the establishment of QS in radiotherapy to ensure patient radiation safety. Also many national nuclear and/or health regulatory commissions are demanding the implementation of such QS as a requirement for hospital licensing and accreditation.

### **12.3. QUALITY ASSURANCE PROGRAM FOR EQUIPMENT**

Within the context of radiotherapy, equipment covers all devices from megavoltage treatment machines to the electrical test equipment used to monitor signals within the machine. This section, however, concentrates on the major items and systems and should be read in conjunction with the appropriate chapters concerned with each of these categories of equipment.

There are many sets of national and international recommendations and protocols covering QA and QC requirements for various radiotherapy equipment items (*e.g.*, IEC (1989), AAPM (1994), IPEM (1996, 1999)) that should be referred to where available. These give recommended tests, test frequencies and tolerances. Some give test methods (IEC (1989), IPEM (1999)); other sources give practical advice on QA and QC tests for many items of equipment (*e.g.*, Van Dyk (1999), Williams and Thwaites (2000)).

### 12.3.1. The structure of an equipment QA programme

A general QA programme for equipment includes:

- *Initial specification, acceptance testing, and commissioning* for clinical use, including calibration where applicable (see Chapter 10 on acceptance testing and commissioning of treatment machines).
- *QC tests.* At the conclusion of the commissioning measurements, before the equipment is put into clinical use, quality control tests should be established and a formal QC programme initiated which will continue for the entire clinical lifetime of the equipment.
- *Additional QC tests* after any significant repair, intervention or adjustment or when there is any indication of changes in performance as observed during use or during the planned preventive maintenance or the routine QC programmes.
- A planned *preventive maintenance* programme, in accordance with manufacturer's recommendations

### *Equipment specification*

In preparation for procurement of equipment, a detailed specification document must be prepared.

- This should set out the essential aspects of the equipment operation, facilities, performance, service, etc., as required by the customer.
- A multi-disciplinary team from the department should be involved in contributing to the specification, including input from radiotherapy physicists, radiation oncologists, radiotherapy technologists, engineering technicians, etc.. It would generally be expected that liaison between the department and the suppliers would be by a radiotherapy physicist.
- In response to the specifications, the various interested suppliers should indicate how the equipment they offer will meet the specifications; if there are any areas that cannot be met or if there are any limiting conditions under which specified requirements can or cannot be met, etc.
- Decisions on procurement should be made by a multi-disciplinary team, comparing specifications as well as considering costs and other factors.

## **Acceptance**

Acceptance of equipment is the process in which the supplier demonstrates the baseline performance of the equipment to the satisfaction of the customer.

- Acceptance is against the specification, which should be part of the agreed contract of what the supplier will provide to the customer.
- All the essential performance, required and expected from the machine, should be agreed upon before acceptance of the equipment begins.
- As an example, methods of declaring the functional performance of megavoltage treatment machines are given in the IEC 976 and 977 (1989) documents.
- It is the professional judgment of the medical physicist responsible for accepting the equipment, if for any reason any aspect of the agreed acceptance criteria is to be waived. This waiver should be recorded along with an agreement from the supplier, for example, to correct the equipment should the performance deteriorate further.
- Acceptance provides a baseline set of equipment performance measurements which should encompass the essential aspects of the equipment's operation.
- During the acceptance of a treatment machine the supplier should demonstrate that the control parameters of the machine are operating well within their range and that none are at an extreme value.
- The aspects covered in acceptance will depend on the equipment involved. However, these would generally include at least any settings, baseline machine running parameters, operations and devices which are critical to safety or clinical accuracy.
- The equipment can only be formally accepted to be transferred from the supplier to the customer when the physicist responsible for the customer side of acceptance is satisfied that the performance of the machine fulfils the specification and formally accepts any waivers, as stated above.

## **Commissioning**

Following acceptance of equipment, a full characterisation of its performance for clinical use over the whole range of possible operation should be undertaken. This is referred to as commissioning.

- Depending on the type of equipment, acceptance and commissioning may partially overlap.
- Together they will establish the baseline-recorded standards of performance to which all future performance and QC tests will be referred.

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- Where appropriate, commissioning will incorporate calibration to agreed protocols and standards.
- For critical parts of commissioning, such as calibration, an independent second checking is recommended.
- Commissioning includes the preparation of procedures, protocols, instructions, data, etc., on the clinical use of the equipment.
- Clinical use can only begin when the physicist responsible for commissioning is satisfied that all the above aspects have been completed and that the equipment and any necessary data, etc., are safe to use on patients.

### ***Quality Control (QC)***

It is essential that the performance of treatment equipment remains consistent within accepted tolerances throughout its clinical life, as patient treatments will be planned and delivered on the basis of performance measurements at acceptance and commissioning. Therefore, an on-going QC programme of regular performance checks is begun immediately after commissioning to test this.

If these QC measurements identify departures from expected performance, corrective actions are required. An equipment quality control programme should specify the following:

- Parameters to be tested and tests to be performed,
- Specific equipment used to perform the tests,
- Geometry of the tests,
- Frequency of the tests,
- Staff group or individual performing the tests; as well as the individual supervising and responsible for the standards of the tests and for actions which may be necessary if problems are identified
- Expected results,
- Tolerance and action levels,
- Actions required when the tolerance levels are exceeded.

No one programme is necessarily suitable in all circumstances and may need tailoring to the specific equipment and the departmental situation. For example, frequencies may need to be adjusted in the light of experience with a given machine.

- Test content should be kept as simple as possible, consistent with the defined aims, in order to optimise time and effort involved to the return required.
- Frequencies normally follow a hierarchy ranging from frequent simple tests of critical parameters, up to complex extended annual tests, where the latter are subsets of the original acceptance and commissioning tests. Various levels lie between these two extremes.
- QC programmes must be flexible for additional testing whenever it seems necessary, following repair, observed equipment behaviour or indications of problems from the regular QC tests.

- To minimize treatment interruption due to non-regular interventions or additional QC measurements, it is essential to maintain the test and measurement equipment in good order and subject to its own QC programme, and also to have adequate equipment readily available.

### **12.3.2. Uncertainties, tolerances and action levels**

**Tolerance level:** performance to within the tolerance level gives acceptable accuracy in any situation.

**Action level:** performance outside the action level is unacceptable and demands action to remedy the situation.

- Any QC test should use measuring equipment appropriate to the task. All such equipment should itself be subject to an appropriate maintenance and QC programme. Irradiation conditions and measuring procedures should be designed appropriate to the task.
- In these circumstances, the QC measurement is expected to give the best estimate of the particular measured parameter. However, this will have an associated uncertainty, dependent upon the measurement technique. The tolerance set for the parameter must take into account the uncertainty of the measurement technique employed.
- If the measurement uncertainty is greater than the tolerance level set, then random variations in the measurement will lead to unnecessary intervention, increased downtime of equipment and inefficient use of staff time.
- Tolerances should be set with the aim of achieving the overall uncertainties desired, as summarized in Section 12.1.3.
- Variances can be combined in quadrature for combined factors and this can be used to determine specific tolerance limits for individual parameters.
- Action levels are related to tolerances, but provide flexibility in monitoring and adjustment. For example, if a measurement on the constancy of dose/MU indicates a result between the tolerance and action levels, then it may be permissible to allow clinical use to continue until this is confirmed by measurements the next day before taking any further action. Thus:
  - If a daily measurement is within tolerance, then no action is required.
  - If the measurement exceeds the action level, then immediate action is necessary and the machine would not be clinically usable until it had been changed.
  - However, if the measurement falls between tolerance and action levels, then this may be considered acceptable until the next daily measurement.

- If repeated measurements remain consistently between tolerance and action levels, adjustment is required.
- Any measurement at any time outside the action level requires immediate investigation and, if confirmed, rectification.
- Action levels are often set at approximately twice the tolerance level, although some critical parameters may require tolerance and action levels to be set much closer to each other or even at the same value.
- Different sets of recommendations may use rather different approaches to set tolerance levels and/or action levels and this should be borne in mind in comparing values from different sources. In some, the term tolerance level is used to indicate values that in others may be closer to action levels, *i.e.*, some workers use the term *tolerance* to indicate levels at which adjustment or correction is necessary. Some recommendations explicitly list performance standards under the two headings.
- Test frequencies need to be considered in the context of the acceptable variation throughout a treatment course and also considering the period of time over which a parameter varies or deteriorates.
- Frequencies may be modified in the light of experience of the performance and stability on a given piece of equipment, initially setting a nominal frequency that may be subsequently reviewed in the light of observation. As machines get older this may need further review.
- Staff resources available to undertake the tests may limit what can be checked, which may have an effect on the structure of the QC programme. Tests should be designed to provide the required information as rapidly as possible with minimal time and equipment. Often customized devices are very useful to make tests easier.

Where available, national organizations' own QC protocols should be applied. The following sections give some examples of *parameters*, *test frequencies* and *tolerances*, for different items of radiotherapy equipment.

For consistency the values are almost all taken from one protocol, AAPM (1994), with some additional comments given considering IPEM (1999). Whilst broadly similar, there are some differences in tolerances and frequencies. For more details the protocols should be referred to. Where local protocols are not available, existing recommendations such as these should be consulted and adapted for local circumstances.

### **12.3.3. QA programme for cobalt-60 teletherapy machines**

A sample QA programme for a cobalt-60 teletherapy machine with recommended test procedures, test frequencies and action levels is given in Table 12.I.

TABLE 12.I. SAMPLE QA PROGRAMME FOR A COBALT-60 UNIT (AAPM 1994).

| Frequency       | Procedure  | Action level <sup>(a)</sup> |
|-----------------|--|-----------------------------|
| <b>Daily</b>    | Door interlock   | <i>functional</i>           |
|                 | Radiation room monitor                                       | <i>functional</i>           |
|                 | Audiovisual monitor  | <i>functional</i>           |
|                 | Lasers   | 2 mm                        |
|                 | Distance indicator   | 2 mm                        |
| <b>Weekly</b>   | Check of source position                                     | 3 mm                        |
| <b>Monthly</b>  | Output constancy   | 2%                          |
|                 | Light/radiation field coincidence                            | 3 mm                        |
|                 | Field size indicator   | 2 mm                        |
|                 | Gantry and collimator angle indicator                        | 1 degree                    |
|                 | Cross-hair centring  | 1 mm                        |
|                 | Latching of wedges, trays                                    | <i>functional</i>           |
|                 | Emergency off  | <i>functional</i>           |
|                 | Wedge interlocks   | <i>functional</i>           |
| <b>Annually</b> | Output constancy   | 2%                          |
|                 | Field size dependence of output constancy                    | 2%                          |
|                 | Central axis dosimetry parameter ( <i>PDD/ TAR/TPR</i> )     | 2%                          |
|                 | Transmission factor constancy for all standard accessories   | 2%                          |
|                 | Wedge transmission factor constancy                          | 2%                          |
|                 | Timer linearity and error                                    | 1%                          |
|                 | Output constancy vs gantry angle                             | 2%                          |
|                 | Beam uniformity with gantry angle                            | 3%                          |
|                 | Safety interlocks: follow test procedures of manufacturers   | <i>functional</i>           |
|                 | Collimator rotation isocentre                                | 2 mm diameter               |
|                 | Gantry rotation isocentre                                    | 2 mm diameter               |
|                 | Couch rotation isocentre                                     | 2 mm diameter               |
|                 | Coincidence of collimator, gantry, couch axis with isocentre | 2 mm diameter               |
|                 | Coincidence of radiation and mechanical isocentre            | 2 mm diameter               |
|                 | Table top sag  | 2 mm                        |
|                 | Vertical travel of table                                     | 2 mm                        |
|                 | Field light intensity  | <i>functional</i>           |

- (a) AAPM (1994) lists these values as tolerances. However, the protocol makes it plain that they are action levels, *i.e.*, they should be interpreted to mean that for any parameter, if the difference between the measured value and the expected value is greater than the figure above (*e.g.*, measured isocentre under gantry rotation exceeds 2 mm diameter), or the change is greater than the figure above (*e.g.*, the output changes by more than 2%), then an action is required. The distinction between absolute differences and changes is emphasized by the use of the term constancy for the latter case. For constancy, the % values are the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal *SSD*.

The IPEM (1999) report recommends that an output check be undertaken weekly and that the source position be monitored monthly. The source positioning may be monitored by measuring the uniformity of the field in the appropriate direction or by inspection of an external mark on the source carrying mechanism. In addition the IPEM requires more dosimetric and geometric checks at monthly intervals and, in its annual recommendations, it emphasizes more safety tests, *e.g.*, radiation wipe-tests, head leakage, electrical safety, etc.

#### 12.3.4. QA programme for linear accelerators

Although there is considerable variation in the practice of quality control on linear accelerators, the three major publications (IEC 977 (1989); IPEM 81 (1999) and AAPM TG-40) are broadly consistent. However, in particular the IEC 977 document does not specify daily checks. Typical QA procedures with frequencies and action levels are given in Table 12.II.

TABLE 12.II. SAMPLE QC PROGRAMME FOR A DUAL MODE LINEAR ACCELERATOR (AAPM 1994).

| Frequency              | Procedure  | Action level <sup>(a)</sup>  |
|------------------------|--|------------------------------|
| <b>Daily</b>           | X-ray output constancy   | 3%                           |
|                        | Electron output constancy <sup>(b)</sup>   | 3%                           |
|                        | Lasers   | 2 mm                         |
|                        | Distance indicator   | 2 mm                         |
|                        | Door interlock   | <i>functional</i>            |
|                        | Audiovisual monitor  | <i>functional</i>            |
| <b>Monthly</b>         | X-ray output constancy <sup>(c)</sup>  | 2%                           |
|                        | Electron output constancy <sup>(c)</sup>   | 2%                           |
|                        | Backup monitor constancy   | 2%                           |
|                        | X-ray central axis dosimetry parameter<br>( <i>PDD</i> , <i>TAR</i> , <i>TPR</i> ) constancy | 2%                           |
|                        | Electron central axis dosimetry parameter<br>constancy ( <i>PDD</i> )                        | 2 mm at therapeutic<br>depth |
| <b>Monthly (cont.)</b> | X-ray beam flatness constancy  | 2%                           |



|                        |   |  |
|------------------------|---|--|
|                        | Electron beam flatness constancy                                | 3%   |
|                        | X-ray and electron symmetry                                     | 3%   |
|                        | Emergency-off switches  | <i>functional</i>                          |
|                        | Wedge, electron cone interlocks                                 | <i>functional</i>                          |
|                        | Light/radiation field coincidence                               | 2 mm or 1% on a side <sup>(d)</sup>        |
|                        | Gantry/collimator angle indicators                              | 1 deg                                      |
|                        | Wedge position  | 2 mm (or 2% change in transmission factor) |
|                        | Tray position, applicator position                              | 2 mm                                       |
|                        | Field size indicators   | 2 mm                                       |
|                        | Cross-hair centering  | 2 mm <i>diameter</i>                       |
|                        | Treatment couch position indicators                             | 2 mm/1 deg                                 |
|                        | Latching of wedges, blocking tray                               | <i>functional</i>                          |
|                        | Jaw symmetry <sup>(e)</sup>                                     | 2 mm                                       |
|                        | Field light intensity   | <i>functional</i>                          |
| <b><i>Annually</i></b> | X-ray/electron output calibration constancy                     | 2%   |
|                        | Field size dependence of x-ray output constancy                 | 2%   |
|                        | Output factor constancy for electron applicators                | 2%   |
|                        | Central axis parameter constancy ( <i>PDD, TAR, TPR</i> )       | 2%   |
|                        | Off-axis factor constancy                                       | 2%   |
|                        | Transmission factor constancy for all treatment accessories     | 2%   |
|                        | Wedge transmission factor constancy <sup>(f)</sup>              | 2%   |
|                        | Monitor chamber linearity                                       | 1%   |
|                        | X-ray output constancy with gantry angle                        | 2%   |
|                        | Electron output constancy with gantry angle                     | 2%   |
|                        | Off-axis factor constancy with gantry angle                     | 2%   |
|                        | Arc mode  | <i>Manufacturer's specifications</i>       |
|                        | Safety interlocks: follow manufacturer's test procedures        | <i>Functional</i>                          |
|                        | Collimator rotation isocentre                                   | 2 mm <i>diameter</i>                       |
|                        | Gantry rotation isocentre                                       | 2 mm <i>diameter</i>                       |
|                        | Couch rotation isocentre  | 2 mm <i>diameter</i>                       |
|                        | Coincidence of collimator, gantry and couch axes with isocentre | 2 mm <i>diameter</i>                       |
|                        | Coincidence of radiation and mechanical isocentre               | 2 mm <i>diameter</i>                       |
|                        | Table top sag   | 2 mm                                       |
|                        | Vertical travel of table  | 2 mm                                       |

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- (a) AAPM (1994) lists these values as tolerances. However, the protocol makes it plain that they are action levels, *i.e.*, they should be interpreted to mean that for any parameter, if the difference between the measured value and the expected value is greater than the figure above (*e.g.*, measured isocentre under gantry rotation exceeds 2 mm diameter), or the change is greater than the figure above (*e.g.*, the output changes by more than 2%), then an action is required. The distinction between absolute differences and changes is emphasized by the use of the term constancy for the latter case. For constancy the % values are  $\pm$  the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.
- (b) All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.
- (c) A constancy check with a field instrument using temperature and pressure corrections.
- (d) Whichever is greater. Should also be checked after a change in light field source.
- (e) Jaw symmetry is defined as difference in distance of each jaw from the isocentre.
- (f) Most wedge transmission factors are field size and depth dependent and this should be checked. In particular, the field size variations for dynamic wedges can be very large.

The IPEM (1999) report recommends a simple field size check daily and has a wider tolerance on daily output constancy, but a weekly check with a tighter tolerance than the AAPM 1994. It has a frequency structure of daily, weekly, two-weekly, monthly, six-monthly and annually and includes tests on some parameters not listed in the AAPM protocols. It also provides a specific QC protocol for electron beams. As a more recent publication than the AAPM 1994, it gives recommendations for QC of dynamic wedges and multileaf collimators.

### **12.3.5. QA programme for treatment simulators**

Treatment simulators replicate the movements of the isocentric cobalt-60 and linear accelerator treatment machines and are also fitted with identical beam and distance indicators. Hence, all measurements that concern these aspects of cobalt-60 and linear accelerator machines also apply to the simulator and should be quality-controlled in a similar manner.

It should be noted that, if mechanical/geometric parameters are out of tolerance on the simulator, this will affect treatments of all patients, whichever treatment machine they are subsequently treated on.

In addition, the performance of the imaging components on the simulator is of equal importance to its satisfactory operation. For this reason, the quality control on simulators requires critical measurements of the imaging system. The imaging system consists of a diagnostic x-ray tube, an image intensifier with manual and automatic kV-mA facilities and an imaging chain that may include digital image capture. Typical QA procedures for a conventional simulator with test frequencies and action levels are given in Table 12.III.

TABLE 12.III. SAMPLE QC PROGRAMME FOR A SIMULATOR (AAPM 1994).

| Frequency       | Procedure   | Action level <sup>(a)</sup> |
|-----------------|---|-----------------------------|
| <b>Daily</b>    | Safety switches   | <i>functional</i>           |
|                 | Door interlock  | <i>functional</i>           |
|                 | Lasers  | 2 mm                        |
|                 | Distance indicator  | 2 mm                        |
| <b>Monthly</b>  | Field size indicator  | 2 mm                        |
|                 | Gantry/collimator angle indicators                            | 1 deg                       |
|                 | Cross-hair centring   | 2 mm <i>diameter</i>        |
|                 | Focal spot-axis indicator                                     | 2 mm                        |
|                 | Fluoroscopic image quality                                    | <i>baseline</i>             |
|                 | Emergency/collision avoidance                                 | <i>functional</i>           |
|                 | Light/radiation field coincidence                             | 2 mm or 1%                  |
|                 | Film processor sensitometry                                   | <i>baseline</i>             |
| <b>Annually</b> | Collimator rotation isocentre                                 | 2 mm <i>diameter</i>        |
|                 | Gantry rotation isocentre                                     | 2 mm <i>diameter</i>        |
|                 | Couch rotation isocentre                                      | 2 mm <i>diameter</i>        |
|                 | Coincidence of collimator, gantry, couch axes with isocentre. | 2 mm <i>diameter</i>        |
|                 | Table top sag   | 2 mm                        |
|                 | Vertical travel of couch                                      | 2 mm                        |
|                 | Exposure rate   | <i>baseline</i>             |
|                 | Table top exposure with fluoroscopy                           | <i>baseline</i>             |
|                 | kVp and mAs calibration                                       | <i>baseline</i>             |
|                 | High and low contrast resolution                              | <i>baseline</i>             |

- (a) AAPM (1994) lists these values as tolerances. However, they are action levels, *i.e.*, they should be interpreted to mean that for any parameter, if the difference between the measured value and the expected value is greater than the figure above (*e.g.*, measured isocentre under gantry rotation exceeds 2 mm diameter) then an action is required.

The IPEM (1999) report includes cross-wire checks and simpler field size and field alignment checks in the daily test schedule, with fuller checks at monthly intervals.

### 12.3.6. QA programme for CT scanners and CT-simulation

For dose prediction as part of the treatment planning process there is an increasing reliance upon CT image data with the patient in a treatment position. Since CT data is used for a more comprehensive indication of the patient's anatomy and to provide tissue density information which is essential for accurate dose prediction, it is essential that the geometry and the CT densities are accurate.

Typical QA procedures with frequencies and action levels are listed in Table 12.IV.

TABLE 12.IV. A SAMPLE QC PROGRAMME FOR A CT SCANNER OR CT-SIMULATOR (IPEM 1999)

| Frequency       | Procedure                              | Action level <sup>(a)</sup> |
|-----------------|--|-----------------------------|
| <i>Daily</i>    | Safety switches                        | <i>functional</i>           |
| <i>Monthly</i>  | Scan plane to alignment laser          | 2 mm                        |
|                 | Indication of x-axis                   | 1°                          |
|                 | Couch position registration            | 1 mm                        |
|                 | Distance between known points in image | 2 mm                        |
|                 | Left and Right registration            | <i>Correct operation</i>    |
|                 | CT Number for water                    | 1%                          |
|                 | CT Number for lung and bone            | 2%                          |
|                 | Reconstructed slice location           | 1 mm                        |
| <i>Annually</i> | Couch deflection under load            | 2 mm                        |

- (a) The IPEM (1999) report lists these values as tolerances, but implies that at least some of them would require action if exceeded.

The protocol also lists tests to be carried out after new software is installed (scanner or TPS).

### 12.3.7. QA programme for treatment planning systems

As an integral part of the radiotherapy process the Treatment Planning System (TPS) provides computer predictions of the dose distributions that can be achieved both in the target volume and also in normal tissue. As this information is used to provide guidance to the clinician on the best treatment for an individual patient, these systems are critical to the treatment process and hence their performance must be assured to work accurately and effectively.

The major aspect of the acceptance and commissioning of the system is to test its fundamental performance and gain an understanding of the algorithms used for the dose prediction. This provides the knowledge of the limitations of the system and a considerable part of this understanding should be gained by comparison with experimental measurement in phantoms for test cases of varying complexity. Some information on this should also be obtainable from the manufacturer, from the literature and from users groups.

Following software upgrades a more limited acceptance and commissioning programme should be undertaken. The extent of this will depend upon the extent of change made to the system. However, it is prudent to take a cautious approach in order to try to ensure that the performance of the system remains satisfactory. Testing should not be deferred simply to reduce the time to making the new software clinical.

Generic tolerances have often been quoted of 2% for isodose distributions where dose gradients are not steep and 2 mm where dose gradients are steep. These may typically be applied to single field or single source isodose distributions. However, these will not necessarily be applicable in less simple situations. A similar generic tolerance of 2% is often quoted on MU calculations, which again may need careful consideration in complex situations. Discussion of the acceptable tolerances for different situations is given, for example, in Van Dyk et al (1993) and Venselaar (2002) (see also Chapter 11).

Acceptance, commissioning and QC recommendations are given, for example, in AAPM Reports (TG-40 and TG-43), IPEM Reports 68 (1996) and 81 (1999), and in Van Dyk et al. (1993) and these protocols should be referred to for more detail. The exact requirements will depend on the level of complexity of the system and of the treatment planning techniques used clinically. Any uncertainty concerning the operation or output of a treatment planning system should be tested by comparing the performance of the treatment planning system to measurements in suitable phantoms.

TABLE 12.V. A SAMPLE OF A ROUTINE REGULAR QC PROGRAMME FOR A TREATMENT PLANNING SYSTEM, FROM IPEM (1996,1999) AND AAPM (1994).

| Frequency       | Procedure                               | Tolerance <sup>(a)</sup>                 |
|-----------------|---|--|
| <b>Daily</b>    | Input and Output devices                | 1 mm                                     |
| <b>Monthly</b>  | Checksum                                | <i>No change</i>                         |
|                 | Reference subset of data <sup>(b)</sup> | 2% <sup>(c)</sup> or 2 mm <sup>(d)</sup> |
|                 | Reference prediction subset             | 2% or 2 mm                               |
|                 | Processor tests                         | <i>pass</i>                              |
|                 | CT transfer                             | 1 mm                                     |
| <b>Annually</b> | Monitor Unit calculations               | 2%                                       |
|                 | Reference QA test set <sup>(e)</sup>    | 2% or 2 mm                               |

- (a) These may be action levels in simple situations, but tolerances in more complex situations (see discussion above).
- (b) These refer to the comparison of dose calculations at commissioning to the same calculations subsequently.
- (c) % difference between calculation by the TPS and measurement (or independent calculation).
- (d) In regions of high dose gradient the distance between isodose lines is more appropriate than % differences. In addition less accuracy may be obtained near the end of single sources for brachytherapy calculations.
- (e) These tests refer to comparison of calculations with measurement in a water tank.

### 12.3.8. QA programme for test equipment

- Test equipment in radiotherapy concerns all the additional equipment required to measure radiation doses, electrical measurements of machine signals and mechanical measurements of machine devices.
- The details of the QC programme will depend on the equipment and its use. Some guidelines are given in, for example, AAPM (1994), IPEM (1999), Van Dyk (1999), Williams and Thwaites (2000).
- Some examples of considerations for a quality control programme for test and measuring equipment (tolerances given in brackets where applicable) include:
  - *Local standard ionisation chamber and electrometer:* must be calibrated according to national protocols at an accredited dosimetry standards laboratory, at between 1 and 3 years frequency, depending on national guidelines and procedures. This must include checks on linearity, scale corrections, etc. Venting should be checked before re-calibration and corrected if faulty.
  - Recombination and stem effects may be checked at this time. If not, they should be checked independently by the user at least when new and after any malfunction or repair. Applied voltage and leakage should be checked at each use. Before and after any use to calibrate field instruments, a Sr-90 or similar check of constancy (to 1%) should be carried out.
  - *Field instrument ionisation and electrometers:* calibration against the local standard, typically yearly depending on national guidelines and procedures (to 1%). Linearity, venting and stem effects should be checked at the same time. Recombination corrections should be determined when the chamber is new and after any malfunction or repair. Applied voltage and leakage should be checked at each use. It is recommended to carry out constancy checks monthly, e.g., comparing response against another chamber or using a strontium-90 or similar check source (agreement is expected within 1%).
  - *Thermometer:* when new, calibration should be checked (to 0.5°C). Regular comparison of thermometers against each other helps to identify damage. Electronic thermometers may require more frequent checks.
  - *Barometer:* when new, pressure calibration should be checked (to 1 mm Hg, or 1 mbar). This should be regularly checked by comparison against an independent system. If comparison is against a local airport system, beware that the airport pressures quoted are normally corrected to sea level and will therefore need a height correction to the hospital height.
  - *Linear rulers:* check the scale when new (to 0.3%).
  - *Phantoms:* check dimensions, densities, etc., when new. Regularly check for damage with time.

- *Automated beam scanning systems:* when new, test the software and hardware functions, *e.g.*, accuracy of data analysis (to 1%), accuracy of printouts (to 1 mm), etc. When new and regularly before use, check electrical and mechanical safety; geometric accuracy of drives and detector positioning (to 1 mm); reproducibility (to 1 mm); backlash/hysteresis (to 1 mm); orthogonality of drives (to 0.5 deg.); check the dosimetry systems in a similar way to the guidance given for checking ionisation chambers and electrometers, or other dosimetry systems, or other dosimetry systems, depending on the specific measuring devices being used with the plotting tank.
- *Other dosimetry systems:* *e.g.*, systems for relative dosimetry (*e.g.*, TLD, diodes, diamonds, film, etc.), *in-vivo* dosimetry (*e.g.*, TLD, diodes, etc.) and for radiation protection measurements should be tested to tolerances and at frequencies consistent with their particular uses in the department. All such systems will require careful assessment when new to determine their range of applicability and any corrections, calibrations required. Usually this will involve comparison and calibration against ionization chamber systems. After that, QC tests and checks will be required to ensure that they perform acceptably and that any changes in behaviour with time or with radiation damage is measured and corrected for. In particular, performance checks (including recalibration where appropriate) will be required after any observed malfunction or after any repair.
- *Electrical test equipment:* any equipment used for testing the running parameters of treatment equipment should be suitably calibrated and quality controlled.

## **12.4. TREATMENT DELIVERY**

### **12.4.1. Patient charts**

- Besides describing disease-related items, a patient chart should also contain all information related to the prescribed and actual treatment.
- Basic components of a patient treatment chart are:
  - *patient name and ID,*
  - *photograph,*
  - *initial physical evaluation of the patient,*
  - *treatment planning data,*
  - *treatment execution data,*
  - *clinical assessment during treatment,*
  - *treatment summary and follow up,*
  - *QA checklist.*
- Any mistakes made at the data entry of the patient chart are likely to be carried through the whole treatment. QA of the patient chart is therefore essential.

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- All planning data should be independently checked ('redundant checking'), including plan integrity, monitor unit calculations, irradiation parameters, etc. (see chapters on treatment planning, treatment planning systems and time and monitor unit calculations). All data entered as the interface between the planning process and the treatment delivery process should be independently checked.
- Regular chart checks should be carried out through the treatment course. The frequency of chart checking should be at least weekly, starting before the third fraction after a new treatment or after modification of the treatment.
- Chart-checking should be performed by a team consisting of a radiation oncologist, a physicist and radiographers. The review should be signed and dated by the checker(s).
- Particular care must be taken to ensure that items such as wedge orientation and block positioning are correct as they may not be correctly set on the simulator.
- Data transferred automatically, *e.g.*, from the treatment planning system, should also be verified to check that no data corruption occurred.
- All errors that are traced during chart checking should be thoroughly investigated and evaluated by the QA team that should include a QA system manager (Quality Management Representative), if available. The causes should be eradicated and may result in (written) changes in the various procedures of the treatment process.
- Electronic treatment charts are applied in some institutions to replace at least parts of the patient chart and these allow direct input of treatment data from the simulator or from a treatment planning system.

### 12.4.2. Portal imaging

Besides dosimetric errors, geometric errors are also of extreme importance in determining the outcome of a radiotherapy treatment. The geometric accuracy is limited by:

- Uncertainties in a particular patient set-up.
- Uncertainties in the beam set-up.
- Movement of the patient or the target volume during treatment.
- In order to verify the patient set-up with respect to the position of the radiation beam, portal imaging is applied at one of the first treatment fractions, repeated if the radiation fields are modified and repeated sometimes during the course of the treatment.
- The purpose of portal imaging is:
  - To verify the *field placement*, characterized by the isocentre or another reference point, relative to anatomical structures of the patient, during the actual treatment.



- To verify that the *beam aperture* (blocks or MLC) has been properly produced and registered.
- Sometimes it is useful to have more than one check during one treatment fraction, for instance to observe the influence of swallowing and breathing or organ motion on patient set-up.
- Portal images are compared with reference images, which can either be (orthogonal) simulator images, digitally reconstructed radiographs or the first portal image made during a treatment series. A double exposure technique can be useful if only limited anatomical information is present in the treatment field.
- If unusual oblique or non-coplanar fields are used, making it difficult to interpret the images, it may be necessary to set up additional orthogonal portal images for comparison to reference images.
- Sequences of portal image series for the same patient throughout treatment can provide verification of day-to-day variations in patient set-up and can give information on changes throughout treatment. Frequency depends on the site, the type of immobilization, the patient conditions, the intended degree of reproducibility, other QA systems in use and the resources and portal imaging systems available.
- Local protocols must be established to specify who has the responsibility for verification of portal images (generally a clinician) and what criteria are used as the basis to judge the acceptability of the information conveyed by portal images.

### ***Portal imaging techniques***

- At present photographic film is still a commonly used modality for portal imaging. The quality of film images produced by high-energy photons is, however, rather poor compared with conventional x-ray images. Portal film enhancement can be performed after digitizing the image, *e.g.*, by means of a video camera or a laser scanner, thus yielding a better visibility of relevant anatomical landmarks.
- Special therapy verification films are commercially available, while cassettes with lead or copper screens are used to reduce the dose needed to form an image.
- A technique that gives portal images of improved quality compared with normal photographic film, is the use of photo-stimulated phosphors. After exposure the phosphor plate is scanned with a laser beam. By erasing the image with another light source, the plate can be reused.
- A disadvantage of these film techniques is their off-line character, which requires a certain amount of time before the result can be applied clinically. For this reason on-line electronic portal imaging devices (EPIDs) have been developed. Reviews of the physics of portal imaging, portal imaging systems as well as their operating principles and clinical applications can be found in AAPM Task Group 58 Report and in book chapters by Munro (1999) and Mayless (2000).

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- Two main EPID approaches have been widely clinically applied.
  - In the first method a *metal plate/phosphor screen* combination is used to convert the photon beam intensity into a light image. The screen is viewed by a sensitive video camera using an angled mirror. A drawback of this approach is the bulkiness of the device as a result of the use of a mirror.
  - In the second approach, a *matrix of liquid-filled ionisation chambers* is used. This type of EPID has similar dimensions to a film cassette.
  - A recent third method is based on *amorphous silicon flat panel* systems.
- For both film and EPID use, tables with recommended, site-specific MU values are necessary. The MU values are a function of beam energy, patient thickness and field size, and must be established by each centre for their systems and techniques.
- Retrospective analysis of portal films demonstrates that the frequency of field placement errors can be quite large, although more recent studies indicate smaller errors, if careful patient positioning is applied. It is therefore important that portal imaging is performed in the beginning of the treatment.
- Gross set-up errors, *e.g.*, the wrong placement of shielding blocks, can be detected by visual inspection of the portal image and comparison with a reference image, and corrected immediately.
- Correction of field placement errors must be carried out with care. Only the systematic component has to be corrected. Decision rules have to be formulated for what magnitude of the deviation a correction has to be performed and how often measurements have to be repeated for an individual patient.
- Various sources of random and systematic set-up errors can be detected by portal imaging. For example, Hurkmans *et al.* (2001), in a review of set-up errors, tabulate the values observed by various authors for different treatment sites. These include the following, given as 1 sd in each specific orthogonal or other relevant direction: head and neck, 1.3-4.6 mm systematic, 1.1-2.5 mm random; prostate, 1.2-3.8 mm systematic, 1.2-3.5 mm random; general pelvic region, 0.6-4.5 mm systematic, 1.1-4.9 mm random; thoracic region, 2.0-5.1 systematic, 2.2-5.4 random; breast, 1.8-15.5 mm overall; mantle field and total body irradiation, typically 4-9 mm overall. The range of values is given to accommodate different techniques, immobilization methods, and QA procedures on set-up, etc. The smaller values indicate what may be achievable in best practice. Such studies indicate significant improvement in observed systematic deviations, when comparing treatments before and after correction of field placement errors.
- Portal imaging may lead to various strategies for improvement of positioning accuracy by the radiation technologists; improvement of patient immobilization; introduction of correction rules; adjustment of margins in combination with dose escalation; incorporation of set-up uncertainties in treatment planning, etc.

- The clinical applications of electronic portal imaging can be separated into off-line and on-line analysis.
  - Off-line analysis can be used to quantify and separate random and systematic uncertainties for individual patients.
  - On-line imaging allows, in principle, a quick decision about continuation of treatment by comparing the portal image with the reference image and looking for unacceptable discrepancies.
- Routine use of EPIDs is currently increasing rapidly, although in many centres it still requires a certain amount of development work and staff training, resulting in a still limited clinical implementation.

#### ***Future developments in portal imaging***

- The field of on-line portal imaging is in rapid development. The currently available EPID systems are still mainly used in larger institutions, demonstrating the usefulness of these systems for verifying patient positioning during intensity modulated radiation therapy (IMRT) or other conformal radiotherapy techniques.
- Specific questions, such as the effect of immobilization devices on the accuracy of patient set-up, the measurement of organ motion during treatment and the use of EPIDs for quality assurance of the functioning of radiotherapy equipment (e.g., MLCs) and for beam and patient dosimetry have been reported. However, much work still needs to be done before automated treatment set-up analysis by on-line portal imaging can be used on a routine basis in the clinic.
- A disadvantage of the current techniques of portal imaging is their poor contrast and limited spatial resolution. Recent developments have allowed the creation of new types of flat-panel detectors for x-ray imaging, both for diagnostic purposes and for use as an EPID, based on amorphous silicon (a-Si). They have been tested in various centres and are now being increasingly supplied with new treatment units. Their use is expected to become significant. The spatial and contrast information content of the a-Si detector array and film images are quite similar.

#### **12.4.3. *In- vivo* dose measurements**

- There are many steps in the chain of processes which determine the dose delivery to a patient undergoing radiotherapy and each of these steps may introduce an uncertainty. It is therefore worthwhile, and maybe even necessary for specific patient groups or for unusual treatment conditions to have an ultimate check of the actual treatment by using *in-vivo* dosimetry.
- *In-vivo* dose measurements can be divided into *entrance dose* measurements, *exit dose* measurements, and *intracavitary dose* measurements.
  - *Entrance dose* measurements serve to check the output and performance of the treatment apparatus as well as the accuracy of patient set-up.

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- *Exit dose* measurements serve, in addition, to check the dose calculation algorithm and to determine the influence of shape, size and density variations of the body of the patient on the dose calculation procedure.
- Sometimes it is also possible to determine the *intracavitary dose* in readily accessible body cavities, such as the oral cavity, oesophagus, vagina, bladder, and rectum.
- *In-vivo* dose measurements not only serve to check the dose delivery to the target volume but are also applied to assess the dose to organs at risk (e.g., eye lens, gonads and lungs during TBI) or situations where the dose is difficult to predict (e.g., non-standard SSD or using bolus).
- If entrance dose measurements alone are applied, then the entrance dose has to be converted to the corresponding target dose using patient and treatment setup information. A combination of entrance and exit dose measurements is a more accurate method of obtaining the target dose. Various methods are available to obtain the midline dose from entrance and exit dose values. These methods give generally good results for homogeneous situations but in the presence of inhomogeneities considerable deviations can occur.

### *In-vivo dose measurement techniques*

- Thermoluminescence dosimeters (TLDs) and semiconductor detectors (silicon diodes) are the types of dosimeters most commonly employed for *in-vivo* dosimetry purposes. Other systems have also been used, including film, gel dosimeters, ionisation chambers, electronic devices (e.g., MOSFETs), and alanine. Characteristics of the main detectors are reviewed in Chapter 3. Here only the most important properties of these dosimeters of relevance for *in-vivo* dosimetry are given.
- TLDs have the advantage that they are small, reasonably tissue-equivalent and are not attached to measuring equipment with any wire .
- TLDs can either be calibrated individually or as part of a batch having the same mean sensitivity. It is recommended to perform a calibration during each series of *in-vivo* dose measurements, for the conditions of the TLD material, read-out equipment and anneal procedure at the time.
- All TL materials suffer from fading of the stored signal to some extent. By applying the same procedure during the patient irradiation and the calibration, the loss of signal due to fading can easily be taken into account.
- The variation of the TLD sensitivity of LiF with photon energy is rather small. Correction factors due to variations in field size, patient thickness or beam hardening by wedges, will therefore also be very small or negligible.
- Diodes have the advantage that they have a high sensitivity, give instant read-out and require simple instrumentation.

- Entrance and exit dose can be derived from diode readings by multiplication with an absorbed *dose-to-water* calibration coefficient and a number of correction factors, which depend on the specific irradiation parameters used. For entrance and exit dose measurements, separate calibrations are required, with the diodes irradiated in both orientations. Because of the decrease in sensitivity with integrated dose, it is necessary to recalibrate the diodes frequently, *e.g.*, once every few weeks, depending on diode workload.
- For accurate dose determinations, a number of small correction factors, both at the entrance and exit side, are required to correct for variation in response of the diode with field size, focus-skin distance, patient thickness, wedge filter thickness, and temperature.
- Three basic physical properties of the diodes are responsible for these correction factors: the energy dependence, the dose per pulse dependence and the temperature dependence of the sensitivity. The latter correction is dependent on the diode type but may amount to 0.3% per degree C. Note that the temperature of a diode on the skin of a patient is about 30°C, which requires a correction factor of about 3% if calibrated at room temperature.
- Diodes may exhibit a directional dependence, which is related to the construction of the diode and its build-up cap. In the direction of the cable the sensitivity is generally lower than in the direction perpendicular to it, depending on the detail of design and construction and the beam energy it is being used for.
- The accuracy of entrance and exit dose measurements in open beams, after proper calibration of the diodes, is of the order of one to two percent (one standard deviation), respectively. For wedged beams an additional uncertainty has to be introduced due to the positioning of the diode with respect to the wedge profile.
- Entrance and exit dose are generally defined at the depth of dose maximum below the surface. *In-vivo* dosimetry detectors should therefore be covered with a build-up cap appropriate to the photon beam energy. The use of such a ‘thick’ detector eliminates the skin sparing effect and introduces an underdosage, up to 5%, in the shadow of the detector.
- For specific dose estimates for eyes, skin, etc., *i.e.*, not at full build-up, appropriately designed dosimeters are required, with build-up to match the clinical situation.
- Errors traced by *in-vivo* dosimetry are related to the set-up of the patient, human errors in the data transfer during the consecutive steps of the treatment preparation, unstable accelerator performance and inaccuracies in dose calculation, *e.g.*, of the treatment planning system. *In-vivo* dosimetry during TBI is often applied to verify the midline dose at various parts of the body and to assess the dose in organs at risk, such as lungs and kidneys.
- The workload involved in an *in-vivo* dosimetry programme depends on many factors such as the accuracy required, the frequency of checks, the time devoted to the analysis of the results and the personnel.

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- Accurate *in-vivo* dosimetry as part of a dosimetric quality assurance programme during a clinical trial of conformal therapy of patients treated for prostate cancer has been reported (Essers and Mijnheer 1999). For patient groups where such a high accuracy in dose delivery is required, routine *in-vivo* dosimetry during a few treatment sessions is highly recommended. After every change in the treatment procedure, *in-vivo* dosimetry for a limited number of patients should again be performed.
- If the action level is, for instance, 5%, then one or a few measurements are sufficient to trace discrepancies larger than this threshold. If the goal is to discover smaller deviations between intended and actual dose values, then a larger number of measurements might be required in order to separate systematic from random uncertainties.
- Other practical aspects, such as workload on accelerators and availability of staff, might also be the limiting factors for *in-vivo* dosimetry. Therefore, the goal of an *in-vivo* dosimetry programme has to be well defined
- As part of treatment planning calculation QA, it is recommended that an independent MU calculation programme be used to check the routine dose calculations. It has been shown that some of the errors found by *in-vivo* dosimetry would also have been traced by independent MU calculations. Therefore, it can be concluded that a combination of a separate check of the MU calculations for all patients, in combination with *in-vivo* dosimetry for a representative subgroup is an effective method of quality assurance.

### *The use of electronic portal imaging systems for in-vivo dosimetry*

- A very interesting development is the use of portal imaging for *in-vivo* dosimetry, or ‘transit dosimetry’, purposes. Portal images can be transformed to “dose images”, which can then be correlated with exit dose values. Various groups are currently studying the usefulness of films or EPIDs for *in-vivo* dosimetry.
- It should be noted that the relation between exit dose and transmission dose at the position of the portal imaging detector is not simple and depends on many factors, such as the skin-detector distance, field size, patient thickness and photon beam energy.
- Because a relatively large number of images can be made during one treatment fraction, EPIDs can be used to measure the influence of organ and patient motion on the dose distribution during one treatment session.
- Portal dose measurements are extremely useful in detecting differences between actual patient data as encountered during treatment and those applied during treatment planning. For dosimetric quality assurance of intensity-modulated beams, EPIDs are likely to become very useful.

#### **12.4.4. Record-and-verify systems**

- Both portal imaging and *in-vivo* dosimetry studies have traced a number of mistakes in the treatment set-up. Computer verification of treatment parameters allows some such errors to be identified and corrected for, before the machine is turned on. Such *record-and-verify systems* have been developing in scope for some time and, based on this experience, electronic patient information systems (or radiotherapy information systems) are rapidly becoming commonplace in the clinic.
- A *record-and-verify system* aims to compare the set-up parameters with the prescribed values. Patient identification data, machine parameters and dose prescription data are entered into the computer beforehand. At the time of treatment, these parameters are identified at the treatment machine and, if there is no difference, the treatment can start. If discrepancies are present this is indicated and the parameters concerned are highlighted.
- Tolerances for verification of machine parameters should be provided by the manufacturer.
- Clinical tolerance tables must also be defined locally in the department for each set of techniques to allow for patient/set-up variations day-to-day. It is recommended not to have too many tolerance tables.
- Record-and-verify systems must have the flexibility to be overridden. This feature must be used with care and only when reasons are clear and properly documented.
- These systems, containing radiation field information for each specific patient, allow the use of assisted set-up, *i.e.*, letting the computer set the machine parameters once the patient is positioned on the couch. This facility is particularly useful if isocentric treatments are performed and can help to optimise set-up times, particularly for complex treatments. A dummy run should be carried out because of the increased risk of collision.
- The computer can also keep a record of the actual machine settings used. A printed record can be kept on a patient record card or on a daily record sheet of all treatments carried out. This can also help to optimise time.
- The treatment delivered, if relying on a record-and-verify system setting or verifying the parameters, is only as good as the information input to the system. Therefore, it is vital that the data in the record-and-verify system is quality-controlled, using independent (redundant) checking to verify the input and to sanction its clinical use.
- The performance of the record-and-verify system should be included in an appropriate QA programme. The details of such QA tests will be specific to the system in question.

## **12.5. QUALITY AUDIT**

### **12.5.1. 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. Some discussion of the structure and operation of various types of quality audit is given in ESTRO (1998); IPEM (1999); IAEA (1999) and McKenzie et al (2000).

Parameters of quality audits are given below. *Quality audits:*

- Are performed by personnel not directly responsible for the areas being audited, preferably in cooperative discussion with the responsible personnel.
- Evaluate the need for improvement or corrective action.
- Should not be confused with a surveillance or inspection.
- Can be conducted for internal or external purposes.
- Can be applied at any level of a QA programme.
- Must be against pre-determined standards, linked to those that the QA programme is trying to achieve.
- Should require action if those standards are not met.
- Should be regular and form part of a quality feedback loop to improve quality.
- Can be of the implementation, or operation, of a quality system or QA programme, *i.e.*, can be mainly procedural, looking at QA procedures, protocols, QC programmes, QC and QA results and records, etc. (procedural quality audit).
- Can also verify the effectiveness, or performance, of a quality system or QA programme, *i.e.*, can be mainly practical (practical quality audit).
- May be voluntary and co-operative, or may be regulatory (*e.g.*, for accreditation of the department or hospital, for QS certification, etc.).

### **12.5.2. Practical quality audit modalities**

- *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. They can be applied at various levels in the clinical dosimetry chain and can include procedural audit by using a questionnaire.
- *Quality audit* visits can audit practical aspects in detail, limited only by time. They can audit procedural aspects by questioning staff and by inspection of procedures and records.

### **12.5.3. What should be reviewed in a quality audit visit?**

The content of a quality audit visit should be pre-defined and will depend on the purpose of the visit, *e.g.*, 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 programme that the centre cannot explain?



**Example of content of a quality audit visit:**

- Check infrastructure, *e.g.*, equipment, personnel, patient load, existence of policies and procedures, quality assurance programme in place, quality improvement programme in place, radiation protection programme in place, data and records, etc.
- Check documentation, *e.g.*, content of policies and procedures, QA programme structure and management, patient dosimetry procedures, simulation procedures, patient positioning, immobilisation and treatment delivery procedures, equipment acceptance and commissioning records, dosimetry system records, machine and treatment planning data, QC programme content, tolerances and frequencies, QC and QA records of results and actions, preventive maintenance programme records and actions, patient data records, follow-up and outcome analysis etc.
- Carry out check measurements of: beam calibration, field size dependence, electron cone factors, depth dose, electron gap corrections, wedge transmissions (with field size), tray, etc. factors, mechanical characteristics, patient dosimetry, dosimetry equipment comparison, temperature and pressure measurement comparison, etc.
- Carry out check measurements on other equipment, such as simulator, CT scanner, etc.
- Assess treatment planning data and procedures. Measure some planned distributions in phantoms.

This is a simple outline of possible things to check and measure. Depending on the type and purpose of the audit visit and the time available, some or all of these may be assessed. Alternatively only a small sub-set may be appropriate. Additionally the auditor should be flexible in approach and be prepared to audit extra things, if it appears necessary from the results of the initial measurements carried out. It may be that some pre-planned audit tasks may need to be modified or reduced if it becomes clear that there are higher priority aspects which need to be followed up in the time available.

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