Chapter 12

QUALITY ASSURANCE OF EXTERNAL BEAM RADIOTHERAPY

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12.1. INTRODUCTION

12.1.1. Definitions

12.1.1.1. Quality assurance

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

12.1.1.2. Quality assurance in radiotherapy

'Quality assurance in radiotherapy' is all procedures that ensure consistency of the medical prescription, and safe fulfilment of that prescription, as regards the 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 the treatment. Again, it must be stressed that quality assurance in radiotherapy is concerned with all aspects of the radiotherapy process and should involve all groups of staff in a cooperative approach, since quality activities are interdependent.

12.1.1.3. Quality control

'Quality control' is the regulatory process through which the actual quality performance is measured, compared with existing standards, and the actions necessary to keep or regain conformance with the standards. Quality control is one part of overall quality assurance. It is concerned with operational techniques and activities used:

- To check that quality requirements are met;
- To adjust and correct performance if the requirements are found not to have been met.

12.1.1.4. Quality standards

'Quality standards' is the set of accepted criteria against which the quality of the activity in question can be assessed. Various national or international organizations, such as the World Health Organization (WHO) in 1988, AAPM in 1994, European Society for Therapeutic Radiation Oncology (ESTRO) in 1995 and Clinical Oncology Information Network (COIN) in 1999, have issued recommendations for standards in radiotherapy. Other organizations, such as the IEC in 1989 and the Institute of Physics and Engineering in Medicine (IPEM) in 1999, have issued recommendations for certain parts of the radiotherapy process. Where recommended standards are not available, local standards need to be developed, based on a local assessment of requirements.

12.1.2. Need for quality assurance in radiotherapy

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

- Quality assurance reduces uncertainties and errors in dosimetry, treatment planning, equipment performance, treatment delivery, etc., thereby improving dosimetric and geometric accuracy and the precision

of dose delivery. This improves radiotherapy results (treatment outcomes), raising tumour control rates as well as reducing complication and recurrence rates.

- Quality assurance not only reduces the likelihood of accidents and errors occurring, it also increases the probability that they will be recognized 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.
- Quality assurance allows a reliable intercomparison 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 if 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 (ALARA) consistent with delivering the required dose to the planning target volume (PTV). 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. Patient safety is therefore automatically integrated with quality assurance of radiotherapy treatments.

12.1.3. Requirements on accuracy in radiotherapy

Definitions of accuracy and precision as applied in a radiotherapy context, as well as discussions of dosimetric and geometric uncertainty requirements, can be found in various publications (see, for example, publications by Dutreix in 1984, Mijnheer et al. in 1987, Dobbs and Thwaites in 1999 and Van Dyk in 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, however, 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 the tumour control probability (TCP) and normal tissue complication probability (NTCP). Both of these need careful consideration in designing radiotherapy treatments for a 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 the TCP or increases in the 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 consideration of the available evidence on clinical data, various recommendations have been made about the required accuracy in radiotherapy:

- The ICRU in its Report No. 24 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. in 1987, considering the NTCP, and Brahme et al. in 1988, considering the effect of dose variations on the TCP, recommend an uncertainty of 3–3.5% (1 SD) (i.e. 6% or 7% at the 95% CL). In general, the smallest of these numbers (6% at the 95% CL) might be applicable to the simplest situations, with the minimum number of parameters involved, while the larger figure (7%) is more realistic for practical clinical radiotherapy when more complex treatment situations and patient factors are considered.
- Geometric uncertainty, for example systematic errors on the field position, block position, etc., relative to target volumes or organs at risk, also leads to dose problems, either underdosing of the required volume

(decreasing the TCP) or overdosing of nearby structures (increasing the NTCP). 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 overall equipment related mechanical/geometric problems, while larger figures (typically 8 or 10 mm) are used to indicate the overall spatial accuracy, including representative contributions for problems related to the patient and to the clinical set-up. The latter factors obviously depend on the site involved, the method of immobilization and the treatment techniques employed.

Thus the recommended accuracy of dose delivery is generally 5–7% (95% CL), depending on the factors intended to be included. Figures of 5–10 mm (95% CL) are usually given on spatial accuracy, 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 quality assurance effort, for example if doses are escalated above normal values (e.g. high dose conformal radiotherapy) or if smaller geometric tolerances are required (e.g. stereotactic radiotherapy).

These recommendations are for the end point of the radiotherapy process (i.e. for the treatment as delivered to the patient). Therefore in 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 quality assurance programme is to maintain each individual step within an acceptable tolerance. Very careful attention is required at all levels and for each process and substage within each process. The more complex the treatment technique, the more stages, substages, parameters and factors are involved, and correspondingly more complex quality assurance is required.

12.1.4. Accidents in radiotherapy

Treatment of disease with radiotherapy represents a twofold risk for the patient:

- Firstly, and primarily, there is the potential failure to control the initial disease, which, when it is malignant, is eventually lethal to the patient;
- Secondly, there is the risk to normal tissue from increased exposure to radiation.

Thus in radiotherapy an accident or a misadministration is significant if it results in either an underdose or an overdose, whereas in conventional radiation protection (and in radiation protection legislation and protocols) only overdoses are generally of concern.

When is a difference between the prescribed and delivered dose considered to be at the level of an accident or a misadministration in external beam radiotherapy? From the general aim of 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 that would lead to a 10% difference in a whole treatment or a 20% difference 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.

In 2000 the IAEA analysed a series of accidental exposures in radiotherapy to draw lessons for the prevention of such occurrences. Criteria for classifying radiological accidents include:

- Direct causes of misadministrations;
- Contributing factors;
- Preventability of misadministration;
- Classification of the potential hazard.

Table 12.1 shows some examples of the direct causes of misadministrations in external beam radiotherapy catalogued and analysed in the IAEA report.

These incidents are representative of typical causes. Recording, categorizing and analysing differences in delivered and prescribed doses in radiotherapy can be carried out at many levels. Table 12.1 gives examples of the relatively small number of events reported that resulted in misadministrations (i.e. in large discrepancies between the prescribed and delivered doses).

Other evaluations have been reported from the results of in vivo dosimetry programmes or other audits of radiotherapy practice in which 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:

TABLE 12.1. SOME EXAMPLES OF THE DIRECT CAUSES OF MISADMINISTRATIONS IN EXTERNAL BEAM RADIOTHERAPY IN THE 2000 IAEA REPORT

Cause	Number of accidents
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 ^{60}Co source	3
Transcription error of prescribed dose	3
Decommissioning of teletherapy source error	2
Human error during simulation	2
Error in commissioning of the TPS[a]	2
Technologist misread the treatment time or MUs[b]	2
Malfunction of accelerator	1
Treatment unit mechanical failure	1
Accelerator control software error	1
Wrong repair followed by human error	1

[a] TPS: treatment planning system.
[b] MU: monitor unit.

- Errors may occur at any stage of the process and be made 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 a lack of an adequate quality assurance 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 and failures in communication.

Human error will always occur in any organization and in any activity. However, one aim of the existence of a comprehensive, systematic and consistently applied quality assurance programme is to minimize the number of

occurrences and to identify them at the earliest possible opportunity, thereby minimizing their consequences.

12.2. MANAGING A QUALITY ASSURANCE PROGRAMME

A number of organizations and publications have given background discussion and recommendations on the structure and management of a quality assurance programme, or quality system management, in radiotherapy or radiotherapy physics (e.g. the WHO in 1988, the AAPM in 1994, ESTRO in 1995 and 1998, the IPEM in 1999, Van Dyk and Purdy in 1999 and McKenzie et al. in 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 quality assurance roles, are interdependent, requiring close cooperation. Each staff member must have qualifications (education, training and experience) appropriate to his or her 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 publications from various organizations (e.g. the WHO in 1988, the AAPM in 1994 and ESTRO in 1995):

- Radiation oncologists (in some systems referred to as radiotherapists or clinical oncologists) are almost always certified (or accredited) in the radiation oncology specialty by recognized national boards and are at least responsible for:
  - — Consultations;
  - — Dose prescriptions;

— On-treatment supervision and evaluations;
— Treatment summary reports;
— Follow-up monitoring and evaluation of treatment outcome and morbidity.

- Medical physicists (or radiation oncology physicists, radiotherapy physicists, clinical physicists) are in many countries certified by a recognized national board and are generally responsible for:
  — Specification, acceptance, commissioning, calibration and quality assurance of all radiotherapy equipment;
  — Measurement of beam data;
  — Calculation procedures for the determination and verification of patient doses;
  — The physics content of treatment planning and patient treatment plans;
  — Supervision of therapy equipment maintenance, safety and performance;
  — Establishment and review of quality assurance procedures;
  — Radiation safety and radiation protection in the radiotherapy department.
- Radiotherapy technologists (in some systems referred to as radiation therapists, therapy radiographers, radiation therapy technologists, radiotherapy nurses) are in many countries certified by recognized national boards and are responsible for:
  — Clinical operation of simulators, computed tomography (CT) scanners, treatment units, etc.;
  — Accurate patient set-up 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 quality assurance of treatment equipment in accordance with physics quality assurance procedures and protocols;
  — Treatment planning;
  — Construction of immobilization devices, etc.

  In many, but by no means all, countries radiotherapy technologists constitute an independent professional group, distinct from general nursing staff.
- Dosimetrists (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). 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 quality assurance under the supervision of a medical physicist and may construct immobilization 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 specialized expertise in the electrical and mechanical maintenance of radiotherapy equipment. Their services may be in-house or via a service contract for equipment maintenance. They also provide a design and build capability for specialized patient related devices and are usually supervised by medical physicists.

12.2.2. Quality system/comprehensive quality assurance programme

A quality system is the organizational structure, responsibilities, procedures, processes and resources required for implementing quality management. A quality system in radiotherapy is a management system that:

- Should be supported by the department management in order 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 of 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 the requirements of national legislation, accreditation, etc.
- Requires the development of a formal written quality assurance programme that details the quality assurance policies and procedures, quality control tests, frequencies, tolerances, action criteria, required records and personnel.

- Must be regularly reviewed as to operation and improvement. To this end a quality assurance committee is required, which should represent all the different disciplines within radiation oncology.
- Requires control of the system itself, including:
  - Responsibility for quality assurance and the quality system: quality management representatives.
  - Document control.
  - Procedures to ensure that the quality system is followed.
  - Ensuring that the status of all parts of the service is clear.
  - Reporting all non-conforming parts and taking corrective action.
  - Recording all quality activities.
  - Establishing regular review and audits of both the implementation of the quality system (quality system audit) and its effectiveness (quality audit).

The quality assurance committee must be appointed by the department management/head of department with the authority to manage quality assurance and should:

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

The comprehensive quality assurance team:

— Is responsible for performing quality assurance 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 or her responsibilities and be adequately trained to perform them, and should also know which actions are to be taken in the event that any result is observed outside the limits of established acceptable criteria. A subgroup of the team can be trained to act as internal auditors of the quality system.

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

12.3. QUALITY ASSURANCE PROGRAMME 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 quality assurance and quality control requirements for various radiotherapy equipment items (see, for example, IEC of 1989, AAPM of 1994 and IPEM of 1999) that should be referred to where available. These give recommended tests, test frequencies and tolerances. Some give test methods, while others give practical advice on quality assurance and quality control tests for many items of equipment.

12.3.1. Structure of an equipment quality assurance programme

A general quality assurance programme for equipment includes:

- Initial specification, acceptance testing and commissioning for clinical use, including calibration where applicable (see Chapter 10).

- Quality control 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 quality control programme initiated that will continue for the entire clinical lifetime of the equipment.
- Additional quality control tests after any significant repair, intervention or adjustment or when there is any indication of a change in performance as observed during use or during planned preventive maintenance or routine quality control programmes.
- A planned preventive maintenance programme, in accordance with the manufacturer's recommendations.

12.3.1.1. 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 multidisciplinary 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 the task of a radiotherapy physicist.

In response to the specifications, the various interested suppliers should indicate how the equipment they offer will meet the specifications and whether there are any areas that cannot be met or whether there are any limiting conditions under which specified requirements can or cannot be met, etc.

Decisions on procurement should be made by a multidisciplinary team, comparing specifications as well as considering costs and other factors.

12.3.1.2. 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. 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 IEC 977 documents. It is a matter of the professional judgement of the medical physicist responsible for accepting the equipment to decide whether 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 performance deteriorate further.

Acceptance provides a baseline set of equipment performance measurements that 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 that 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 medical physicist responsible for the customer side of acceptance either is satisfied that the performance of the machine fulfils all specifications as listed in the contract document or formally accepts any waivers as stated above.

12.3.1.3. Commissioning

Following acceptance of the equipment, a full characterization 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 quality control tests will be referred.

Where appropriate, commissioning will incorporate calibration to agreed protocols and standards. For critical parts of commissioning, such as calibration, an independent second check 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.

12.3.1.4. Quality control

It is essential that the performance of treatment equipment remain consistent within accepted tolerances throughout its clinical life, as patient treatments will be planned and delivered on the basis of the performance measurements at acceptance and commissioning. An ongoing quality control

programme of regular performance checks is therefore begun immediately after commissioning to test this.

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

- The parameters to be tested and the tests to be performed;
- The specific equipment to be used to perform the tests;
- The geometry of the tests;
- The frequency of the tests;
- The staff group or individual performing the tests, as well as the individual supervising and responsible for the standards of the tests and for actions that may be necessary if problems are identified;
- The expected results;
- The tolerance and action levels;
- The actions required when the tolerance levels are exceeded.

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

The test content should be kept as simple as possible, consistent with the defined aims, in order to optimize the time and effort with 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.

Quality control programmes must be flexible to permit additional testing whenever it seems necessary following repair, observed equipment behaviour or indications of problems from the regular quality control tests.

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

12.3.2. Uncertainties, tolerances and action levels

Performance to within the tolerance level gives acceptable accuracy in any situation. Performance outside the action level is unacceptable and demands action to remedy the situation.

Any quality control test should use measuring equipment appropriate to the task. All such equipment should itself be subject to an appropriate maintenance and quality control programme. Irradiation conditions and measuring procedures should be designed to be appropriate to the task. In these circumstances the quality control 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, 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, which 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/MUs indicates a result between the tolerance and action levels, it may be permissible to allow clinical use to continue until this is confirmed by measurement the next day before taking any further action. Thus:

- If a daily measurement is within tolerance, no action is required;
- If the measurement exceeds the action level, immediate action is necessary and the machine must not be used clinically until the problem is corrected and the correction is verified by measurement;
- However, if the measurement falls between tolerance and action levels, 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 of 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.

The staff resources available to undertake the tests may limit what can be checked, which may have an effect on the structure of the quality control programme. Tests should be designed to provide the required information as rapidly as possible with minimal time and equipment. Customized devices are often very useful to make tests easier.

Where available, national organizations' own quality control 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 AAPM TG 40, with some additional comments from the IPEM report on quality control in radiotherapy published in 1999; while broadly similar, there are some differences in tolerances and frequencies. The protocols should be referred to for more details. Where local protocols are not available, existing recommendations such as these should be consulted and adapted for local circumstances.

12.3.3. Quality assurance programme for cobalt-60 teletherapy machines

A sample quality assurance programme for a ^{60}Co teletherapy machine with recommended test procedures, test frequencies and action levels is given in Table 12.2.

The IPEM report on quality control in radiotherapy published in 1999 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, for example radiation wipe tests and tests on head leakage and electrical safety, etc.

TABLE 12.2. SAMPLE QUALITY ASSURANCE PROGRAMME FOR A COBALT-60 UNIT (AAPM TG 40)

Frequency	Procedure	Action level[a]
Daily	Door interlock	Functional
	Radiation room monitor	Functional
	Audiovisual monitor	Functional
	Lasers	2 mm
	Distance indicator	2 mm
Weekly	Check of source position	3 mm
Monthly	Output constancy	2%
	Light/radiation field coincidence	3 mm
	Field size indicator	2 mm
	Gantry and collimator angle indicator	1°
	Cross-hair centring	1 mm
	Latching of wedges and trays	Functional
	Emergency off	Functional
	Wedge interlocks	Functional
Annually	Output constancy	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD[b], TAR[c], TPR[d])	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Timer linearity and error	1%
	Output constancy versus gantry angle	2%
	Beam uniformity with gantry angle	3%
	Safety interlocks: follow test procedures of manufacturer	Functional
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Table rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry and table axis with the isocentre	2 mm diameter
	Coincidence of the radiation and mechanical isocentre	2 mm diameter

TABLE 12.2. SAMPLE QUALITY ASSURANCE PROGRAMME FOR A COBALT-60 UNIT (AAPM TG 40) (cont.)

Frequency	Procedure	Action level[a]
	Table top sag	2 mm
	Vertical travel of table	2 mm
	Field light intensity	Functional

[a] AAPM TG 40 lists these values as tolerances. However, the protocol makes it plain that they are action levels; that is, 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. the measured isocentre under the gantry rotation exceeds 2 mm diameter), or the change is greater than the figure above (e.g. the output changes by more than 2%), 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 per cent values are the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal source to surface distance (SSD).

[b] PDD: percentage depth dose.

[c] TAR: tissue–air ratio.

[d] TPR: tissue–phantom ratio.

12.3.4. Quality assurance programme for linacs

Although there is considerable variation in the practice of quality control on linacs, the three major publications (IEC 977, IPEM 81 and AAPM TG 40) are broadly consistent. However, in particular the IEC 977 document does not specify daily checks. Typical quality assurance procedures for a dual mode linac with frequencies and action levels are given in Table 12.3.

IPEM 81 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 AAPM TG 40. 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 quality control protocol for electron beams. As a more recent publication than AAPM TG 40, it gives recommendations for the quality control of dynamic wedges and multileaf collimators (MLCs).

12.3.5. Quality assurance programme for treatment simulators

Treatment simulators replicate the movements of isocentric ^{60}Co and linac treatment machines and are fitted with identical beam and distance

TABLE 12.3. SAMPLE QUALITY CONTROL PROGRAMME FOR A DUAL MODE LINAC (AAPM TG 40)

Frequency	Procedure	Action level[a]
Daily	X ray output constancy	3%
	Electron output constancy[b]	3%
	Lasers	2 mm
	Distance indicator	2 mm
	Door interlock	Functional
	Audiovisual monitor	Functional
Monthly	X ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X ray central axis dosimetry parameter constancy (PDD, TAR, TPR)	2%
	Electron central axis dosimetry parameter constancy (PDD)	2 mm at therapeutic depth
	X ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X ray and electron symmetry	3%
	Emergency off switches	Functional
	Wedge and electron cone interlocks	Functional
	Light/radiation field coincidence	2 mm or 1% on a side[d]
	Gantry/collimator angle indicators	1°
	Wedge position	2 mm (or 2% change in transmission factor)
	Tray position and applicator position	2 mm
	Field size indicators	2 mm
	Cross-hair centring	2 mm diameter
	Treatment table position indicators	2 mm/1°
	Latching of wedges and blocking tray	Functional
	Jaw symmetry[e]	2 mm
	Field light intensity	Functional
Annually	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 (PDD, TAR, TPR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X ray output constancy with the gantry angle	2%
	Electron output constancy with the gantry angle	2%

TABLE 12.3. SAMPLE QUALITY CONTROL PROGRAMME FOR A DUAL MODE LINAC (AAPM TG 40) (cont.)

Frequency	Procedure	Action level[a]
Annually	Off-axis factor constancy with the gantry angle	2%
	Arc mode	Manufacturer's specifications
	Safety interlocks: follow manufacturer's test procedures	Functional
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Table rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry and table axes with the isocentre	2 mm diameter
	Coincidence of the radiation and mechanical isocentre	2 mm diameter
	Table top sag	2 mm
	Vertical travel of the table	2 mm

[a] AAPM TG 40 lists these values as tolerances. However, the protocol makes it plain that they are action levels; that is, 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. the measured isocentre under the gantry rotation exceeds 2 mm diameter), or the change is greater than the figure above (e.g. the output changes by more than 2%), 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 per cent values are plus or minus 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 the light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocentre.

[f] Most wedge transmission factors are field size and depth dependent, and should be checked. In particular, the field size variations for dynamic wedges can be very large.

indicators. Hence all measurements that concern these aspects of ^{60}Co and linac 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, 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 quality assurance procedures for a conventional simulator with test frequencies and action levels are given in Table 12.4.

TABLE 12.4. SAMPLE QUALITY CONTROL PROGRAMME FOR A SIMULATOR (AAPM TG 40)

Frequency	Procedure	Action level[a]
Daily	Safety switches	Functional
	Door interlock	Functional
	Lasers	2 mm
	Distance indicator	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1°
	Cross-hair centring	2 mm diameter
	Focal spot axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency collision avoidance	Functional
	Light/radiation field coincidence	2 mm or 1%
	Film processor sensitometry	Baseline
Annually	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Table rotation isocentre	2 mm diameter
	Coincidence of the collimator, gantry and table axes with the isocentre	2 mm diameter
	Table top sag	2 mm
	Vertical travel of the table	2 mm
	Exposure rate	Baseline
	Table top exposure with fluoroscopy	Baseline
	kVp and mAs calibration	Baseline
	High and low contrast resolution	Baseline

[a] AAPM TG 40 lists these values as tolerances. However, they are action levels; that is, 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. the measured isocentre under gantry rotation exceeds 2 mm diameter), an action is required.

TABLE 12.5. SAMPLE OF A ROUTINE REGULAR QUALITY CONTROL PROGRAMME FOR A COMPUTED TOMOGRAPHY SCANNER OR COMPUTED TOMOGRAPHY SIMULATOR (IPEM 81)

Frequency	Procedure	Action level[a]
Daily	Safety switches	Functional
Monthly	Scan plane to alignment laser	2 mm
	Indication of *x* axis	1°
	Table position registration	1 mm
	Distance between known points in the image	2 mm
	Left and right registration	Correct operation
	CT number for water	1%
	CT number for lung and bone	2%
	Reconstructed slice location	1 mm
Annually	Table deflection under load	2 mm

[a] IPEM 81 lists these values as tolerances but implies that at least some of them would require action if exceeded.

IPEM 81 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. Quality assurance programme for computed tomography scanners and computed tomography 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 are 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 CT densities be accurate.

Typical quality assurance procedures with frequencies and action levels are listed in Table 12.5. The protocol also lists the tests to be carried out after new software is installed (scanner or TPS).

AAPM TG 66 provides extensive coverage of quality assurance in CT simulation.

12.3.7. Quality assurance programme for treatment planning systems

As an integral part of the radiotherapy process the TPS provides computer predictions of the dose distributions that can be achieved both in the target volume and 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.

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 dose prediction. This provides knowledge of the limitations of the system; a considerable part of this understanding should be gained by comparison with experimental measurements 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 in order simply to speed up the introduction of new software into clinical use.

Generic tolerances of 2% have often been quoted for isodose distributions where dose gradients are not steep and of 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 has been given by various authors, for example Van Dyk and colleagues and Venselaar (see also Chapter 11).

Acceptance, commissioning and quality control recommendations are given, for example, by the AAPM (TG 40 and TG 43) and the IPEM (in Reports 68 and 81); these should be referred to for more details. The exact requirements will depend on the level of complexity of the system and on the treatment planning techniques used clinically. Any uncertainty concerning the operation or output of a TPS should be tested by comparing the performance of the TPS with measurements in suitable phantoms. A sample of a routine regular quality control programme for a TPS is given in Table 12.6.

TABLE 12.6. SAMPLE OF A ROUTINE REGULAR QUALITY CONTROL PROGRAMME FOR A TREATMENT PLANNING SYSTEM, FROM IPEM 68 AND 81 AND AAPM TG 40

Frequency	Procedure	Tolerance[a]
Daily	Input and output devices	1 mm
Monthly	Checksum	No change
	Reference subset of data[b]	2%[c] or 2 mm[d]
	Reference prediction subset	2% or 2 mm
	Processor tests	Pass
	CT transfer	1 mm
Annually	MU calculations	2%
	Reference quality assurance test set[e]	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] Per cent 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 per cent differences. In addition, less accuracy may be obtained near the end of single sources for brachytherapy calculations.

[e] These tests refer to the comparison of calculations with measurement in a water tank.

12.3.8. Quality assurance programme for test equipment

Test equipment in radiotherapy concerns all the additional equipment required to measure radiation doses and to perform electrical measurements of machine signals and mechanical measurements of machine devices. The details of the quality control programme will depend on the equipment and its use.

Some examples of considerations for a quality control programme for test and measuring equipment (tolerances given in brackets where applicable) include the following:

- Local standard ionization chamber and electrometer. These must be calibrated in accordance with national protocols at an accredited dosimetry standards laboratory at between one and three years' frequency, depending on national guidelines and procedures. This must include checks on linearity, scale corrections, etc. Venting should be checked before recalibration 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. The applied voltage and leakage should be checked at each use. Before and after any use to calibrate field instruments, a ^{90}Sr or similar check of constancy (to 1%) should be carried out.
- Field instrument ionization chamber and electrometers. These should be calibrated 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. The applied voltage and leakage should be checked at each use. It is recommended to carry out constancy checks monthly, for example comparing response against another chamber or using a ^{90}Sr or similar check source (agreement is expected to be within 1%).
- Thermometer. When new, the calibration should be checked (to 0.5ºC). Regular comparisons of thermometers against each other help 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, for example the accuracy of data analysis (to 1%), accuracy of printouts (to 1 mm), etc. When new and regularly before use, check electrical and mechanical safety; the geometric accuracy of drives and detector positioning (to 1 mm); reproducibility (to 1 mm); backlash/hysteresis (to 1 mm); and orthogonality of drives (to 0.5º). Check the dosimetry systems in a similar way to the guidance given for checking ionization chambers and electrometers, or other dosimetry systems, depending on the specific measuring devices being used with the plotting tank.
- Other dosimetry systems. Systems for relative dosimetry (e.g. thermoluminescent dosimeters (TLDs), diodes, diamonds and film), in vivo dosimetry (e.g. TLDs and diodes) and for radiation protection measurements, for example, 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 and calibrations required. Usually this will involve comparison and calibration against ionization chamber systems. After that, quality control tests and checks will be required to ensure that they perform acceptably and that any changes in behaviour with time or with radiation damage are 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. The basic components of a patient treatment chart are:

- The patient's name and identification;
- A photograph;
- An initial physical evaluation of the patient;
- Treatment planning data;
- Treatment execution data;
- Clinical assessment during treatment;
- The treatment summary and follow-up;
- A quality assurance checklist.

Any mistakes made in the data entry of the patient chart are likely to be carried through the whole treatment; quality assurance of the patient chart is therefore essential. All planning data should be independently checked ('redundant checking'), including the plan integrity, MU calculations, irradiation parameters, etc. (see Chapters 7 and 11). 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 of a new treatment course or after each 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 checkers.

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, for example from the TPS, should also be verified to check that no data corruption has occurred.

All errors that are traced during chart checking should be thoroughly investigated and evaluated by the quality assurance team, which should include a quality assurance 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 part of the patient chart; they allow direct input of treatment data from the simulator or from a TPS.

12.4.2. Portal imaging

Besides dosimetric errors, geometric errors are also of extreme importance in determining the outcome of a radiotherapy treatment. 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, is repeated if the fields are modified and is sometimes repeated during the course of 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 produced by blocks or by an MLC has been properly produced and registered.

Sometimes it is useful to have more than one check during one treatment fraction, for example to observe the influence of swallowing and breathing or organ motion on the patient set-up.

Portal images are compared with reference images, which can be either (orthogonal) simulator images, digitally reconstructed radiographs (DRRs) 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. An example is provided in Fig. 12.1, in which DRRs of anterior and lateral pelvic treatments and electronic portal imaging device (EPID) fields are shown for comparison with images obtained with an EPID.

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 with reference images.

Sequences of portal image series for the same patient throughout the treatment can provide verification of day to day variations in the patient set-up and can give information on changes throughout the treatment; the frequency depends on the site, the type of immobilization, the patient conditions, the intended degree of reproducibility, the other quality assurance 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 information conveyed by portal images.

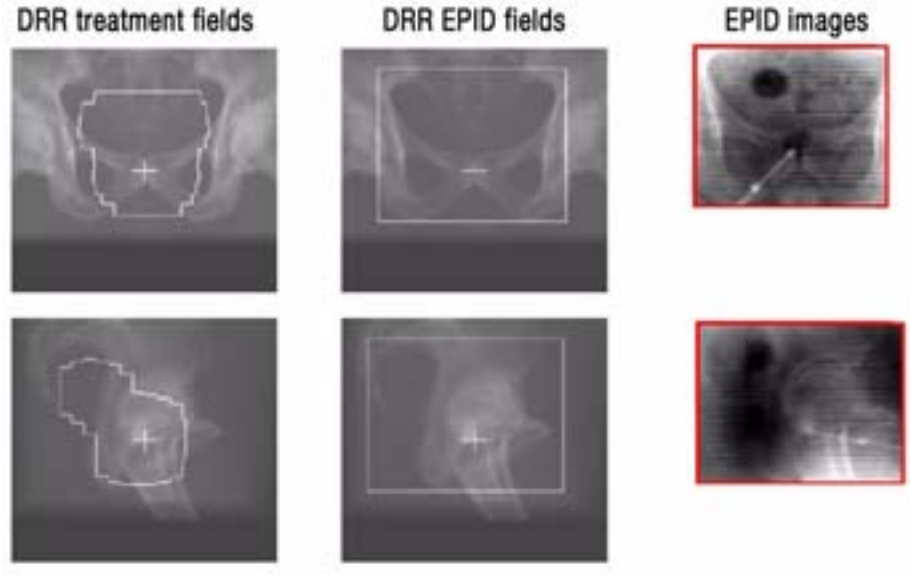

FIG. 12.1. DRRs from treatment fields and large fields to verify the position of the isocentre and the corresponding EPID fields.

12.4.2.1. 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, for example 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 photostimulated 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 EPIDs have been developed. Reviews of the physics of portal imaging and portal imaging systems, as well as of their operating principles and clinical applications, can be found in AAPM TG 58.

Two main EPID approaches have been widely applied clinically:

- 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.
- The second approach uses a matrix of liquid filled ionization chambers. This type of EPID has similar dimensions to a film cassette (see Fig. 12.2).

A recent, third method is based on amorphous silicon flat panel systems. A typical example is shown in Fig. 12.3.

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 its systems and techniques.

Retrospective analysis of portal films demonstrates that the frequency of field placement errors can be quite high, although more recent studies indicate both a lower frequency of errors and smaller errors if careful patient positioning is applied.

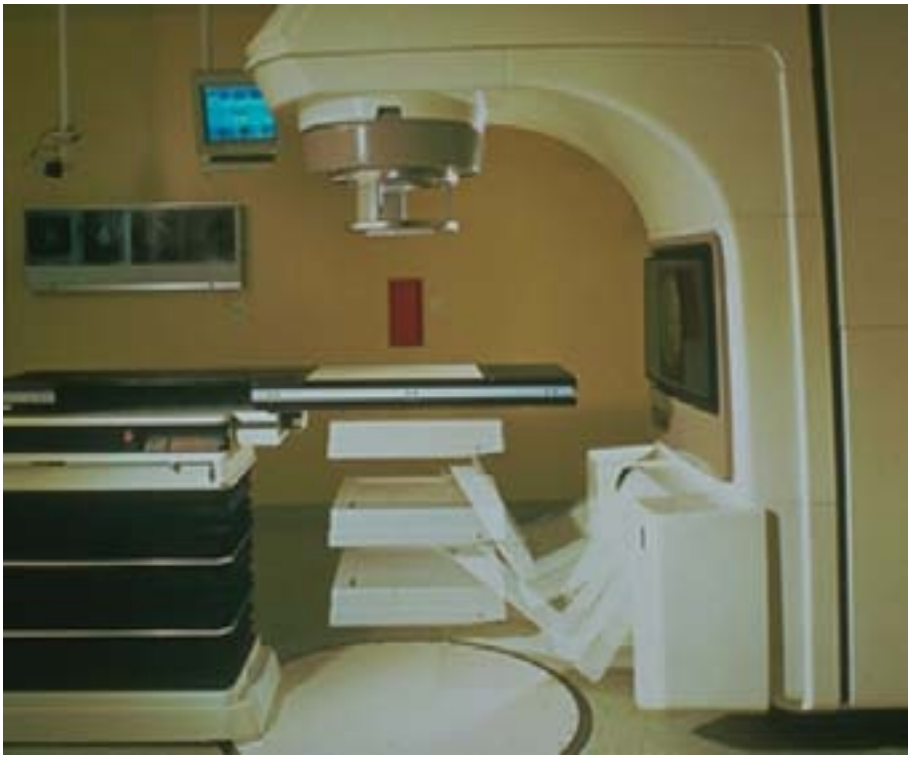

FIG. 12.2. Liquid filled matrix ionization chamber type of EPID connected via a retractable arm to a linac.

Gross set-up errors, for example 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 deviation a correction has to be performed for 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 and colleagues, in a review of set-up errors, tabulated 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 mm systematic, 2.2–5.4 mm random; breast, 1.8–15.5 mm overall;

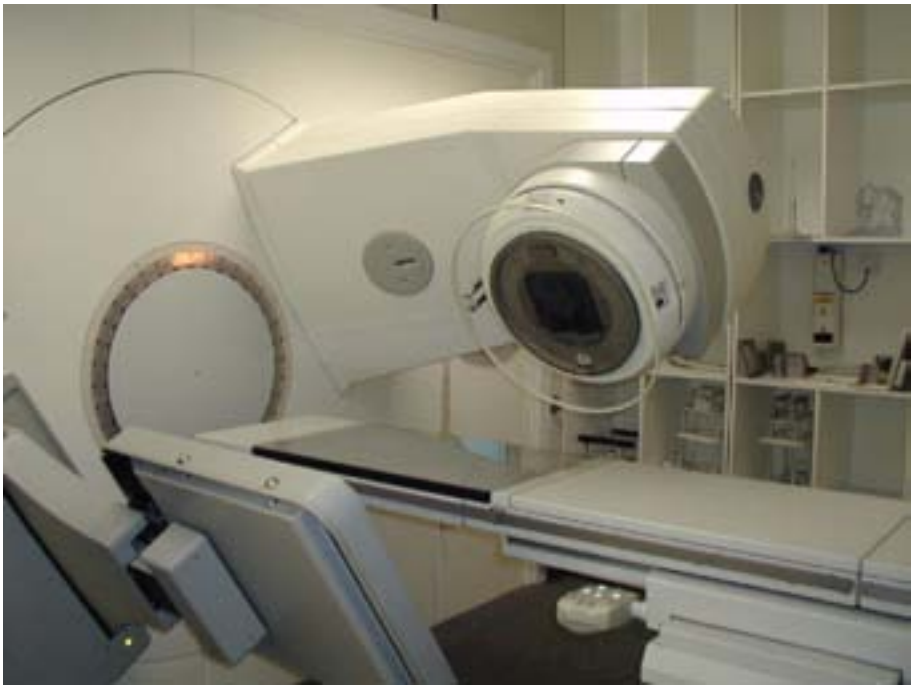

FIG. 12.3. Amorphous silicon type of EPID installed on the gantry of a linac.

mantle field and total body irradiation (TBI), typically 4–9 mm overall. The range of values is given to accommodate different techniques, immobilization methods and quality assurance 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 technologist through 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. 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.

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.

12.4.2.2. 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 radiotherapy (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 studied. 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 detector 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 widespread. The spatial and contrast information content of the a-Si detector array and film images is quite similar.

12.4.3. In vivo dose measurements

There are many steps in the chain of processes that determine the dose delivery to a patient undergoing radiotherapy, and each of these steps may introduce an uncertainty. It is therefore worth while, and may even be necessary, for specific patient groups or for unusual treatment conditions to be given 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;
- 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. the eye lens, gonads and lungs during TBI) or in situations in which the dose is difficult to predict (e.g. non-standard SSD or using bolus).

If entrance dose measurements alone are applied, the entrance dose has to be converted to the corresponding target dose using patient and treatment set-up 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.

12.4.3.1. In vivo dose measurement techniques

TLDs and semiconductor detectors (silicon diodes) are the types of dosimeter most commonly employed for in vivo dosimetry purposes. Other systems have also been used, including film, gel dosimeters, ionization chambers, electronic devices (e.g. metal oxide semiconductor field effect transistors (MOSFETs)) and alanine. The characteristics of the main detectors are reviewed in detail in Chapter 3.

TLDs have the advantage that they are small, reasonably tissue equivalent and not attached to measuring equipment with cables or wires. TLDs can be calibrated either 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, readout equipment and anneal procedure at the time.

All thermoluminescent materials suffer from fading of the stored signal to some extent. By applying the same procedure during patient irradiation and calibration, the loss of signal due to fading can easily be taken into account.

The variation of the thermoluminescent 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 an instant readout and require only simple instrumentation. An example of a diode dosimetry system is given in Fig. 12.4.

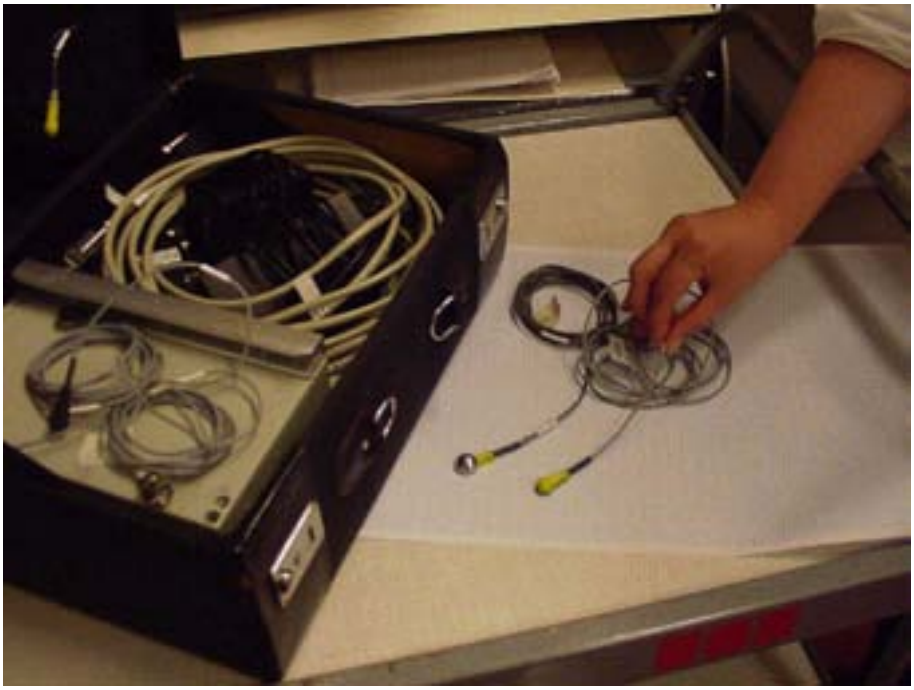

FIG. 12.4. Diodes applied for in vivo dosimetry.

The entrance dose and the exit dose can be derived from diode readings by multiplication with an absorbed dose to water calibration coefficient and a number of correction factors that depend on the specific irradiation parameters used. For entrance and exit dose measurements, separate calibrations are required, with the diodes irradiated in both orientations. Owing to the decrease in sensitivity with integrated dose, it is necessary to recalibrate the diodes frequently, for example once every few weeks, depending on the diode workload.

For accurate dose determinations a number of small correction factors, at both the entrance and exit side, are required to correct for variation in response of the diode with field size, focus to 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%/ºC. Note that the temperature of a diode on the skin of a patient is about 30ºC, which requires a correction factor of about 3% if calibrated at room temperature.

Diodes may exhibit a directional dependence that is related to the construction of the diode and its buildup cap. The sensitivity in the direction of the cable is generally lower than in the direction perpendicular to it, depending on the details of design and construction and the beam energy it is being used for.

The entrance dose and the exit dose are generally defined at the depth of dose maximum below the surface. In vivo dosimetry detectors should therefore be covered with a buildup 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.

The accuracy of entrance and exit dose measurements in open beams, after proper calibration of the diodes, is of the order of 1% and 2% (1 SD), respectively. For wedged beams an additional uncertainty has to be introduced due to the positioning of the diode with respect to the wedge profile.

For specific dose estimates for eyes, skin, etc. (i.e. not at full buildup), appropriately designed dosimeters are required, with buildup 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 treatment preparation, unstable accelerator performance and inaccuracies in dose calculation, for example by the TPS. 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 the 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.

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. For patient groups for which 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 example, 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 the 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 the workload on accelerators and availability of staff, might also be limiting factors for in vivo dosimetry. The goal of an in vivo dosimetry programme has therefore to be well defined.

As part of the quality assurance of treatment planning calculations, 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. It can therefore be concluded that a combination of a separate check of the MU calculations for all patients with in vivo dosimetry for a representative subgroup is an effective method of quality assurance.

12.4.3.2. 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. Two different approaches (forwards and backwards) are described schematically in Fig. 12.5.

It should be noted that the relationship between the exit dose and the transmission dose at the position of the portal imaging detector is not simple and depends on many factors, such as the skin to detector distance, field size, patient thickness and photon beam energy.

Since 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. EPIDs are likely to become very useful for dosimetric quality assurance of intensity modulated beams.

12.4.4. Record and verify systems

Both portal imaging and in vivo dosimetry studies have traced a number of mistakes in treatment set-ups. 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

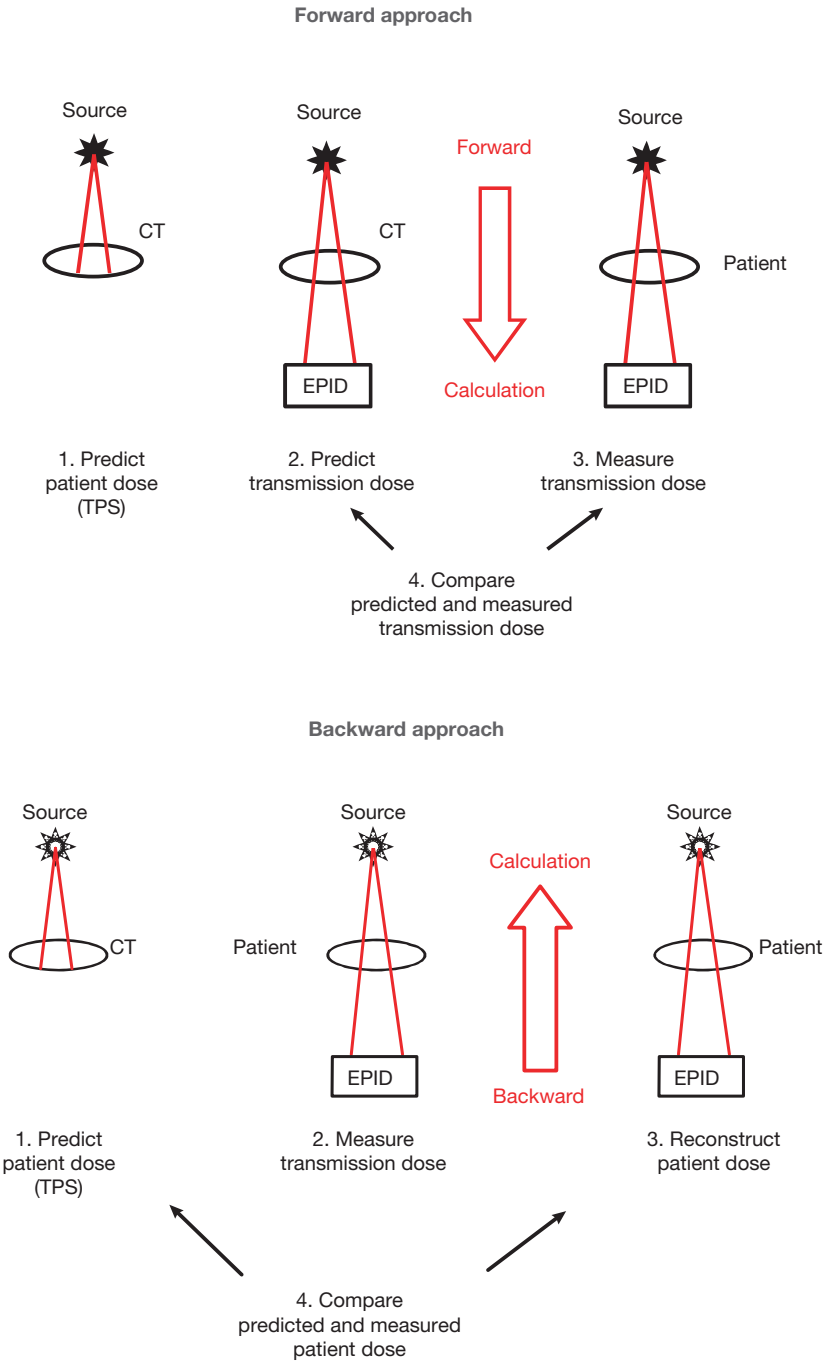

FIG. 12.5. Two different approaches for applying portal imaging for in vivo dosimetry.

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 in order 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 table). This facility is particularly useful if isocentric treatments are performed and can help to optimize 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 help to optimize 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. It is therefore vital that the data in the record and verify system be 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 quality assurance programme. The details of such quality assurance tests will be specific to the system in question.

12.5. QUALITY AUDIT

12.5.1. Definition

A quality audit is a systematic and independent examination to determine whether quality activities and results comply with planned arrangements and whether the arrangements are implemented effectively and are suitable to achieve the stated objectives.

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 surveillance or inspection.
- Can be conducted for internal or external purposes.
- Can be applied at any level of a quality assurance programme.
- Must be against predetermined standards, linked to those that the quality assurance 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 quality assurance programme (i.e. can be mainly procedural), looking at quality assurance procedures, protocols, quality control programmes, quality control and quality assurance results and records, etc.: procedural quality audit.
- Can also verify the effectiveness, or performance, of a quality system or quality assurance programme (i.e. can be mainly practical): practical quality audit.
- May be voluntary and cooperative, or may be regulatory (e.g. for accreditation of the department or hospital or for quality system certification).

12.5.2. Practical quality audit modalities

12.5.2.1. Postal audit with mailed dosimeters

Postal audits with mailed dosimeters (usually TLDs) are generally organized by secondary standards dosimetry laboratories (SSDLs), agencies such as the IAEA, the Radiological Physics Center (RPC) in the USA and ESTRO (EQUAL), national societies or national quality networks. They can be applied at various levels in the clinical dosimetry chain and can include procedural audits by using a questionnaire.

12.5.2.2. Quality audit visits

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 predefined and will depend on the purpose of the visit; for example, is it a routine regular visit within a national or regional quality audit network, is it regulatory or cooperative between peer professionals, is it a visit following a possible misadministration, or is it a visit following an observed higher than expected deviation in a mailed TLD audit programme that the centre cannot explain?

An example of the contents of a quality audit visit is the following:

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

This is a simple outline of possible items 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, assessment of only a small subset may be appropriate. Additionally, the auditor should be flexible in approach and be prepared to audit extra aspects if this appears necessary from the results of the initial measurements carried out. Some preplanned audit tasks may need to be modified or reduced if it becomes clear that there are higher priority aspects that need to be followed up in the time available.

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