Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement

Quality Assurance Team for Radiation Oncology (QUATRO)

SEFOMP ESTRO







Second Edition





COMPREHENSIVE AUDITS OF RADIOTHERAPY PRACTICES: A TOOL FOR QUALITY IMPROVEMENT

Second Edition

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COMPREHENSIVE AUDITS OF RADIOTHERAPY PRACTICES: A TOOL FOR QUALITY IMPROVEMENT

QUALITY ASSURANCE TEAM FOR RADIATION ONCOLOGY (QUATRO)

Second Edition

ENDORSED BY:

EUROPEAN FEDERATION OF ORGANISATIONS FOR MEDICAL PHYSICS, EUROPEAN SOCIETY FOR RADIOTHERAPY AND ONCOLOGY, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS

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FOREWORD

As part of a comprehensive approach to quality assurance in the treatment of cancer by radiation, an independent external audit (peer review) is important to ensure adequate quality of practice and delivery of treatment. Quality audits can be of various types and at various levels, either reviewing specific critical parts of the radiotherapy process (partial audit) or assessing the whole process (comprehensive audit).

The IAEA has a long history of providing assistance for dosimetry (partial) audits to its Member States. Together with the World Health Organization, it has operated postal dose audit programmes using thermoluminescence dosimetry to verify the calibration of radiotherapy beams since 1969, followed by radiophotoluminescent glass dosimetry since 2017. Furthermore, it has developed a set of procedures for experts undertaking missions to radiotherapy departments for the on-site review of dosimetry equipment, data, techniques and measurements, and education programmes for local staff. This methodology involves dosimetry and medical radiation physics aspects of the radiotherapy process without assessing clinical areas.

The IAEA, through its technical cooperation programme, has received numerous requests from low and middle income countries to perform comprehensive audits to assess the whole radiotherapy process, including aspects such as organization, infrastructure, and clinical and medical physics components. The objective of a comprehensive audit is to review and evaluate the quality of all components of the radiotherapy programme at an institution, including professional competence, with a view to quality improvement. A multidisciplinary team, comprising a radiation oncologist, a medical physicist and a radiation therapist, is required to carry out the audit.

The first edition of Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement was published in 2007 and provided guidance for conducting comprehensive clinical audits within a Quality Assurance Team for Radiation Oncology (QUATRO) framework. These 'QUATRO guidelines' have been successfully applied in numerous clinical audits worldwide. However, in the light of developments in techniques and equipment, and lessons learned from past audits, an update is required.

This second edition provides the necessary revision of the 2007 QUATRO guidelines. It includes procedures for new technologies and modalities now routinely applied in radiotherapy departments, builds on the knowledge and feedback of the QUATRO audit teams, and incorporates recommendations from experienced QUATRO auditors. The QUATRO methodology has been endorsed by the European Federation of Organisations for Medical Physics, the European Society for Radiotherapy and Oncology, and the International Organization for Medical Physics.

The IAEA officers responsible for this publication were J. Izewska and E. Zubizarreta of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

Independent external audits are a necessary part of a comprehensive quality assurance (QA) programme in radiation oncology [1–3]. Quality audits can be of various types and levels, either reviewing specific critical parts of the radiotherapy process (partial audits) or assessing the whole process (comprehensive audits). The term 'audit', as used in this publication, is synonymous with an independent external evaluation, assessment or peer review.

The audits of radiation dose and other relevant medical physics procedures are well described in various IAEA and peer reviewed publications [4–7]. The IAEA, through its technical cooperation programme, has received several requests from low and middle income countries to perform more comprehensive audits of their radiotherapy services, either at a national or individual institution level. In 2005, the IAEA convened an advisory group, comprised of radiation oncologists, medical physicists and radiation therapists (RTTs)¹, to devise guidelines for IAEA audit teams on the initiation, performance and reporting of such comprehensive audits. The group proposed the name Quality Assurance Team for Radiation Oncology (QUATRO). In 2018, a second advisory group was convened to review and revise the guidelines to reflect technological and technical developments that had taken place in the interim period.

1.2. OBJECTIVE

This publication presents revised guidelines for QUATRO audit teams. It contains revised checklists that may be considered helpful audit tools, to be used flexibly by the auditors depending on the local situation. It does not represent one radiotherapy standard applicable to all visited departments. The objective is to provide a general audit methodology that can be applied in a range of economic settings. The audit includes an assessment of an institution's practices, educational activities and ability to maintain radiotherapy technology at the level corresponding to the best clinical practice in the specific economic setting (which is related to the ability of a country to sustain that technology). The interpretation

¹ The abbreviation RTT is used to describe a radiotherapy technology professional. Different terms for this role are used in different countries (e.g. radiation therapist, therapy radiographer or radiotherapy technologist).

of the results of the audit is made against appropriate criteria of good radiotherapy practice (quality standards).

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

The QUATRO audit methodology presented in this publication places the emphasis on radiotherapy structure and process rather than treatment outcome². The value of an outcome oriented audit will be recognized, although it is not anticipated that the data from such audits will be accessible for a QUATRO audit. The QUATRO audit includes radiation oncology, medical physics and radiotherapy technology aspects of radiation treatment. It is intended to be comprehensive, but cannot be exhaustive as it is only a snapshot of a radiotherapy department at a specific point in time. Opportunities for improvement exist in all institutions.

1.4. STRUCTURE

To capture the actual level of competence of a department, the audit addresses simultaneously the issues of equipment, infrastructure and operation of clinical practice. A major part of the audit is patient oriented. Therefore, the structure of this publication follows the path of the patient, from diagnosis and decision to treat, through treatment prescription, planning, treatment preparation and delivery, to the end of the follow-up process. Clinical and medical physics procedures include radiation safety and patient protection when appropriate. Professional education and training programmes for radiation oncologists, medical physicists and RTTs are given special attention.

² Treatment outcome depends on the multidisciplinary treatment of cancer patients; it seldom depends on a single modality. Because of the timescale involved, it reflects the practice from five to ten years ago, which is not necessarily related to the current practice. Finally, treatment outcome data are not always immediately available. To capture the treatment outcome data, a follow-up audit three to five years after the QUATRO audit would need to be organized.

1.5. IAEA ACTIVITIES IN DOSIMETRY AUDITING

The IAEA has a long history of providing assistance for dosimetry audits in low and middle income countries, for the education and support of radiotherapy professionals and for the review of the radiotherapy process in a variety of situations. Teletherapy dosimetry audits have been widely performed by several national and international organizations for approximately 60% of radiotherapy centres operating worldwide [5].

The IAEA, together with the World Health Organization (WHO), has performed dosimetry audits by mail to verify the calibration of teletherapy beams in radiotherapy departments (or hospitals) in low and middle income countries since 1969 [4, 6]. The programme aims to improve the accuracy and consistency of clinical dosimetry in radiotherapy hospitals worldwide. Over a period of 50 years, the IAEA/WHO programme has performed more than 15 500 dosimetry audits in over 2500 radiotherapy hospitals in 139 countries. Detailed follow-up procedures for audit results outside the acceptance limits have been implemented since 1996, including on-site visits for which the IAEA has developed a standardized set of procedures to aid the radiotherapy physics experts in resolving discrepancies in dosimetry at hospitals [7]. The procedures include a review of the dosimetry equipment, data and techniques, verification measurements and training of local staff.

1.6. PURPOSE OF A QUALITY AUDIT

The ultimate purpose of a quality audit is to assess the current situation and to improve the quality of the radiotherapy process at the reviewed institution or programme.

A comprehensive audit of a radiotherapy programme reviews and evaluates the quality of all the elements involved in radiation therapy, including staff, equipment and procedures, patient protection and safety, and the overall performance of the radiotherapy department, as well as its interaction with external service providers. Possible gaps in technology, human resources and procedures are identified so that the institutions audited are able to address areas for improvement. Radiotherapy departments operating at a high level of competence have the following capabilities:

- (a) To deliver a sustainable radiotherapy service to international standards³ (see Refs [8–10] and Appendix I);
- (b) To serve as a model for other radiotherapy centres in the country or region;
- (c) To provide training for professional staff working in radiotherapy.

The high standard of radiotherapy services, once achieved, needs to be maintained over a long timescale to ensure the adequate sustainability of competence level. A follow-up comprehensive audit would need to be organized after a period of three to five years through IAEA, regional or national structures, or professional bodies⁴, in order to demonstrate that the standard of radiotherapy services delivered by such a department continuously complies with the competence capabilities listed above.

Institutions in Member States may request an audit for the following purposes:

- (a) To support their application to become an accredited training centre;
- (b) To receive assistance to improve clinical practice;
- (c) To strengthen their QA programme;
- (d) To receive assistance to ensure that the requirements for patient safety are met;
- (e) To serve as guidance for further departmental development;
- (f) To document gaps in technology, training and practices in order to solicit funding from national authorities or other funding bodies, including the IAEA;
- (g) To obtain an independent review of their level of competence.

This audit is not designed for the following purposes:

- (a) Regulatory purposes (i.e. the teams are not convened as an enforcing tool, but solely as an impartial source of advice on quality improvement).
- (b) Investigation of accidents or reportable medical events (misadministration). In the event of an investigation specifically into these aspects, a more focused audit is required.
- (c) Assessment for entry into cooperative clinical research studies, as these are conducted by peers within the group involved in the study and are focused on

 $^{^3}$ The standards achievable need to be sustainable in the Member State's economic environment. Therefore, this will represent a value judgement of the auditors on the appropriateness of the infrastructure on-site and whether it is being used effectively.

⁴ Such regional or national auditing structures are for the most part still to be developed.

the strict adherence of an institute to a single specified clinical protocol on a selected group of patients.

2. AUDIT STRUCTURE FOR QUATRO MISSIONS

2.1. REQUEST FOR A QUATRO AUDIT

Comprehensive audits in radiotherapy are voluntary. The request for a QUATRO audit normally originates from the radiotherapy department to be audited. The administration of the institution or the national Ministry of Health may also request an audit. The head of the audited department has to endorse it, in order to assure optimum cooperation and to maximize the benefit of the audit.

The institution requesting an audit needs to have the basic equipment infrastructure to deliver good quality radiotherapy. This includes teletherapy and brachytherapy treatment machines, supported by appropriate equipment for dosimetry, imaging and treatment planning, computers, and immobilization devices. Should the IAEA see that these criteria are not met, it could offer guidance on how to achieve this basic level.

In order for the audit team to be chosen appropriately, as much information as possible about the current status of the department and the reasons for the audit needs to be received by the IAEA prior to the audit visit. It is the responsibility of the requesting institution to clearly formulate the purpose of the audit and to transmit this to the audit team.

2.2. COMPOSITION OF THE ON-SITE AUDIT TEAM

The audit methodology is designed for execution by a multidisciplinary peer review panel (audit team), whose expertise is predominantly in radiotherapy. It is important that the on-site audit team includes experts in all aspects of the programme to be audited. The members of the audit team need to be familiar with the audit methodology. Preferably, at least one member is able to interview staff members of the audited department in a language they understand.

The composition of the on-site audit team depends on the scope, level and expected content of the audit visit, but usually includes as a minimum the following members:

(a) A radiation oncologist;

- (b) A radiotherapy medical physicist;
- (c) An RTT;
- (d) An engineer, quality manager or other member with special competencies (e.g. a qualified expert in radiation safety) as appropriate.

2.3. PREPARATION FOR THE AUDIT

The success of an audit depends heavily on the thorough preparation of all parties involved, including the participating institution, the audit team and the sponsoring organization (IAEA).

2.3.1. Role of the institution

The institution's tasks in preparation for an audit are the following:

- (a) To formulate the objectives of the audit;
- (b) To prepare data and relevant documentation to enable the auditors to complete their evaluation in accordance with the methodology presented in this publication (see Sections 3–7), and using the dedicated templates provided by the IAEA;
- (c) To provide the information needed to review and prepare to perform the dosimetry audit(s);
- (d) To identify and ensure the participation of individuals needed for the audit, although ideally the audit team would be free to interview any staff member it deems appropriate;
- (e) To inform the entire department and hospital management of the audit and its time frame;
- (f) To provide the treatment records requested by the audit team, although ideally the audit team would be free to review any of the records available when they are on site;
- (g) To provide any clinical records from outside the department deemed relevant to the cases reviewed.

2.3.2. Role of the auditors

Auditors are required to prepare as follows:

- (a) To be familiar with the audit procedures, discuss the approach to be taken and allocate responsibilities⁵;
- (b) To review the preparatory and background information prepared by the institution and that provided by the IAEA;
- (c) To request additional information if necessary;
- (d) To prepare entrance and exit briefings;
- (e) To commit to provide a comprehensive report about their visit.

2.3.3. Role of the IAEA

The IAEA has the following role:

- (a) To select an appropriate audit team.
- (b) To inform the institution about the methodology to be applied in accordance with this publication.
- (c) To prepare a clear outline of the objectives of the audit visit in collaboration with the requesting institution.
- (d) To request all necessary data from the institution (e.g. type of equipment, persons in charge, size of department, type of department, staffing and patient load).
- (e) To brief the audit team, emphasizing the control on the dissemination of the audit report (see Sections 2.6 and 2.7).
- (f) To facilitate the introduction of the audit team to the institution.
- (g) To review all prior interactions with the IAEA, including dosimetry audits, expert visits and special audits (e.g. recent IAEA/WHO or other dosimetry audit results and expert reports). If a dosimetry audit has not recently taken place, the IAEA will arrange one prior to the comprehensive audit.
- (h) To arrange for the availability of a dosimetry kit for independent audit measurements.

⁵ Experts should consult Appendix II to ensure that commonly used terms are correctly interpreted in the audited department (e.g. treatment, session and patient).

2.4. GUIDING PRINCIPLES AND PROCEDURES OF THE AUDIT

The auditors will evaluate the overall performance of the radiotherapy department. In the process, the team will ideally obtain a comprehensive understanding of the operational setting of the department. Auditors need to consider the interaction of the radiotherapy department with other hospital departments involved in cancer management, such as gynaecology, surgical specialities and medical oncology, diagnostic imaging and pathology laboratories, and with the hospital administration. Auditors need to be able to interview all relevant staff members to assess the smooth and efficient flow of information and cooperation between the different professionals involved.

Auditors need to seek evidence of a patient oriented organization, with a culture of improvement through learning, openness to new technologies and strong cooperation among staff members. An appropriate quality management programme or system is ideally in place to ensure continuous quality improvement. If research is conducted, its integration into clinical practice and contribution to patient care needs to be assessed.

The tasks to be performed during any clinical audit are described in Sections 2.4.1–2.4.3.

2.4.1. Entrance briefing

An entrance briefing is required to introduce the auditors to the various staff members and to discuss the methods, objectives and details of the audit. The auditors will reassure the department that institutional and patient confidentiality will be respected.

2.4.2. Assessment

Both the infrastructure of the department and the overall radiotherapy programme will be audited. The infrastructure includes staffing, equipment and facilities. An examination of the radiotherapy programme — from the initial introduction of the patient, evaluation, staging, treatment planning and delivery through to follow-up — will be carried out.

Checklists have been designed to help auditors organize the audit programme and to ensure coverage of all relevant topics (see Sections 3–7). The detailed programme of an audit depends on the reasons for the audit, and a selection of topics may be made from the full audit checklists as appropriate. In addition to the checklists, the following tools are used:

(a) Staff interviews;

- (b) Complete tour of the facility;
- (c) Review and evaluation of procedures and all relevant documentation, including a review of treatment records;
- (d) Practical measurements and other tests of the performance of local systems and procedures, where appropriate and relevant;
- (e) Observation of practical implementation of working procedures.⁶

Coordinated input from clinicians, medical physicists and RTTs on aspects of the treatment process will ideally be audited by the whole audit team. Only specialized aspects of the treatment process will be audited by individual audit team members. A sign-off procedure by the audit team, assuring the department of institutional and patient confidentiality, may be required.

2.4.3. Exit briefing

It is essential that the auditors present their preliminary feedback to the department. At the completion of the audit, the institution will convene appropriate members from all groups of the therapy team who were interviewed for an interactive exit briefing. This will include time for questions, and ideally allows for a detailed and open discussion of all the findings of the experts. Initial commendations and recommendations could also be made if they are not controversial.

Immediately after the audit, preliminary recommendations are to be presented in written format. The institution is to be encouraged to ask questions and make an initial response to the assessment. The steps intended by the institution to respond to the recommendations and improve the activities of the department also need to be discussed and recorded.

When measurements have been performed as part of the audit, completed forms and calculations are to remain with the institution (see Section 5.1.4).

2.5. CONCLUSIONS OF THE AUDIT TEAM

Auditors are expected to comment on how well the institution has satisfied the criteria set out in the checklists. They will form and express an opinion regarding the appropriateness of the staffing in relation to the patient throughput. They are also expected to comment on type, quality and amount of equipment.

⁶ Direct observation of patient treatment is part of the review of records. This may require the consent of both the patient and their radiation oncologist.

An evaluation of the quality of patient care will be given in the context of the audit objective and the resources available.

If the department wishes to expand to new areas of expertise, appropriate separate recommendations will be made.

Auditors may recommend whether a follow-up visit or internal audit is required. If the recipients of the audit report fail to implement recommendations, and these are considered to be significant because of their potential impact on patient treatment outcomes, the recipients are to be informed of their responsibility to notify the regulatory authorities.

With respect to gaps in technology, infrastructure and procedures, the audit team may identify two levels of issues:

- (1) Easily resolved areas. These may either require minor changes, which are relatively easy to implement, or involve major changes that require modifications to infrastructure but are feasible for the department. These will be included in the detailed recommendations of the audit team.
- (2) Major problems that cannot be resolved by the radiotherapy department without significant changes outside the hospital or without significant additional resources. The solution to these problems may require government action and, if so, the relevant recommendations need to be included in the audit report.

In some cases, the audit team may wish to recognize the department as operating at a high level of competence (see Section 1.6).

2.6. THE AUDIT REPORT

The audit results are presented in the form of an audit report, which consists of two parts: a summary report and a detailed report. The summary report summarizes the visit and its conclusion, while the detailed report includes the details of the audit, comments by the auditors, and their conclusions, commendations and recommendations, if any.

A useful audit report contains conclusions formulated in an unambiguous way, with clear and practical recommendations. To arrive at valid conclusions, the audit group addresses a series of key topics and measurements, which will constitute the objective part of the report. These items will be discussed from the broader perspective of the local radiotherapy organization and culture to produce a comprehensive document describing the audited department. The report is ideally concise. A report template will be made available by the IAEA to assist auditors in the report preparation and at the same time ensure consistency across the audit teams. A suggested structure includes the following:

- (a) Objectives of the audit;
- (b) A brief description of audit activities;
- (c) Description of the facility (infrastructure, workload, etc.);
- (d) Findings and results of the visit (including checklists);
- (e) Benchmarking, if appropriate;
- (f) Conclusions;
- (g) Commendations and recommendations (to the institution, to the IAEA and to the government);
- (h) Annexes.

It is important that the audit report mentions whether the audit team was welcomed or not. The degree of cooperation from the institution, department and various members of the radiotherapy team has a significant impact on the credibility of the final report. Audit reports are kept confidential at all times, with access allowed only for clearly designated recipients and the IAEA staff facilitating the audit.

It should be understood that while it is the responsibility of the IAEA experts to discuss shortfalls in the services of the audited institution, the audit does not necessarily commit the IAEA to rectifying any deficiencies identified.

2.7. DISSEMINATION OF THE REPORT

The detailed audit report will only be sent to staff in responsible positions in the radiotherapy department. This includes, for example, the head of the department, the chief medical physicist, the head RTT and other staff members whose role in the institution is significant to the audit.

In QUATRO audits sponsored by the IAEA, a summary report is prepared by experts for dissemination through the IAEA to the relevant national authorities. Amongst these are the National Liaison Officer for technical cooperation and the national Permanent Mission. This summary report will include a short description of the audit findings and its main conclusions. It will refer only to essential verifiable facts and exclude any value judgements.

Recommendations in the summary report will be directed to the institution, the national authorities and the IAEA. Recommendations to the IAEA are to be confined to general statements (e.g. the need for a follow-up visit). Only if the audit is performed in the context of a national technical cooperation project are specific IAEA interventions for training fellowships, expert missions or equipment to be recommended.

3. INFRASTRUCTURE

3.1. CONTEXT OF THE RADIOTHERAPY DEPARTMENT

The auditors will assess the adequacy of the objectives of the radiotherapy department in the context of national cancer care, and the degree to which the existing infrastructure is sufficient and properly used for addressing those objectives.

3.1.1. Objectives of a radiotherapy department

The head of the radiotherapy department is responsible for answering the following questions about the department:

- (a) What is its role within the health care system?
- (b) What is its relationship with neighbouring oncology services (if any)?
- (c) What is its relationship with other specialities within the hospital?
- (d) What is its role in teaching: undergraduate and/or postgraduate?
- (e) What is its role in research?
- (f) What are its current objectives (as they relate to quality, utilization of resources and institutional approach to patient care) and what documentation does it have to support these objectives?
- (g) What is its financial structure and source of funding (state, private, etc.)?
- (h) What are its visions and plans for the future?

3.1.2. Patient demographics

Auditors need to familiarize themselves with the definitions used to determine a 'new patient' and a 'new cancer' in order to assess patient numbers and statistics. A number of different conventions exist, some of which are addressed in Appendix II. Demographic factors may be assessed in terms of the following:

- (a) Source of information (e.g. a cancer registry).
- (b) Number of new cases (cancer or patients) per year (see Appendices II and III). Is information on new cases registered in a cancer registry?
- (c) Types of cancer (primary tumour sites and numbers).
- (d) Stages of disease of the more common tumours.
- (e) Criteria for defining curative (radical) and palliative treatments.

- (f) Ratios of curative treatments to moderately high dose palliative therapy to palliative treatments.
- (g) Fraction of cancer patients (of the total number in the catchment area) who are referred for radiotherapy, where statistical data are available.
- (h) Socioeconomic concerns with an impact on treatment,⁷ which include the type of payment required by hospitals from patients (e.g. medical insurance, private funding (paid by patient), government funding (free for patient) or co-payment), as well as reimbursement systems (e.g. payments per patient or payments based on treatment technique, total dose or dose per fraction).

3.2. STRUCTURE OF THE RADIOTHERAPY DEPARTMENT

An important aspect of the audit is the assessment of the levels of staffing, the professional competence of the staff, the organization of the work and the adequacy of the premises.

3.2.1. Personnel

Consideration of the following aspects will help auditors gain an understanding of the appropriateness of staffing numbers in different professional groups, and of the professional qualifications of personnel.

- (a) Number of radiation oncologists:
 - Professional qualifications (e.g. degrees, specializations, certifications or fellowships);
 - (ii) Additional responsibilities (e.g. chemotherapy or nuclear medicine).
- (b) Number of medical physicists in radiotherapy, including clinically qualified radiotherapy medical physicists, physics assistants and dosimetrists:
 - (i) Professional qualifications (e.g. degrees, specializations, certifications or fellowships);
 - (ii) Additional responsibilities (e.g. diagnostics or radiation protection).
- (c) Number of RTTs:
 - (i) Professional qualifications (e.g. degrees, specializations, certifications or fellowships);
 - (ii) Additional responsibilities (e.g. treatment planning, equipment QA, quality management).

 $^{^7}$ The most common confounding factor is the proportion of the cost of therapy that is levied on the patients (and their families). In some societies this will militate against the elderly or women receiving treatment.

- (d) Number of other personnel (e.g. nurses).
- (e) If there is no professional title in one or more of these professions, is there a local policy on education?
- (f) What other members of staff (e.g. clinical engineers, dosimetrists, nurses, social workers, psychologists) are there?
- (g) Is there a programme for teaching junior medical staff (residents), medical students, medical physicists in training and RTT students? If yes:
 - (i) Number of residents;
 - (ii) Number of medical students;
 - (iii) Number of medical physicists in training;
 - (iv) Number of RTT students.
- (h) Is teaching part of routine activity?
- (i) Which professionals are involved in teaching?
 - (i) In an academic setting;
 - (ii) In a clinical setting.
- (j) Is research (basic and/or clinical) part of routine clinical activity?
- (k) Are any staff allocated to clinical research?

Additional questions are included in Checklists 40–42. Essential staffing levels are provided in Appendix I and in Refs [8, 11].

3.2.2. Departmental operation

The questions listed in this section will help the auditors to understand the organization of work in the department.

- (a) What are the working hours (within the department) of the radiation oncologists, medical physicists and RTTs?
- (b) What are the hours during which treatment is available at the department?
- (c) How many days per week is the department in operation?
- (d) Are emergency radiation services provided after hours?
- (e) What is the minimum number of RTTs for each shift for each major item of equipment?
- (f) What is the minimum number of radiation oncologists on-site or on duty during treatment hours?
- (g) What is the minimum number of medical physicists on-site during treatment hours?

3.2.3. Premises

The physical layout of the department is ideally disclosed to the auditors in advance, prior to the audit. The following aspects may help the audit team to assess the adequacy of the premises in the context of departmental objectives and operations:

- (a) Location of the radiotherapy department relative to the main hospital (off-site or standalone, on-site, integrated into main building.
- (b) Size and layout of the department:
 - (i) Treatment rooms and control rooms;
 - (ii) Rooms for imaging equipment required for treatment planning;
 - (iii) Examination rooms, changing rooms, consultation rooms, toilets and waiting rooms;
 - (iv) Dosimetry, treatment planning and physics rooms, workshop and laboratory space;
 - (v) Block cutting rooms (with appropriate ventilation) and storage rooms.
- (c) Secretarial areas, meeting rooms and filing rooms.
- (d) Proximity of radiotherapy department to teaching facilities, laboratories, imaging services, etc.
- (e) Extent of access to additional sources of information related to medical sciences, such as a library, research journals or the Internet.
- (f) Wards and numbers of beds (e.g. male, female, paediatric).
- (g) Availability of guest house accommodation for patients and/or families.

3.2.4. Radiotherapy equipment

A full inventory needs to be made of all major equipment on-site. This includes teletherapy equipment (status: functional, partially functional or redundant), brachytherapy equipment, imaging equipment, radiotherapy workshop (or mould room) and treatment planning equipment, as well as non-functional and decommissioned equipment that may occupy useful space. The inventory would contain the following information:

- (a) Type, age and number of teletherapy machines;
- (b) Type, age and number of brachytherapy units;
- (c) Radioactive sources, storage facilities, radiation safety equipment;
- (d) Available imaging equipment (including simulation);
- (e) Available treatment planning equipment;
- (f) Oncology information system;
- (g) Radiotherapy workshop (or mould room) equipment;

- (h) View boxes, film processors, computerized networked image review stations;
- (i) Immobilization and positioning devices;
- (j) Patient alignment equipment, lasers, etc.;
- (k) Dosimetry and QA equipment: phantoms, dosimeters, etc.;
- (1) Supporting equipment, items and spaces:
 - (i) Secretarial areas, computers, printers, fax machines, typewriters and telephones;
 - (ii) Access to filing rooms, storage and delivery of records (off-site or on-site);
 - (iii) Patient reception area, waiting room chairs, wheelchairs and stretchers.

A list of major equipment items relevant to a radiotherapy department in a limited resource setting is provided in Appendix I. In terms of sustainability, it would be important to establish whether an institutional equipment replacement programme exists and whether there is a calendar for preventative maintenance work on the major equipment in the department.

3.3. COMMUNICATIONS

Communication between professionals internal and external to the radiotherapy department is of the utmost importance to ensure the quality, accuracy and safety of practices. The following aspects will be evaluated by the auditors in the areas audited:

- (a) Record keeping and documentation (clinical and medical physics data). Access to relevant documents and clinical records for professionals, as appropriate and required.
- (b) Across disciplines and different hospital services; access to hospital and physician records.
- (c) Horizontal communication (between staff members with the same function) and vertical communication (between senior and junior staff members).
- (d) Between different areas of the radiotherapy process.
- (e) Between staff on different shifts, when applicable.
- (f) Adequacy of electronic and telephone communication.

3.4. WORKLOAD

3.4.1. Patient throughput on radiotherapy equipment

When assessing the quality of radiotherapy services, patient throughput on radiotherapy equipment is an important aspect to consider. The following information needs to be made available to the auditors:

- (a) The annual number of new cancer cases⁸ or consultations of patients entering the department. (This figure can be much larger than the number of radiotherapy treatments if the department integrates medical oncology and/or haematology.)
- (b) The number of new radiotherapy cases treated annually in the department.
- (c) The number of sessions/fractions⁹ delivered monthly over a one year period by each teletherapy machine (T).
- (d) The number of applications/fractions delivered annually by each brachytherapy machine (B).¹⁰
- (e) The annual number of computed tomography (CT) scans performed for planning purposes.
- (f) The annual number of other imaging modality scans (e.g. positron emission tomography (PET)–CT, magnetic resonance imaging) used for treatment planning purposes.
- (g) The annual number of simulations performed.
- (h) The annual number of treatment plans generated by computer treatment planning.
- (i) The relative proportion of simple, intermediate and complex treatments each machine delivers.
- (j) The average time slot allocated for a standard treatment on each machine.
- (k) The methods of allocation and calculation of time slots for more complex treatments.
- (1) The maximum number of fractions and fields in any one day on each therapy machine. (Although case accrual may fluctuate during the year, the maximum daily figures give an indication of what the department can handle when under pressure.)

⁸ Appendix III provides details of annotations on the quantification of 'cancer cases'.

⁹ Definitions are provided in Appendix II.

¹⁰ Patients receiving both external beam radiotherapy and brachytherapy are recorded twice. Therefore, the number of individuals treated in a department is not simply the sum of T + B. Auditors need to address this point unambiguously.

3.4.2. Statistics

The following data need to be considered when analysing the adequacy of the existing infrastructure in terms of human resources and equipment in the context of departmental operations:¹¹

- (a) The annual number of patients seen by each radiation oncologist. Separate data for radiotherapy and chemotherapy, if appropriate. (It is to be specified whether the radiation oncologist also prescribes chemotherapy.)
- (b) The annual number of courses per teletherapy machine.
- (c) The number of treatment fractions per day.
- (d) The average number of fractions per course of treatment.
- (e) The annual number of courses of treatment per radiation oncologist.
- (f) The annual number of courses of treatment per medical physicist.
- (g) The annual number of treatment plans generated by treatment planning systems (TPSs) per medical physicist, RTT or dosimetrist (as applicable).
- (h) The annual number of courses of treatment per RTT.
- (i) The annual number of treatment fractions per RTT.
- (j) The number of RTTs per equipment item.

3.5. CONSIDERATIONS FOR THE INTRODUCTION OF NEW TECHNOLOGY IN THE RADIOTHERAPY DEPARTMENT

Radiotherapy technologies evolve continuously. Equipment ranges from versatile modern linear accelerators equipped with imaging devices to highly specialized stereotactic radiosurgery or intraoperative radiotherapy equipment.

In the context of this publication, new technologies and techniques are defined as follows:

- (a) New installations, including buildings, equipment, hardware and software;
- (b) Upgrades of existing technology to provide new functionalities;
- (c) Updates of processes and procedures, including changes in treatment techniques;
- (d) Changes in treatment approaches and workflows (e.g. fractionation).

Consideration needs also to be given to changes, upgrades or installation of new equipment in other parts of the hospital that may affect radiotherapy practices (e.g. the introduction of picture archiving and communication systems,

¹¹ Definitions are provided in Appendix II.

the installation of a new diagnostic CT scanner or the introduction of PET, PET–CT and/or MRI in radiology). Wherever possible, radiotherapy staff should consider how these developments can benefit their services.

It is important to audit the framework and approach followed for the introduction, use and QA of new technologies and techniques in a radiotherapy department. Particular emphasis is given to how the objectives of the new technologies or techniques within an evidence based and patient centred environment are defined and agreed by the professionals in the department. The roles and responsibilities of the professionals and their education and training associated with the introduction of new technology and techniques are also to be reviewed by the auditors.

Planning for the introduction of new technology is another area to be reviewed and includes the analysis of needs, budgeting, tendering, specifications, and consideration of the requirements of associated services and devices, both within and external to the radiotherapy department. The following questions are to be answered by the auditors:

- (a) Have the timelines for the project been defined?
- (b) Was a needs analysis carried out at the local, regional and national levels?
- (c) Is new equipment replacing the existing equipment?
- (d) Will the new equipment/process extend the departmental capability in radiation treatments?
- (e) Will the new equipment/process improve the quality of radiotherapy practices?
- (f) Has the integration of new technology/techniques/processes with the existing facilities, services and processes been addressed? How will it impact on them?
- (g) Were the relevant members of the multidisciplinary team involved in planning the new facility/equipment?
- (h) Did the planning address the need for new staff?
- (i) Did the planning include staff training?
- (j) Were the building costs estimated and budgeted for?
- (k) Were the main equipment costs included? Was a life cycle costing conducted?
- (1) Is there an equipment warranty in place? What is the length of the warranty period? What are the arrangements for the maintenance services?
- (m) Were dosimetry, QA and patient-specific accessory devices considered and budgeted for?
- (n) Have any additional requirements been defined?
- (o) Have radiation protection issues been addressed? Were the local regulatory requirements integrated in planning? Was a prospective risk evaluation made?

- (p) Was a responsible person identified for the acceptance testing? Was an acceptance testing report prepared? Was all acceptance testing documentation readily available for review?
- (q) Was a responsible person identified for the new equipment commissioning? Has protected time been allocated for the medical physicist(s) to perform the equipment commissioning?
- (r) What are the considerations for long term planning and sustainability of new technology?

3.6. OVERALL ASSESSMENT OF AUDIT FINDINGS

The QUATRO checklists in Sections 4–7 have been designed to assist auditors in their evaluation of radiotherapy practices in audited departments. Lists of topics to review are included together with the checklists. Required answers may be simply yes or no, but they may also indicate the frequency of a process or a procedure, or reflect the quality of practices. The descriptors categorizing items undergoing an audit and the assessment criteria are provided for each checklist to help the auditors in their evaluation and to ensure consistency between the audit teams. The descriptors and the assessment criteria are presented in Table 1.

At the end of each checklist or group of checklists, the auditors are asked to give an overall assessment of their findings, taking into account the variation in importance of the topics identified. The auditors are also expected to comment on their observations and findings with more detailed explanations of the reasons for the overall assessment, detailing any deviations that need special attention. This will assist in drawing up the final conclusions, commendations and recommendations.

Descriptor	1	2	3	4
Frequency	None of the time	Some of the time	Most of the time	All of the time
Processes and practices	Poor	Needs major improvement	Needs minor improvement	Appropriate
Policies and procedures	Not developed	Started	Advanced/ in progress	Appropriate

TABLE 1. DESCRIPTORS OF ITEMS UNDER REVIEW AND ASSESSMENT CRITERIA

TABLE 1. DESCRIPTORS OF ITEMS UNDER REVIEW AND ASSESSMENT CRITERIA (cont.)

Descriptor	1	2	3	4
Resources (capital, human, educational)	Poor	Needs major improvement	Needs minor improvement	Appropriate
Overall assessment	Poor	Needs major improvement	Needs minor improvement	Appropriate

4. PATIENT RELATED PROCEDURES

Patient related procedures describing the clinical process are to be reviewed by the whole audit team, except for those procedures where the expertise resides exclusively with radiation oncologists. Checklists may need to be completed by some or all members of the audit team.

4.1. IDENTIFICATION OF PATIENTS

It is crucial that mechanisms are in place to ensure that the correct patient, and the correct anatomical area of the patient, are treatment planned and treated (Checklist 1). The risk of radiotherapy misadministration otherwise increases.

A precise system to confirm patient identity is needed (e.g. checking an official identification document against the information in the radiotherapy file). Methods will depend on national regulations regarding confidentiality of patient information. However, the audit team needs to ensure that an appropriate system is in place and in use.

CHECKLIST 1. IDENTIFICATION OF THE PATIENT AT THE START OF THE DIAGNOSTIC WORKUP AND THROUGHOUT THE TREATMENT PROCESS

Items to be reviewed by auditors	Response		
	YES NO		
How is a patient identified? Name Gender Address/telephone number Age (date of birth, if known) National identification number Hospital identification number Departmental identification number File number Bar code Biometric system Image of the patient			
Comment on the identification process:			
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$		

4.2. DIAGNOSIS AND STAGING

Investigations leading to tumour diagnosis and staging are necessary to deliver radiotherapy. The auditors will assess the degree to which the available infrastructure is used for patient diagnosis, staging and planning. The intent is to evaluate the presence and use of appropriate tools. The auditors may also consider recommendations on the introduction of cost effective additional investigations that may be justifiable.

Checklists 2–7 will help to document the existence and use of these tools.

CHECKLIST 2. CLINICAL RECORDS

Items to be reviewed by auditors	Response		
Processes and practices: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	1 2 3 4		
Filing system			
Clinical history			
Physical examination			
Comment on the status of clinical records:			
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$		

CHECKLIST 3. PATHOLOGY DOCUMENTATION

Items to be reviewed by auditors	Response		
	YES NO		
Location of pathology services On-site Off-site			
Is the pathology report in all patients' files?			
<i>Resources:</i> 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	1 2 3 4		
Hospital policy with regard to review of outside pathology			
Ability to obtain outside pathology consultation			
Access to special stains, immunohistochemistry, hormonal receptors, etc.			

CHECKLIST 3. PATHOLOGY DOCUMENTATION (cont.)

Comment on the quality and timeliness of services:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

CHECKLIST 4. ACCESS TO RADIOLOGICAL, ULTRASONOGRAPHIC AND NUCLEAR MEDICINE IMAGING (IN THE CONTEXT OF THE DIAGNOSTIC WORKUP)

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(Refer also to Checklist 25 in Section 5.1.2)

Items to be reviewed by auditors	Response			
	YES	NO		
Access to X rays				
Access to mammography				
Access to ultrasound				
Access to CT				
Access to MRI				
Access to PET, PET-CT, etc.				
Are significant radiological findings reported in the patient's chart?				
Delay (days) for diagnostic procedures:				
Comment on the quality of service related to national resources (i.e. waiting times or any other impairment in access to staging procedures):				
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate		3 4		

Note: CT – computed tomography, MRI – magnetic resonance imaging, PET – positron emission tomography.

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CHECKLIST 5. ACCESS TO LABORATORY FACILITIES

Items to be reviewed by auditors	Response	
	YES NO	
Haematology		
Biochemistry		
Delay (days) to obtain results:		
Access to immunology, genetics, mutation testing, etc.		
Are significant laboratory findings reported in the patient's folder?		
Comment on the quality and timeliness of services related to national resources:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

CHECKLIST 6. ENDOSCOPY PROCEDURES

Items to be reviewed by auditors	Response	
	YES NO	
Are specialists available?		
Are there endoscopy reports in patient charts?		
Comment on endoscopy procedures:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

CHECKLIST 7. STAGING

Items to be reviewed by auditors	Response	
	YES NO	
Are patients staged?		
Is the staging documented?		
Staging system: TNM AJCC FIGO Institutional Other		
Performance status: WHO Karnofsky ECOG		
<i>Frequency:</i> 1–None of the time, 2–Some of the time, 3–Most of the time, 4–All of the time	1 2 3 4	
Consistency of documentation: Consistency of reporting of surgical staging when appropriate Consistency of reporting of prior chemotherapy when appropriate		
Comment on staging procedures:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

Note: AJCC – American Joint Committee on Cancer, ECOG – Eastern Cooperative Oncology Group, FIGO – International Federation of Gynecology and Obstetrics, TNM – tumour, node, metastasis, WHO – World Health Organization.

4.3. INDICATIONS AND DECISION TO TREAT

Indications and decision to treat are based on clinical assessment and existing guidelines. For any patient in the radiotherapy department, the decision to treat will have been taken by a radiation oncologist (Checklists 8–10).

CHECKLIST 8. MULTIDISCIPLINARY MEDICAL APPROACH

Items to be reviewed by auditors	Response	
Frequency: 1-None of the time, 2-Some of the time, 3-Most of the time, 4-All of the time	1 2 3 4	
Are decisions to treat based upon meetings of multidisciplinary teams (tumour boards)?		
Comments:		
If meetings do take place, comment on the meetings with respect to: Whether every patient is discussed Which specific types of tumours are discussed by each team The frequency of meetings The meeting location (radiotherapy department, hospital)		
If not a multidisciplinary team, who generally refers the patient to the radiotherapy department (e.g. self-referred, a general practitioner or a specialist)?		
Is the decision to treat inappropriately affected by outside factors (e.g. economical, other specialities)?		
Comment on multidisciplinary practice:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

CHECKLIST 9. PRACTICE GUIDELINES

Items to be reviewed by auditors	Response	
Frequency: 1-None of the time, 2-Some of the time, 3-Most of the time, 4-All of the time	1 2 3 4	
Are written departmental protocols available for the most common clinical management situations?		
What standards are followed by the department (hospital protocol manuals, national or international guidelines, textbooks, evidence based medicine)?		
Are clinical protocols ratified by a departmental committee?		
Are the treatment protocols reviewed regularly?		
Indicate frequency of review:		
Are the tumour/site specific protocols applied consistently within the department (i.e. are tumours of a particular site and stage treated the same way)?		
Are regular meetings held to verify adherence to protocols?		
Comment on the adequacy of guidelines and departmental policy:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

CHECKLIST 10. PATIENT INFORMATION AND CONSENT

Items to be reviewed by auditors	Response
	YES NO
Does a formal consent and agreement form exist in each patient's file?	
Are the benefits and risks of radiotherapy explained to patients?	

CHECKLIST 10. PATIENT INFORMATION AND CONSENT (cont.)

Is there a protocol for the role of specific radiotherapy staff in the informed consent process?	
Comment on patient information and consent:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

4.4. TREATMENT PREPARATION: INSTRUCTIONS FOR PLANNING

Preparation and planning phases need to precede delivery of treatment and be completed in a precise and reproducible way. Checklists will assess the equipment and procedures used for localization, simulation and immobilization (Checklist 11), including mould room devices and procedures (Checklist 12).

CHECKLIST 11. LOCALIZATION, SIMULATION AND IMMOBILIZATION

(Refer also to Checklists 26 and 27 in Section 5.1.2)

Items to be reviewed by auditors	Response
	YES NO
Specify major equipment used for localization: Fluoroscopic simulator CT simulator CT dedicated for planning — 4-D CT — Dual energy CT — Shared with diagnostics Treatment unit (on-board imaging) MRI PET or PET-CT Other (e.g. bone scan image)	
Film processor, if applicable: Type: Location relative to simulator:	

CHECKLIST 11. LOCALIZATION, SIMULATION AND IMMOBILIZATION

(Refer also to Checklists 26 and 27 in Section 5.1.2) (cont.)

Is there an image viewing system close to the simulator?		
Comment on the integrity of geometric accuracy throughout the treatment preparation process (e.g. fiducial marks, coordinate system or lasers, flat couch on CT):		
Are localization/simulation resources used appropriately?		
Comments:		
Who is present during simulation/localization? Radiation oncologist Medical physicist RTT Other		
What is the role of the radiation oncologist/medical physicist/RTT, if present?		
Is a procedures manual available for simulation?		
Are specific imaging protocols for simulation configured in the treatment console?		
Is an exposure chart available (e.g. kVp, mA·s)?		
Are X ray film geometric parameters available?		
Do the clinical tumour/site specific protocols contain instructions for immobilization?		
Comment on geometric accuracy:		
Is a field (skin) marking protocol to refer the beam setting for treatment available? How are fields marked?		
How are marks maintained during treatment? Are tattoos used in routine practice? How are marks documented for RTTs?		

CHECKLIST 11. LOCALIZATION, SIMULATION AND IMMOBILIZATION

(Refer also to Checklists 26 and 27 in Section 5.1.2) (cont.)

RTT pre-treatment quality control procedures (simulation, localization, planning): Labelling of simulation/portal film images (e.g. patient name/ ID, date, field size, treatment parameters, signature of radiation oncologist/RTT):	
Is there adequate time for simulation procedures?	
Is a procedures manual available?	
Describe the process for RTTs to review the procedures manual:	
Body contouring method (e.g. machine, wire): Who carries out contouring? Comment on contouring practice:	
Are photographic images acquired?	
Data transfer from imaging to planning: Manual transfer? Automatic transfer? Comment on data transfer:	
Comment on overall procedures:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

Note: CT – computed tomography, MRI – magnetic resonance imaging, PET – positron emission tomography, RTT – radiation therapist.

CHECKLIST 12. MOULD ROOM (ONCOLOGY WORKSHOP) AND BEAM MODIFICATION DEVICES, IF APPLICABLE (*Refer also to Checklist 28 in Section 5.1.2*)

Items to be reviewed by auditors	Response	
	YES NO	
Is an MLC used?		
 Are standard blocks used? Is the inventory sufficient? Are standard blocks mounted? If blocks are to be mounted on a shadow tray, who mounts them? For unmounted blocks, how is the block position determined daily? Comment on standard blocks: 		
Are blocks customized (individualized)? Are they used for photon beams? Are they used for electron beams? Who designs the blocks?		
Who cuts the blocks?Are customized blocks fixed to shadow trays?Is there sufficient stock of alloy for the clinical throughput?Comment on customized (individualized) block production and use:		
Is there a sufficient number of shadow trays for clinical throughput?		
How are blocks verified? Prior to treatment With first portal film (image)		
Are missing tissue or dose compensators manufactured and used?		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

Note: MLC – multileaf collimator.

4.5. PRESCRIPTION AND PLANNING

This section describes auditing the process of teletherapy planning. The auditors will evaluate the following (Checklists 13 and 14):

- (a) The interaction between different members of staff and whether they work well together as a functional unit;
- (b) The means for ensuring the reproducibility of radiation administration;
- (c) Quality assurance procedures.

CHECKLIST 13. TREATMENT PRESCRIPTION

(Refer also to Checklists 29 and 30 in Section 5.1.2)

Items to be reviewed by auditors	Response	
Specify type of TPS:		
	YES NO	
Is there a procedures manual (treatment guidelines or protocols) for treatment prescription and planning, including site specific geometric arrangement of beams?		
2-D procedures (beam arrangements)3-D procedures (e.g. organs at risk, definition of target volumes)		
 4-D procedures^a Comment on the relative proportions of manual, 2-D, 3-D and 4-D treatment techniques: 		
Frequency: 1-None of the time, 2-Some of the time, 3-Most of the time, 4-All of the time	1 2 3 4	
Are tumour volumes delineated? For curative (radical) patients For palliative patients		
Are the following target volumes used (see ICRU Reports 50, 62 and 83 ^b)? GTV CTV PTV ITV Others:		

CHECKLIST 13. TREATMENT PRESCRIPTION

(Refer also to Checklists 29 and 30 in Section 5.1.2) (cont.)

Are there standardized and documented CTV to PTV margins for different tumours?	
Comment on volume delineation:	
For which sites is planning optimization used?	
Does the treatment prescription include: Definition of volumes? Definition of critical organs?	
Is the modality (photons, electrons) specified?	
Is the beam energy specified?	
Are the beam modifiers (e.g. wedges, blocks) specified?	
Is the patient position (e.g. supine, prone) specified?	
Is the dose per fraction specified?	
Is the total dose specified?	
Are the number of fractions specified?	
Is the total treatment time for schedules other than once daily, five times per week specified?	
Is the prescription checked before planning?	
Is the prescription signed by the radiation oncologist?	
Comment on the dose specification:	
Comment on documentation pertaining to treatment prescription:	

CHECKLIST 13. TREATMENT PRESCRIPTION (*Refer also to Checklists 29 and 30 in Section 5.1.2*) (cont.)

Overall assessment:

1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate

Note: CTV – clinical target volume, GTV – gross tumour volume, ITV – internal target volume, PTV – planning target volume, TPS – treatment planning system.

- ^a All methods of motion management used in 4-D procedures are typically based on the breathing patterns of the patient.
- ^b See International Commission on Radiation Units and Measurements (ICRU) Reports 50 [12], 62 [13] and 83 [14].

CHECKLIST 14. TREATMENT PLANNING

(Refer also to Checklists 29 and 30 in Section 5.1.2)

Items to be reviewed by auditors	Response	
	YES NO	
Which treatment planning technique is used? Isocentric, SAD SSD Other (for Tomotherapy, CyberKnife, etc.)		
How are calculations performed? Manually By computer — 2-D TPS — 3-D TPS		
How many individuals check treatment plans and dose calculations before first treatment?		
Are the checks carried out by personnel from different professional groups?		
What beam data are used by the TPS? Generic Specific		
Are treatment machines uniquely identified in the TPS?		

CHECKLIST 14. TREATMENT PLANNING (*Refer also to Checklists 29 and 30 in Section 5.1.2*) (cont.)

Does the TPS have the capacity to generate dose-volume histograms?	
If so, are dose–volume histograms used by: Radiation oncologists? Medical physicists? RTTs? Other staff? Unused?	
Comments:	
Policies and procedures: 1–Not developed, 2–Started, 3–Advanced/in progress, 4–Appropriate	1 2 3 4
Policies on maximum and minimum doses to PTV	
Procedure for treatment plan endorsement (signed) by the radiation oncologist	
Procedure for treatment plan endorsement (signed) by the medical physicist	
Procedure for treatment plan endorsement or handover (signed) by an RTT (or other appropriate staff member)	
What is the procedure if planning is not endorsed?	
Frequency: 1-None of the time, 2-Some of the time, 3-Most of the time, 4-All of the time	1 2 3 4
Quality checks of treatment plans Specify:	
Quality checks of dose calculations Specify:	

CHECKLIST 14. TREATMENT PLANNING (*Refer also to Checklists 29 and 30 in Section 5.1.2*) (cont.)

Patient specific quality assurance for advanced treatment techniques (e.g. IMRT, VMAT) prior to treatment		
What type of other quality checks are performed?		
	YES NO	
Are protocols in place for quality checks of treatment plans?		
Are protocols in place for quality checks of dose calculations?		
Are there planning review meetings? Who are the participants? What is the frequency of these meetings?		
Comment on the quality of treatment planning:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

Note: Checklist 14 should be filled in separately for photon and electron beams. IMRT – intensity modulated radiation therapy, PTV – planning target volume, RTT – radiation therapist, SAD – source–axis distance, SSD – source–skin distance, TPS – treatment planning system, VMAT – volumetric modulated arc therapy.

4.6. FROM PLANNING TO DELIVERY

This section refers to the audit of data transfer from treatment planning to treatment delivery (Checklist 15).

CHECKLIST 15. DATA TRANSFER FROM PLANNING TO DELIVERY

Items to be reviewed by auditors	Response	
	YES NO	
Are simulation or virtual simulation reference images agreed prior to the course of treatment?		
Are data transferred from planning to delivery: Manually? Automatically?		
Is the data transfer double-checked? What is the frequency of checks? Who is the person in charge?		
Comments (include medical physics and RTT input):	<u>.</u>	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate		

Note: RTT – radiation therapist.

4.7. TREATMENT DELIVERY: TELETHERAPY

Auditors are encouraged to visit the different treatment units and explore the treatment delivery procedures directly on-site (Checklists 16–17). If the department treats children, auditors need to consider any necessary differences (e.g. general anaesthesia, immobilization).

CHECKLIST 16. ORGANIZATION OF WORK AT THE TREATMENT MACHINE

Items to be reviewed by auditors	Response		
	Comments		
What is the number of RTTs assigned to each treatment unit?			
What is the minimum number of RTTs physically present at the treatment unit for each individual treatment?			
What is the number of RTTs inside the treatment room for each individual treatment set-up?			
What is the time allowed for each patient on the treatment sched	lule?		
Policies and procedures: 1–Not developed, 2–Started, 3–Advanced/in progress, 4–Appropriate	1 2 3 4		
Procedures to ensure the correct patient is treated with the correct field and accessory devices			
Procedure to deal with side effects observed or reported to the RTT			
Comments:			
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$		

Note: RTT – radiation therapist.

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CHECKLIST 17. IDENTIFICATION OF THE PATIENT ON A DAILY BASIS

Items to be reviewed by auditors	Response	
	YES NO	
How is a patient identified on a daily basis? Name (e.g. 'What is your name?', not 'Are you Mr./Ms. X?') Date of birth One or more of the accepted ID numbers Photograph ID (face) Photograph of the treatment site or field marks Anatomical sketch (diagram) showing location of treatment fields to be applied Other (e.g. barcode, etc.)		
Are children handled differently from adults?		
How is patient confidentiality ensured?		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate		

Note: ID – identification.

(Refer also to Checklist 31 (megavoltage and orthovoltage units) in Section 5.1.2)

Items to be reviewed by auditors	Response	
	YES	NO
Is a patient appointment book kept at each individual machine? Computerized By hand (paper based)		
Comments:		
Time allocated for the first treatment session: Is the time allocated adequate? Do RTTs have enough time to familiarize with the new treatment parameters and any special requirements before the patient is		
called in? Is a radiation oncologist present? Does the radiation oncologist physically check the set-up? Does the radiation oncologist check the portal film?		
Is the medical physicist present: — For all treatments? — For difficult set-up problems only? Is the medical physicist's presence mandatory? If not mandatory, is the medical physicist's presence an option? Is the treatment process explained to the patient? Are portal films/images obtained prior to the first treatment? Are there initial portal imaging protocols for each tumour site and technique? Comment on the protocols for initial image review and approval,		
and how changes in the set-up are managed:		

(*Refer also to Checklist 31 (megavoltage and orthovoltage units) in Section 5.1.2)* (cont.)

Verification of patient set-up (positioning and immobilization): Skin marks? Tattoos? Are immobilization devices available? Comments: Are notes/diagrams or photographs of the treatment position available?	
Is a laser used for setting up? Is optical guidance technology used? Is portal verification carried out throughout the treatment? — If yes, when? — How frequently? Comment on the procedures for patient set-up and portal imaging verification:	
MUs and treatment times: Is there an independent daily check of MUs? Is this cross-checked with a calculator on the first treatment day? Is this a part of the QA of treatment plans?	
Are routine checks made of treatment charts? If yes, how often? By whom?	
How are patients monitored during exposure? With a video system With an audio system Other methods (describe):	
 How is in vivo dosimetry performed? Using passive dosimetry (e.g. thermoluminescence dosimeters or optically stimulated luminescence dosimeters) Using on-line point dosimetry with diodes, MOSFET, etc. Using EPID based dosimetry Other methods (describe): Comment on the frequency of in vivo dosimetry and the patients on whom it is used: 	

(*Refer also to Checklist 31 (megavoltage and orthovoltage units) in Section 5.1.2)* (cont.)

Policies and procedures: 1–Not developed, 2–Started, 3–Advanced/in progress, 4–Appropriate	1	2	3	4
IGRT procedures: Is patient set-up verified through volumetric IGRT? If yes, for which sites? Are protocols available? Is there a procedure for on-line image review? Is there a procedure for off-line image review? Who is responsible for performing image co-registration? Comments:				
	Y	TES	N	0
Are all patients clinically reviewed during treatment? If yes, how frequently? By whom (radiation oncologist, nurse, medical practitioner, RTT)? Comments:	[]
Does the facility have the infrastructure to manage combined chemotherapy and radiotherapy treatments? Comments:	[]
Policies and procedures: 1–Not developed, 2–Started, 3–Advanced/in progress, 4–Appropriate	1	2	3	4
Policy for managing interruptions in treatment: Machine breakdowns Patient related:				
 Acute side effects Non-attendance Policy for adjusting time/dose following interruptions Are the reasons for interruption of a treatment reported? Are the reasons for not completing a treatment (early termination) reported? 				
Protocol for handling acute medical emergencies in the treatment room				

(*Refer also to Checklist 31 (megavoltage and orthovoltage units) in Section 5.1.2)* (cont.)

	YES	NO
Are emergency trolleys available? Is staff training for dealing with medical emergencies in place?		
Comments:		
<i>Frequency:</i> 1–None of the time, 2–Some of the time, 3–Most of the time, 4–All of the time	1 2	3 4
RTT quality control procedures: Are treatment set-ups double checked? Are set-up notes current and accurate? Special instruction compliance (e.g. review films)? Are new orders from the radiation oncologist checked? Are any field/dose parameter changes noted? Are any gap/separation changes noted? Are recalculations done and approved? Are dose additions complete and correct? Are independent checks of the MUs performed? Are portal films/images retaken? Are portal films/images approved? Are blood-work compliance and results checked? Are nursing instructions recorded? Is there a procedure for patient care? Is the patient condition documented? Are daily treatment entries complete and signed? Is there weekly quality control of charts/records? Is documentation complete?		
	YES	NO
 Patient documentation retained in the treatment area: Is retrieval of patient documents satisfactory? Is there a signature protocol when documents are removed? Are RTTs involved in patient review? Is this on a daily basis? Is this on a weekly basis? What is recorded on the treatment sheet, how is it recorded and by whom? 		

(*Refer also to Checklist 31 (megavoltage and orthovoltage units) in Section 5.1.2)* (cont.)

Protocol on patient care: Is there a protocol on patient education (including psychosocial aspects)? Is there a health and safety protocol (including infection control)?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	3 4 □ □

Note: EPID – electronic portal imaging device, IGRT – image guided radiotherapy, MOSFET – metal oxide semiconductor field-effect transistor, MU – monitor unit, QA – quality assurance, RTT – radiation therapist.

4.8. DEVIATIONS IN RADIOTHERAPY ADMINISTRATION

A deviation in radiotherapy administration refers to any therapeutic treatment delivered to the wrong patient or the wrong tissue, or where a dose or dose fractionation differs substantially from the values prescribed. It also refers to any equipment fault, error, mishap or occurrence with the potential to cause patient exposure different from that intended (Checklist 19).

CHECKLIST 19. DEVIATIONS IN RADIOTHERAPY ADMINISTRATION (Refer also to Checklists 38 and 39 in Section 6)

Items to be reviewed by auditors	Response	
Comment on how an incident that requires reporting to the regulatory authority is defined:		
Comment on how an incident that is not considered reportable to the is defined:	regulatory	authority
	YES	NO
Are all incidents reported?		
Are 'near incidents' reported?		
Are incidents reported to the general hospital incident reporting system?		
Is a radiotherapy-specific reporting system in place? Is it easily accessible?		
Is the treating radiation oncologist immediately notified of an incident?		
Is there a committee in place to deal with incidents?		
Is there a systematic reporting of incidents to a hospital committee?		
— Verbal? — Written?		
Is a decision taken on the significance of the deviation?		
authority?		
Are improvement actions based on the incident/'near incident' reported?		
Comment on the mechanism for implementation of improvement ac	tions:	
Comment on how feedback is given following the incident report and analysis:		

CHECKLIST 19. DEVIATIONS IN RADIOTHERAPY ADMINISTRATION (*Refer also to Checklists 38 and 39 in Section 6*) (cont.)

What is the procedure for the reporting of an error made by a radiation oncologist, a medical physicist or an RTT?		
Is a system in place to enable anonymous reporting?		
Is a 'just culture' ^a policy in place in the department? Comments:		
What is the process to review errors and 'near misses'? Who is involved in the review process?		
What is the feedback policy?		
What is the policy for informing patients about incidents?		
What is the mechanism for corrective actions, and are all profession team involved?	s of the radi	otherapy
What is the mechanism for the implementation and monitoring of ch	nange?	
Have incidents been reported? If yes, how many?		
Have 'near incidents' been reported? If yes, how many and/or how often?		
Is there an awareness of general health and safety regulations?		
Is a policy in place to manage non-radiation-related incidents?		
Is a reporting mechanism in place for non-radiation-related incidents?		
Comment on how non-patient-related incidents are managed: Staff, radiation related Staff, non-radiation related Members of the general public, radiation related Members of the general public, non-radiation related		
Is a policy in place for managing disclosure following an incident?		

CHECKLIST 19. DEVIATIONS IN RADIOTHERAPY ADMINISTRATION (*Refer also to Checklists 38 and 39 in Section 6*) (cont.)

Comment on the overall management of incidents in the department	:
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

Note: RTT – radiation therapist.

A just culture recognizes that individual staff members should not be held accountable for system failings over which they have no control. It further recognizes that many errors result from predictable interactions between humans and the system in which they work. It also recognizes that competent professionals can make mistakes.

4.9. BRACHYTHERAPY

This section guides audits of the process of administering brachytherapy to patients (Checklists 20–22). Gynaecological cancer is the most frequent indication for brachytherapy worldwide, and the auditor will place particular emphasis on gynaecological brachytherapy. If other brachytherapy activities are carried out regularly in a visited department, the auditor will record them. It is at the discretion of the auditor to evaluate any of the non-gynaecological applications in further depth by using the gynaecology checklist (Checklist 21) as a guide.

CHECKLIST 20. BRACHYTHERAPY PRACTICE (*Refer also to Checklist 33 in Section 5.1.2*)

Items to be reviewed by auditors	Response	
Where is the brachytherapy treatment area located relative to teletherapy?		
	YES NO	
The types of brachytherapy applications performed: Surface Intraluminal Intracavitary Intraoperative Interstitial		
The utilization of brachytherapy: As a boost after external beam therapy Alone Intraoperative		
Mode of operation: Manual Remote		
The isotopes and systems used for brachytherapy: Caesium-137 LDR Caesium-137 MDR Iridium-192 HDR Cobalt-60 HDR Electronic Other (specify):		
Comments:		
Which imaging systems are available for daily clinical routine? X ray CT Ultrasound MRI Other (specify):		
Is a TPS available that can handle CT or MRI DICOM images?		
Is a TPS available that can handle radiographic image digitalization?		

CHECKLIST 20. BRACHYTHERAPY PRACTICE *(Refer also to Checklist 33 in Section 5.1.2)* (cont.)

Is a TPS available that can only perform 2-D planning?	
Comment on the brachytherapy suite design (e.g. space, shielding, ap treatment room, separate afterloading and implant room):	ppropriateness of
Comments:	
Overall assessment:	
1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Note: CT – computed tomography, DICOM – Digital Imaging and Communications in Medicine, HDR – high dose rate, LDR – low dose rate, MDR – medium dose rate, MRI – magnetic resonance imaging, TPS – treatment planning system.

CHECKLIST 21. GYNAECOLOGICAL BRACHYTHERAPY PROCEDURE (Refer also to Checklists 33 and 34 in Section 5.1.2)

Items to be reviewed by auditors	Response	
	YES NO	
What types of applicators are used? Ring type applicators Ovoid type applicators Cylinder Mould technique Combined intracavitary/interstitial Interstitial perineal templates Which of those are single use? Which of those are CT/MRI compatible?		
— Manual? — Automatic?		
Are there aseptic conditions for the insertion of applicators?		
Are applicators sterilized between uses?		

CHECKLIST 21. GYNAECOLOGICAL BRACHYTHERAPY PROCEDURE (*Refer also to Checklists 33 and 34 in Section 5.1.2*) (cont.)

Who inserts the applicators? Radiation oncologist Gynaecologist RTT Nurse		
What type of anaesthesia/analgesia is generally used for cervical ca	ancer?	
Is an anaesthesiologist available?		
Comments:		
Are the recommendations of ICRU Reports 38 and/or 89 ^a for dose prescribing, reporting and recording in use?		
	Manual	Computer
For cervical cancer, what is the method of dose prescription/ calculation? ICRU Report 38 ICRU Report 89 To point A To point B Other reference points/volumes Rectum Bladder Other organs at risk		
	YES	NO
Is in vivo dosimetry performed for cervical cancer treatment? Rectum Bladder		
Comment on the prescribing, recording and reporting in gynaecological brachytherapy:		
Does the radiation oncologist validate the prescription?		
Is the radiation oncologist (or a medical practitioner) present throughout the dose delivery procedure?		
Who removes the applicators?		

CHECKLIST 21. GYNAECOLOGICAL BRACHYTHERAPY PROCEDURE (*Refer also to Checklists 33 and 34 in Section 5.1.2*) (cont.)

Does the responsible medical physicist see and sign the dose calculation?		l]
Does the responsible radiation oncologist see and sign the dose calculation?]
Are dose calculations cross-checked?]
Is there a check to identify the patient in relation to the treatment plan?]
Is there a cross-check process at the treatment console?]
Is there an independent dose calculation?]
What is the procedure for ensuring no source loss during treatment	?			
If low dose rate non-automatic brachytherapy is employed, how are the medical and nursing staff informed of the time to remove the source?				
What is the procedure for unloading sources (e.g. handling, transposurces)?	ortation, s	tora	ige (of
Policies and procedures: 1–Not developed, 2–Started, 3–Advanced/in progress, 4–Appropriate	1	2	3	4
Safety training for staff: Source loading Source unloading Source handling Source transportation Control of visitors				
Are emergency procedures in place? Are safety drills for HDR brachytherapy performed periodically? Comments:				
Is there coordination in scheduling treatment between brachytherapy and teletherapy units?				

CHECKLIST 21. GYNAECOLOGICAL BRACHYTHERAPY PROCEDURE (*Refer also to Checklists 33 and 34 in Section 5.1.2*) (cont.)

Comments:

Overall assessment:

1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate

Note: CT – computed tomography, HDR – high dose rate, MRI – magnetic resonance imaging, RTT – radiation therapist.

^a See International Commission on Radiation Units and Measurements (ICRU) Report 38 [15] and Report 89 [16].

CHECKLIST 22. BRACHYTHERAPY OTHER THAN GYNAECOLOGY

(Refer also to Checklists 33 and 34 in Section 5.1.2)

Items to be reviewed by auditors	Response	
	YES	NO
Is brachytherapy performed for the following clinical sites?		
Head and neck		
Comment on technique(s) used:		
Prostate		
Comment on technique(s) used:		
Breast		
Comment on technique(s) used:		
Skin		
Comment on technique(s) used:		
Other (specify):		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	1 2 □ □	3 4 □ □

4.10. DOCUMENTATION OF TREATMENT

This section refers to the recording and reporting of a treatment after its delivery for patients not participating in clinical trials (Checklist 23). Usually there is a legal requirement for record keeping. Additionally, internal audits and clinical research require access to previous treatment data.

CHECKLIST 23. DOCUMENTATION OF TREATMENT

Items to be reviewed by auditors	Response	
<i>Frequency:</i> 1–None of the time, 2–Some of the time, 3–Most of the time, 4–All of the time	1 2 3 4	
Preservation of the treatment record at the completion of treatment: Final chart check by the medical physicist or other appropriate staff member (RTT)		
A treatment summary is compiled		
Comment on the long term archiving of patient files including ease of a retrieval:	ccess and	
Is there a record of the treatment in the patient's (hospital) records? Are the hospital records readily available?		
Is a copy of the treatment summary sent to the referring physician?		
Is a copy of any details in the treatment file given to the patient?		
Are cancer data communicated to a national/regional cancer registry?		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	

Note: RTT – radiation therapist.

4.11. FOLLOW-UP

Patient follow-up is essential as a means of determining the outcome of treatment (e.g. cancer control, side effects or misadministration). Follow-up is an important tool for internal and external audits. Auditors will ideally evaluate the level of consistency of the follow-up policy throughout the department (Checklist 24).

Items to be reviewed by auditors Response YES NO Do all radiotherapy patients get a follow-up appointment after П treatment? Curative? Palliative? П What is the interval between the last treatment and the first follow-up appointment? Is the follow-up policy the same for curative and palliative intents? Is there a follow-up policy for the different types of cancer? П For how long are patients followed up? One year П П Two years Five years In excess of five years Where is the follow-up done? In the radiotherapy department Elsewhere Is the follow-up done by physicians other than radiation oncologists? П Is the follow-up done by nurses or social workers? If follow-up is performed outside the radiotherapy department, are the reports on the patient outcomes available to the radiotherapy department?

CHECKLIST 24. PATIENT FOLLOW-UP

CHECKLIST 24. PATIENT FOLLOW-UP (cont.)

 Are tumour control, failure and complications recorded at follow-up? Is radiation toxicity documented? Is radiation toxicity graded? Are the follow-up data analysed in terms of the above? — By whom? 	
Is there a policy of systematic review of patients with serious complications?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

4.12. REVIEW OF TYPICAL TREATMENTS

The auditors will request examples of the documentation for typical treatments of common cancer cases for review and analysis. Such cases may include the following:

- (a) Solitary bone metastasis in arms (non-weight bearing bones);
- (b) Multiple brain metastases;
- (c) Radical treatment for common cancers (e.g. head and neck, cervix, lung);
- (d) Breast cancer after conservative surgery;
- (e) Brachytherapy, as appropriate.

Ideally, a representative number of cases of curative, palliative and post-operative treatment will be selected by the auditors; the ratios of these types of treatments can be different in different departments.

The auditors will interpret these cases in relation to whether the funding of the department:

- Is sufficient;
- Is insufficient;
- Is based on fees for specific services versus packages per type of tumour/pathology;
- Is based on fees per annum.

5. EQUIPMENT RELATED PROCEDURES

5.1. EQUIPMENT QUALITY ASSURANCE: ASPECTS RELATED TO MEDICAL PHYSICS

5.1.1. Introduction

The purpose of this part of the audit is to obtain an overview of the medical physics QA processes, procedures, documentation and records, as well as to obtain a sampling of the physics dosimetry data, to assess whether all appropriate medical physics aspects are covered and properly implemented. Auditors are again advised that the goal is to perform representative tests without being exhaustive.

The structure of an equipment related quality audit is similar to the overall audit structure and is closely integrated with it (i.e. it is based on checklists, discussion with local personnel and observation). However, in addition, measurements need to be carried out as part of the review of the dosimetry dataset, along with sample checks for data consistency and examples of clinical dose (and related) calculations for benchmark cases.

The data review, measurements and calculations are necessarily limited in scope by the time available. The measurements are only of basic parameters. The calculations are only for relatively simple situations. Therefore, the conclusions from the data evaluation are only valid within these limitations (i.e. of what it is possible to examine in the time available).

Any significant discrepancies or possible inconsistencies in the dataset need to be recorded and discussed with the local medical physics personnel. The QUATRO medical physics auditor may recommend that the IAEA identify an expert to visit the department to perform more exhaustive tests, as described in Ref. [7].

The medical physics auditor is expected to be fully occupied with the structure and general process audit, along with the other auditors, in the normal time frame of the first three days of the group audit. Therefore, it is not possible to carry out measurements or a more detailed evaluation of data and calculations in that time frame. Instead, the medical physics auditor will normally be expected to carry out these measurements after hours or on Day 4 of the audit. For part of the review (e.g. immobilization), the presence of the RTT may be useful.

5.1.2. Quality assurance checklists for medical physicists

Quality control (QC) procedures and their documentation and records, where appropriate, need to be reviewed for all items of medical physics equipment.

The auditors will note who routinely performs the medical physics activities: a resident medical physicist(s), a contracted medical physicist, or other personnel to whom the duties have been delegated (Checklists 25–35).

CHECKLIST 25. 3-D IMAGING FOR TREATMENT PLANNING (INCLUDING CT, CT SIMULATOR, PET–CT, MRI AND OTHER)

Items to be reviewed by auditors	Response	
	Comments	
Equipment specifications: Make and model Type Date of installation Location (in-house identification)		
	YES	NO
Are operations manuals available?		
Are radiotherapy personnel trained to use the equipment? CT CT simulator PET–CT MRI Other (specify):		
Who is involved in the preparation of imaging procedures?		
If the CT is in the diagnostic imaging department, is a flat table top available?		
Is a laser light system available? Fixed Mobile		
How are data transferred to the TPS?		

CHECKLIST 25. 3-D IMAGING FOR TREATMENT PLANNING (INCLUDING CT, CT SIMULATOR, PET–CT, MRI AND OTHER) (cont.)

Is the system 4-D capable?	
QA programme: Is a QA manual available? Are acceptance procedures in place? Are commissioning procedures in place? Is a QC programme in place? Comment on tests, frequencies, responsible persons, action levels,	
actions: Is QC carried out for mobile lasers? Is an incident log book available? Is there a procedure/policy for equipment breakdown?	
Is there an adequate radiation protection and safety system in place?	
Repair and maintenance programme: Is a maintenance contract in place? Is a log book available? What is the frequency of preventive maintenance? Who is in charge of repairs? What is the procedure to accept repairs before the clinical use of equipment?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	3 4 □ □

Note: CT – computed tomography, MRI – magnetic resonance imaging, PET – positron emission tomography, QA – quality assurance, QC – quality control, TPS – treatment planning system.

CHECKLIST 26. LOCALIZATION AND X RAY SIMULATION (*To be completed for X ray fluoroscopic simulators only*)

Items to be reviewed by auditors	Response		
	Comments		
Equipment specifications: Make and model Date of construction Date of installation			
	YES NO		
Is an operations manual available?			
Education and training of personnel on the use of equipment:			
Localization/simulation procedure and involvement of medical physicist:			
QA manual used:			
Acceptance procedures:			
Commissioning procedures:			
 QA programme including tests, frequencies, responsible persons, tolerance and action levels, actions and reports: Mechanical and geometrical tests, including: Lasers ODI Central axis Field size indicators Light and radiation field coincidence Angle indicators (gantry angle and collimator angle) Collimator rotation isocentre Gantry rotation isocentre Couch movements (vertical, lateral, rotation) Coincidence of simulator and couch rotation isocentres Compatibility of couches and scales between simulator and treatment unit Field wires and contouring devices Image quality tests (dose rate, kVp and mA·s calibration, high and low contrast resolution, film/image processing) 			
CHECKLIST 26. LOCALIZATION AND X RAY SIMULATION (*To be completed for X ray fluoroscopic simulators only*) (cont.)

Are simulation parameters automatically transferred to the planning system?		
Incident log book:		
	YES NO	
Repair and maintenance programme: Is a maintenance contract in place? Is a log book available? What is the frequency of preventive maintenance? Who is in charge of repairs? What is the procedure to accept repairs before the clinical use of equipment?		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate		

Note: ODI – optical distance indicator, QA – quality assurance.

CHECKLIST 27. IMMOBILIZATION

Items to be reviewed by auditors	Response
	Comments
Role of radiation oncologists:	
Role of medical physicists:	
Role of RTTs:	
Education and training of personnel:	
Commercial or in-house devices:	
Appropriateness of devices:	

CHECKLIST 27. IMMOBILIZATION (cont.)

Availability of devices:	
Identification of devices (e.g. RFID, interlocks to machines):	
Acceptance, commissioning and QC of devices:	
Storage of devices:	
Dosimetry checks, where appropriate:	
Documented procedures, where relevant:	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Note: QC – quality control, RFID – radio frequency identification, RTT – radiation therapist.

CHECKLIST 28. MOULD ROOM (ONCOLOGY WORKSHOP) AND BEAM MODIFICATION DEVICES, IF APPLICABLE

(Complete in conjunction with Checklist 12)

Items to be reviewed by auditors	Response	
	Comments	
Role of medical physicist/RTT:		
Dosimetry checks, as appropriate:		
Equipment and devices available:		
Identification of modification devices (e.g. RFID, interlocks to machines):		
Acceptance, commissioning and QC of devices:		
Repair procedures, where appropriate:		

CHECKLIST 28. MOULD ROOM (ONCOLOGY WORKSHOP) AND BEAM MODIFICATION DEVICES, IF APPLICABLE (*Complete in conjunction with Checklist 12*) (cont.)

Data transfer and verification:		
Communication:		
Comment on standard blocks:		
	YES NO	
Are QA procedures performed on a hot wire cutter?		
Are customized blocks fixed to shadow trays?		
Are there sufficient shadow trays for clinical load?		
Is there sufficient low melting point alloy for clinical throughput?		
Comment on customized (individualized) block/cut-out production and use:		
Comment on QA and medical physicists' role in mould room and workshop procedures:		
Comment on compensators and bolus:		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate		

Note: QA – quality assurance, QC – quality control, RFID – radio frequency identification, RTT – radiation therapist.

CHECKLIST 29. TREATMENT PLANNING SYSTEM

Items to be reviewed by auditors	Response	
	Comments	
 Specifications of the TPS: Make, model and version: Algorithm types (specify for different modalities): — Are Monte Carlo algorithms available? Date of installation/acceptance: Latest upgrade: 		
	YES NO	
Manual of operation/documentation of algorithms?		
Treatment modalities supported: 2-D 3-D CRT IMRT VMAT SRS SABR/SBRT Electrons Brachytherapy Protons/ions Other (e.g. knowledge based or automatic planning)		
Image handling: Import licences CT to relative electron density curve(s) (generic/locally acquired) Handling of non-CT datasets (MRI, PET, SPECT) Image fusion — 2-D (rigid) — 3-D (rigid) — Deformable Are data available from previous treatments?		

CHECKLIST 29. TREATMENT PLANNING SYSTEM (cont.)

Contouring: Tools available (e.g. contouring in non-axial planes) Auto-contouring tools (e.g. Atlas based? Artificial intelligence?) Statistics (e.g. volume, dimensions) Margin creation (e.g. isotropic, non-isotropic, automated, editable) Boolean operations Training of personnel for use: OA manual used: Acceptance procedures and reports: Commissioning procedures and reports: Methods to obtain beam data Beam modelling (vendor or user) Smallest field commissioned Verification methodology (what recommendations were followed?) End-to-end tests Image registration (e.g. automatic, rigid, deformable) Volumes, automatic contouring and dose-volume histogram accuracy Measurement and QA procedures for Hounsfield units Archiving and retrieving of plans Participation in external dosimetry audits: Consistency of TPS data with other departmental dosimetry data sets: OA programme including tests, frequencies, responsible persons, action levels, actions and reports that includes the following: Test calculations/sample plans Checks of single field Geometric accuracy Checks of dose distributions Reproduction of dose distribution for input data Monitor unit/treatment time calculation Hardware input/output devices Data transfer Incident log book and reporting:

CHECKLIST 29. TREATMENT PLANNING SYSTEM (cont.)

	YES	NO
 Breakdown management: Is there a policy/procedure for managing breakdowns? Does it include: Procedure for patient treatment planning continuity? Type of fault? Repair procedure documentation? Is a machine fault log book in place? Are data analysed regularly? Are corrective and preventive actions defined in accordance with breakdown analysis? Procedure for the occurrence of a fault: 		
Repair, maintenance and upgrade programme: Is a maintenance contract in place? What is the frequency of preventive maintenance? Are hardware and software upgrades included in the maintenance contract? Are hardware and software updates included in the maintenance contract?		
Is there a procedure to accept repairs, updates or upgrades and then authorize clinical use?		
Documentation pertaining to upgrades of the TPS includes: Log book Responsible person Procedure to accept changes prior to clinical use		
Is there support from manufacturers (assistance with		
Are there links to user groups?		
Is a TPS PC/workstation/server used for any purpose other than treatment planning (since non-TPS software increases the chances of corrupting the TPS files)?		
Who has access to the TPS server and how is it secured?		

CHECKLIST 29. TREATMENT PLANNING SYSTEM (cont.)

Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Note: Checklist 29 should be completed for every TPS in use. CRT – conformal radiotherapy, CT – computed tomography, IMRT – intensity modulated radiation therapy, MRI – magnetic resonance imaging, PET – positron emission tomography, QA – quality assurance, SABR/SBRT – stereotactic ablative radiotherapy/stereotactic body radiotherapy, SPECT – single photon emission computed tomography, SRS – stereotactic radiosurgery, TPS – treatment planning system, VMAT – volumetric modulated arc therapy.

CHECKLIST 30. PATIENT DOSE CALCULATION AND VERIFICATION PROCEDURES

Items to be reviewed by auditors	Response
	Comments
Responsibility for planning:	
Role of medical physicists or RTTs in planning:	
Procedures manual:	
Records of end to end audits when introducing new techniques:	
Request for planning and information provided:	
Interaction with responsible RO:	
Comment on plan optimization methodology:	

CHECKLIST 30. PATIENT DOSE CALCULATION AND VERIFICATION PROCEDURES (cont.)

	YES NO
Is there a peer review meeting so that the planning team uses consistent criteria for plan optimization?	
Is there a policy for the storage, archive, retrieval and backup of plans?	
 Patient specific QA: Documented plan and chart check methodology (tolerance and a Pre-treatment phantom measurements for individual patient plan Verification of the integrity of treatment plan transfer for deliver Independent MU/dose calculation system and method: 2-D 3-D CRT IMRT VMAT SRS SABR/SBRT Electrons Brachytherapy Protons/ions Other 	action levels) a verification y
Procedures and instructions for plan changes or replanning during	treatment:
General comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

Note: CRT – conformal radiotherapy, IMRT – intensity modulated radiation therapy, MU – monitor unit, QA – quality assurance, RO – radiation oncologist, RTT – radiation therapist, SABR/SBRT – stereotactic ablative radiotherapy/stereotactic body radiotherapy, SRS – stereotactic radiosurgery, VMAT – volumetric modulated arc therapy.

CHECKLIST 31. TREATMENT DELIVERY: TELETHERAPY (COBALT UNITS, MEDICAL ACCELERATORS AND ORTHOVOLTAGE X RAYS)

Items to be reviewed by auditors	Response	
	Comments	
Specifications of equipment: Make and model Date of construction Date of installation Location/local identification Machine configuration: — X ray energies — Flattening filter free option — Electron energies — MLC type/model — Wedges: physical/dynamic — IMRT capability — VMAT capability — In-room imaging capabilities — Other		
	YES NO	
Is an operations manual available?		
Training of personnel on use:		
Emergency procedures in place:		
Training on emergency procedures:		
QA manual:		
Acceptance procedures ^a and reports:		
Commissioning procedures and reports:		
Participation in external dosimetry audits:		
Radiation safety surveys:		

CHECKLIST 31. TREATMENT DELIVERY: TELETHERAPY (COBALT UNITS, MEDICAL ACCELERATORS AND ORTHOVOLTAGE X RAYS) (cont.)

QA programme including tests, frequencies, responsible persons, action levels, actions and reports:

Start-up procedures:

Mechanical and geometrical tests, including:

- Lasers
- ODI
- Central axis
- Field size indicators
- Light and radiation field coincidence
- Applicators and cones (electrons and kV X rays), including interlock checks
- MLC position and movements
- Angle indicators (gantry angle, collimator angle)
- Collimator rotation isocentre
- Gantry rotation isocentre
- Gantry rotation speed
- Couch movements (vertical, lateral, isocentre and column rotation)
- Coincidence of collimator, gantry and couch isocentres
- Coincidence of mechanical and radiation isocentres for the accelerator and imaging devices
- Dynamic couch checks
- Tabletop movements (with weight applied)
- Beam dosimetry and QC:
- Output constancy (daily test)
- Dosimeter for daily test
 - Calibration (certificate)
 - Constancy
- Beam calibration
- Code of practice for reference dosimetry
- Field size factors (including asymmetric jaws)
- Beam quality (TPR20, 10, R50, half-value layer)
- Depth dose dependence
- Beam profiles (including wedges and flattening filter free beams, as applicable)
- Small field dosimetry
- Other systems (e.g. MLC)
- Monitor units/timer set calculation
- Wedge and tray factors
- Virtual source position
- SSD variation
- Timer (Co-60 and kV units; linearity, timer error)
- Monitor unit linearity (X rays, electrons)
- Gantry angle dependence (e.g. beam quality, output factors, profiles, wedge factors, gantry speed)

CHECKLIST 31. TREATMENT DELIVERY: TELETHERAPY (COBALT UNITS, MEDICAL ACCELERATORS AND ORTHOVOLTAGE X RAYS) (cont.)

- MLC checks (e.g. leaf transmission)
- Special accessories (e.g. stereotactic equipment)

Additional parameters for electron beams (cone ratios, gap factors, others):

QC for special techniques, if any (total body irradiation, others):

Specific QC for intensity modulated techniques: CBCT vs linac isocentre check MLC performance checks (e.g. picket fence) End-to-end tests Machine log files Other tests (specify):

Specific QC for motion management:

Specific QC for adaptive radiotherapy:

Machine-integrated in vivo dosimetry (e.g. transit dosimetry using EPID): Equipment/software and methodology Calibration and QC Practical use

In-room imaging:

Equipment and methodology:

- 2-D (list all)
- 3-D (CBCT/in-room CT)
- 4-D

Acceptance, commissioning and QC Practical use

Motion management, if applicable: Surrogate marker type Gated delivery Breath-hold Feedback to patients (audio, video)

Connectivity to the oncology information system, e.g. record and verify functionality, patient information and scheduling system, as appropriate:

Incident log book and reporting:

CHECKLIST 31. TREATMENT DELIVERY: TELETHERAPY (COBALT UNITS, MEDICAL ACCELERATORS AND ORTHOVOLTAGE X RAYS) (cont.)

	YES	NO
Breakdown management:		
Is there a policy/procedure for managing breakdown?		
Does it include:		
 Compensation for loss of treatment time? 		
— Procedure for patient treatment replanning for continuity?		
 Prioritization of patients when transferring to another machine? 		
— Type of fault?		
— Repair procedure documentation?		
Is a machine fault log book in place?		
Are data analysed regularly?		
Are corrective and preventive actions defined in accordance with		
breakdown analysis?		
Procedure for the occurrence of a fault including communication		
channels:		
Repair and maintenance programme:		
Is a maintenance contract in place?		
Is a log book available?		
What is the frequency of preventive maintenance?		
Who is in charge of repairs?		
What is the procedure to accept repairs and/or upgrades before the		
clinical use of equipment?		
Comments:		
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	1 2 □ □	3 4 □ □

- Note: CBCT cone-beam computed tomography, EPID electronic portal imaging device, CT computed tomography, IMRT intensity modulated radiation therapy, MLC multileaf collimator, ODI optical distance indicator, QA quality assurance, QC quality control, SSD source–skin distance, VMAT volumetric modulated arc therapy.
- ^a These should include at least an independent verification of the beam calibration.

CHECKLIST 32. ONCOLOGY INFORMATION SYSTEMS/ RADIOTHERAPY INFORMATION TECHNOLOGY

Items to be reviewed by auditors	Response	
	Comments	
Specifications of equipment: Make, model and software version Date of installation		
	YES NO	
Is the radiotherapy network linked to the hospital information system, electronic medical record system and/or picture archiving and communication system networks?		
Are communication directions between the systems well described and secure?		
Are the radiotherapy servers located: In the department? Elsewhere? Are they easily accessible?		
Is an operations manual available?		
Are personnel trained in the use of IT systems?		
Are there designated staff members responsible for system management of the radiotherapy IT systems?		
Is there a QA manual?		
Acceptance procedures and reports?		
Commissioning procedures and reports?		
QA programme including tests, frequencies, data transfer robustness between systems, responsible persons, action levels, actions and reports:		
Is a specific backup policy in place? Archive and retrieval of data? Are hard copies maintained? — For how long?		

CHECKLIST 32. ONCOLOGY INFORMATION SYSTEMS/ RADIOTHERAPY INFORMATION TECHNOLOGY (cont.)

Is data storage: Physical? Virtual? On site? Is the format DICOM or DICOM-compatible? Are procedures in place for data integrity and security? Incident log book and reporting:	
Breakdown management: Is there a policy/procedure for managing breakdowns? Does it include: — Type of fault? — Repair procedure documentation? Is a system fault log book in place? Are data analysed regularly? Are corrective and preventive actions defined in accordance with breakdown analysis? Procedure for the occurrence of a fault, including communication channels:	
Repair, maintenance and upgrade programme: Is a maintenance contract in place?What is the frequency of preventive maintenance?Are hardware and software upgrades included in the maintenance contract?Are hardware and software updates included in the maintenance contract?	
Is there a procedure to accept repairs, updates or upgrades and then authorize clinical use?	
Who is responsible for support and repair? Company Hospital IT staff Radiotherapy department's staff	
Comments:	

CHECKLIST 32. ONCOLOGY INFORMATION SYSTEMS/ RADIOTHERAPY INFORMATION TECHNOLOGY (cont.)

Overall assessment:

1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate



Note: DICOM – Digital Imaging and Communications in Medicine, IT – information technology, QA – quality assurance.

CHECKLIST 33. BRACHYTHERAPY

Items to be reviewed by auditors	Response	
	Comments	
Specifications of equipment and systems: Manual Remote		
If remote: Make and model Date of manufacture Date of installation		
Type of services (HDR, LDR, PDR, electronic brachytherapy, robotic system):		
Brachytherapy sources used:		
Operations manual used:		
Training of personnel on use:		
QA manual:		
Acceptance procedures and reports:		
Source calibration (HDR or long lived sources): Certificate Traceability		
Commissioning procedures and reports:		

CHECKLIST 33. BRACHYTHERAPY (cont.)

Participation in external dosimetry audits:

QA programme including tests, frequencies, responsible persons, action levels, actions and reports:

Specific QC for brachytherapy:

Consistency of quantities and units between all components of brachytherapy treatment Accuracy of source positioning Coincidence of dummy and active sources Interlocks function Timer function

In vivo dosimetry, if used:

Radiation safety and radiation protection tests: Door interlocks Radiation warning lights and alarms Area monitor Portable survey meter Emergency on/off switches (LDR and HDR units) Emergency container and emergency kit for source handling Movable lead shields (manual LDR) Exposure in brachytherapy room during 'beam off' condition

Source dosimetry:

Dosimeter (well type ionization chamber or equivalent)

- Calibration (certificate)
- Constancy
- Source calibration
- Uniformity of a batch of sources
- Uniformity of 'linear' activity

Other items:

Source storage and disposal Transfer of sources Inventory of sources Source replacement policy Checking of contamination Source guides Mechanical integrity of applicators Cleaning, sterilization and check for contamination of applicators

Incident log book and reporting:

CHECKLIST 33. BRACHYTHERAPY (cont.)

	YES NO
 Breakdown management: Is there a policy/procedure for managing breakdowns? Does it include: Compensation for loss of treatment time? Procedure for rescheduling patient treatment? Type of fault? Repair procedure documentation? Is a machine fault log book in place? Are data analysed regularly? Are corrective and preventive actions defined in accordance with breakdown analysis? Procedure for the occurrence of a fault including communication channels: 	
Source incidents: What are the procedures for a stuck or damaged source? What is the procedure for a lost source? Incident log book and reporting: Comment:	
Repair and maintenance programme: Is a maintenance contract in place? Is a log book available? What is the frequency of preventive maintenance? Who is in charge of repairs? What is the procedure to accept repairs before the clinical use of equipment:	
Are source security systems, policies and procedures in place? Do they comply with the local regulations?	
General condition of the equipment and room:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Note: HDR – high dose rate, LDR – low dose rate, PDR – pulsed dose rate, QA – quality assurance, QC – quality control.

CHECKLIST 34. BRACHYTHERAPY TREATMENT PLANNING AND VERIFICATION

Items to be reviewed by auditors	Response
	Comments
Specifications of the TPS: Make, model and software version Algorithm type Date of installation/acceptance Latest upgrade of the TPS	
Treatment modalities supported and number of licences: HDR LDR Seeds Other	
Responsibility for planning: Who performs planning?	
Treatment planning methods (e.g. preplanning, on-line planning	, post-planning):
Procedures manual:	
 TPS commissioning: Comment on the commissioning procedures and reports: Methods to obtain source data: What source modelling (vendor or user) is used? — Based on the AAPM Task Group No. 43 Report^a, or equ — Monte Carlo based Verification methodology 	ivalent
Image registration (e.g. automatic, rigid, deformable):	
Localization and reconstruction for applicators, catheters, sources, moulds, etc.: Volumes, automatic contouring and dose–volume histogram accuracy Management of Hounsfield units Archiving and retrieving of plans	
Participation in external dose audits:	
Consistency of TPS data with other departmental dosimetry data	a sets:

CHECKLIST 34. BRACHYTHERAPY TREATMENT PLANNING AND VERIFICATION (cont.)

Plan optimization methodology:

Methodology for checking plans and charts (action levels):

Independent dose/time calculation system and method:

Methodology for approval of plans:

Methodology for transfer of data to treatment delivery unit:

Imaging specific to brachytherapy, if applicable:

Type of imaging for planning:

- C-arm
- Simulator
- CT
- MRI
- Ultrasound
- Other

Type of imaging for verification Image handling Image QA

Incident log book and reporting:

	YES NO
 Breakdown management: Is there a policy/procedure for managing breakdowns? Does it include: Procedure for patient treatment planning continuity? Type of fault? Repair procedure documentation? Is a machine fault log book in place? Are data analysed regularly? Are corrective and preventive actions defined in accordance with breakdown analysis? Procedure for the occurrence of a fault: 	
Documentation pertaining to upgrades of the TPS includes: Log book Responsible person Procedure to accept changes prior to clinical use	

CHECKLIST 34. BRACHYTHERAPY TREATMENT PLANNING AND VERIFICATION (cont.)

Is there support from manufacturers (assistance with troubleshooting)? Are there links to user groups?	
Is the TPS PC/workstation/server used for any purpose other than treatment planning (since non-TPS software increases the chances of corrupting the TPS files)?	
Is there integration with teletherapy?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

Note: CT – computed tomography, HDR – high dose rate, LDR – low dose rate, MRI – magnetic resonance imaging, PDR – pulsed dose rate, QA – quality assurance, TPS – treatment planning system.

^a American Association of Physicists in Medicine Task Group No. 43 Report [17].

CHECKLIST 35. DOSIMETRY EQUIPMENT

Items to be reviewed by auditors	Response
	Comments
List of dosimetry equipment available (including dosimeters, scanning devices, dosimetry arrays, check sources, software, barometers and thermometers, other):	
Operations manual used:	
List of acceptance and QA programmes (each item):	
Comment on local standard ionization chamber(s) calibration, traceability to Primary or Secondary Standards Dosimetry Laboratories, certificate(s) and frequency of calibration(s):	
Comment on calibration of field dosimeter procedures and protoc (e.g. cross calibration):	cols

CHECKLIST 35. DOSIMETRY EQUIPMENT (cont.)

Comment on whether the equipment is sufficient and appropriate use:	for the intended clinical
Comment on the general condition of the equipment:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Note: QA – quality assurance.

5.1.3. Verification of consistency of dosimetry data and procedures

The suggested timescale for the more detailed evaluation or review of the consistency of dosimetry data and procedures is immediately after the first three days of the audit. The timing of the dosimetry evaluation will have to fit in with the constraints on the medical physics auditor's time arising from other audit requirements and also those from access to the treatment equipment and local personnel. The proposed audit pattern outlined below involves physics measurements to be conducted between Day 3 and Day 4.

- (a) Days 1–3: Common activities with other members of the audit team.
- (b) Evening of Day 3: Measurements on at least one teletherapy machine. If a multimodality linac is present, measurements will be carried out on at least one X ray beam and at least one electron beam. If no multimodality linac is in use, but a linac with X rays only is in use, measurements will be carried out on at least that machine, and finally, if no linac is in use, measurements will be carried out on at least one cobalt unit.
- (c) Day 4 morning: Measurements on at least a selection of brachytherapy source systems.
- (d) Day 4 afternoon: Measurement data analysis; a more detailed evaluation of the dosimetric data sets available, both manual and in the TPS; and dose and related calculations for a selection of benchmark cases.
- (e) Day 4 evening, if required: If inconsistencies or problems are observed from previous measurements, data evaluations or calculations, access to the treatment machines may be necessary to carry out any additional measurements that the auditor deems necessary to resolve or to further investigate these issues.

(f) Day 5: Discussion between the medical physics auditor and the local medical physics personnel on the dosimetry data and processes, as part of the overall feedback to the department.

The suggested measurements are relatively simple and are for basic parameters only. The calculations are also for relatively straightforward situations. However, the depth of audit in the given circumstances depends on the judgement of the auditor. Measurements may be performed after normal working hours to minimize the impact on patient treatments and allow initial assessments to be carried out earlier in the week. This needs to be coordinated with the local team and possibly a service engineer.

The radiotherapy department needs to be informed of the measurement programme in advance as services may need to be rescheduled, and it is advisable to maintain flexibility during the audit.

The recommended tests are to be conducted as described in this publication and performed at the judgement of the auditor.

Comprehensive audits of electron beams can be time consuming. Engaging in such audits therefore depends on the judgement of the auditors in determining the depth of audit.

5.1.3.1. Dosimetry for external beam radiotherapy

(a) Basic safety tests

The medical physics auditor will ideally perform the following checks to ensure the radiation safety of working conditions before conducting any tests on the treatment unit:

- (i) Door interlock operational;
- (ii) Radiation light warning operational;
- (iii) Exposure within the room with treatment unit in 'beam off' condition.

The auditor will wear a personnel radiation monitoring device and, if available, a radiation survey meter with an active alarm option.

(b) Mechanical tests

A few basic geometric tests are necessary to ensure proper set-up conditions on the radiotherapy units and for the positioning of patients for daily treatments. Any differences between the auditor's measurements and the institution's values need to be noted. The minimum tests involve the following checks of lasers, optical distance indicators (ODIs) and field sizes:

- (i) Lasers: The congruence of the lateral lasers and the isocentre horizontal plane, 20 cm on either side of the isocentre, at the nominal treatment distance.
- (ii) Optical distance indicator: The congruence of the ODI and the mechanical isocentre; the ODI at -10 cm and +10 cm from the mechanical isocentre.
- (iii) Field size indicator: The field size indicator compared with the light field at the nominal treatment distance for three field sizes $(5 \text{ cm} \times 5 \text{ cm}, 10 \text{ cm} \times 10 \text{ cm}, 20 \text{ cm} \times 20 \text{ cm}).$

Once the auditor has verified these geometric parameters, the dosimetry measurements outlined in (c) below can be made.

(c) Dosimetry calibrations and measurements

Before performing the beam output calibration, it is necessary for the auditor to compare his or her barometer and thermometer with those of the institution.

Under the observation of the auditor, the local medical physicist will calibrate the beam output according to the institution's standard procedure for at least one photon beam and at least one electron beam if available (or more if time allows). The auditor will carefully follow the procedure step by step to acquire a full understanding of it.

The auditor will then perform a beam output calibration for each of the beams mentioned above according to the IAEA code of practice described in Ref. [18], and will compare the measured output with the institution's specification.

5.1.3.2. Clinical dosimetry

At this stage, the auditor will ideally have gained sufficient knowledge of the clinical techniques routinely used at the institution. The auditor will therefore focus on the relevant clinical dosimetry data.

Some of the items described below have already appeared in the checklists. However, they are repeated here for completeness. It is assumed that during a normal procedural audit, an auditor may not have performed a full data evaluation and review. Therefore, the intention here is to carry out a more detailed evaluation.

(a) Basic dosimetry data

The auditor will review the beam data tables available, determine if the data are measured or based on published data and obtain copies of appropriate data (if possible).

The auditor will review and evaluate the consistency and normalization of the basic beam dosimetry data used by the institution by comparison with expected reference data. In addition, he or she will ascertain how the basic dosimetry data set is used by the TPS and/or any in-house software.

(b) Monitor units or time set calculation

The auditor will evaluate the method used routinely by the institution to calculate the number of monitor units (MU) or the time set for patient treatments. This evaluation needs to be carried out for all photon beams and at least one electron beam per linac. For this, the local medical physicist has to be requested to determine MU or time set for the clinical dosimetry tests as described below. In addition, the auditor will independently calculate the MU/time set for the same standard dosimetry tests using the output value that he or she has measured and the beam data tables supplied. The auditor's results will be compared with those determined by the institution.

The standard clinical dosimetry tests will be performed for a simple water phantom treated with a single field. Monitor units or time set need to be calculated to deliver 2 Gy at the various points of interest. The following set-ups are recommended:

- (i) Photon beams:
 - Field size: 10 cm \times 10 cm, depth 10 cm, with and without a steep clinically used wedge;
 - Field size: 7 cm \times 20 cm, depth 10 cm, with and without the same wedge.

(ii) Electron beams:

- Field size: $10 \text{ cm} \times 10 \text{ cm}$, depth of calibration;
- Field size: large applicator with rectangular cut-out, depth of calibration.

If blocks are used at the institution, the auditor and the local medical physicist will calculate MU or time set for a typical blocked field used clinically at the institution.

(c) End-to-end testing/patient specific quality assurance

If the department has tools to perform patient specific measurements in a phantom or a device (e.g. a diode array or electronic portal imaging device (EPID) dosimetry), the auditor will participate in such a measurement.

5.1.3.3. External beam treatment planning system

The auditor will perform a set of tests to verify the performance of the TPS:

- (a) To confirm that the field sizes on printouts and the entered field sizes match;
- (b) To compare a sample of dosimetry data with expected reference data (including open and wedged fields);
- (c) To observe and question the process to produce plans and calculations for at least one or two normal clinical cases.

5.1.3.4. Brachytherapy

(a) Basic safety tests

Before conducting any tests on the brachytherapy unit, auditors need to check the availability and functionality of the following items to ensure the radiation safety of the working conditions:

- (i) Door interlocks, warning lights and alarms (in particular for high dose rate (HDR) afterloading units);
- (ii) An area radiation monitor that can operate during a power failure and a portable survey meter;
- (iii) An emergency container and emergency kit for source handling in the case of a failure of the source to retract into its storage container (HDR afterloading units);
- (iv) Movable lead shields (for manual low dose rate (LDR) source handling).

In addition, the auditors need to check the exposure within the room with the treatment unit in the 'source off' condition.

The auditor will wear a personnel radiation monitoring device and (for manual LDR source handling) a finger dosimeter.

(b) Check of source calibration

Under the observation of the auditor, the local medical physicist will check the source calibration (in terms of the reference air kerma rate) for at least one source of at least a selection of activities, according to the institution's standard procedure for brachytherapy units (remote afterloading) or a sample of individual sources (wires or seeds for manual afterloading). The auditor will carefully follow the procedure step by step to acquire a full understanding of it.

The auditor will then perform independent checks of the source calibrations according to the guidelines given in Ref. [19] using a calibrated well-type ionization chamber.

(c) Clinical dosimetry

At this stage, the auditor will ideally have gained sufficient knowledge of the clinical techniques routinely used for brachytherapy at the institution. The auditor will therefore focus on the relevant clinical dosimetry data.

The auditor will perform a set of tests to verify the performance of the brachytherapy TPS or planning calculation method:

- (i) To compare a sample of dosimetry data with expected data for standard brachytherapy applications;
- (ii) To observe and question the process to produce plans and calculations for at least one normal clinical case (including reconstruction, source distribution and time).

5.1.4. Exit interview and the end-of-mission report

As their contribution to the exit interview and the end-of-mission report, the QUATRO medical physics expert will prepare a preliminary report of the review of medical physics procedures. The expert will leave a copy of the signed and dated measurements, the calculations and a report of the results with the local medical physicist. These data and information will provide the institution's medical physicist with a set of independently measured reference data that can be used later to compare with the institution's own measurements for possible future dosimetry changes. Any records left at the institution will be clearly marked 'preliminary'.

The expert may be required to address, to the radiation oncologist, any important changes recommended in dosimetry practices that might have an impact on the clinical outcome of patient treatments.

The end-of-mission report to the IAEA will contain the following data and information:

- (a) A summary of the tests and measurements performed by the expert;
- (b) Results of the measurements;

- (c) Results of clinical dosimetry;
- (d) Analysis of the results of the measurements;
- (e) Recommendations to the institution (general and specific);
- (f) Recommendations to the IAEA.

The relevant forms, measurement records, spreadsheets and worksheets [7] need to be properly dated and signed.

5.2. EQUIPMENT QUALITY ASSURANCE: ASPECTS RELATED TO RADIATION THERAPISTS

5.2.1. Introduction

The RTT audit structure is integrated into the overall audit, which is based on checklists, discussion with local personnel and observation. Infrastructure and both patient related and equipment related procedures require the input of the RTT auditor, as appropriate. The RTT auditor is expected to be fully involved during the general audit.

During the first three days of the audit, the RTT auditor will gain an insight into the management structure and organizational relationships of the department and the level of responsibility expected of the RTT in the specific context of this department. In addition, the RTT auditor will need to spend time with the RTTs in the clinical setting. During this time, the RTT auditor is advised to observe the normal working conditions of the RTTs and to discuss with them in more detail the topics identified in the RTT checklists.

The purpose of this part of the audit is to obtain an overview of the role of the RTTs within the multidisciplinary team in radiation oncology with regard to the preparation and delivery of radiotherapy, with a special focus on equipment QA.

5.2.2. Quality assurance checklists: aspects related to radiation therapists

Quality assurance procedures and practices, as well as QC protocols and records, need to be reviewed by the auditor for all items involving the practice of RTTs. Checklist 36 will help the auditor to review the quality of the RTT infrastructure. Quality control procedures for equipment are listed in Checklist 37.

CHECKLIST 36. QUALITY ASSURANCE INFRASTRUCTURE FOR RADIATION THERAPISTS

Items to be reviewed by the RTT auditor	Response
	YES NO
Professional infrastructure: Is the role of RTTs articulated (in their job description)? Is there a reporting structure? Are RTTs autonomous (equal team members)?	
Number of RTTs per teletherapy unit: Superficial X ray unit Orthovoltage X ray unit Cobalt-60 unit Single energy X ray linac Multienergy linac (X rays plus electron beams): — CT or simulator — Other	
Number of days per week that the department is in operation:	
Number of hours per day that the department is in operation:	
Number of normal working hours per day/per week:	
Average number of fractions treated per teletherapy unit/day: Is there a shift system and changeover protocol?	
Are RTTs knowledgeable about treatment protocols?	
Is there an orientation programme for new RTTs?	
Do RTTs participate in equipment selection?	
Do RTTs participate in training provided by vendors?	
Comments:	
Radiation safety: Are RTTs familiar with radiation safety protocols for patients, staff and the public?	
Comments:	

CHECKLIST 36. QUALITY ASSURANCE INFRASTRUCTURE FOR RADIATION THERAPISTS (cont.)

Departmental policies and procedures for QA: Do RTTs contribute to QC procedures? Is there a procedure for RTTs to question deviations?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	

CHECKLIST 37. QUALITY CONTROL PROCEDURES FOR RADIATION THERAPISTS

Items to be reviewed by auditors	Resp	onse
	YES	NO
QC procedures at the imaging units: Are there QC procedures on the image processing equipment? Is there a policy for radiation safety at the simulator (or CT simulator) including call-out 'screening' and checking lead aprons?		
Is the consistency of table tops, laser lights, field sizes and gantry		
Are door interlocks checked? Are room monitors checked?		
Comments:		
Comment on the QC in the radiation oncology laboratory (mould room)	:	
Is there a procedure for checking the construction of immobilization/ positioning devices?		
Is there a procedure for checking the construction of shielding devices?		

Note: CT – computed tomography, QA – quality assurance, QC – quality control, RTT – radiation therapist.

CHECKLIST 37. QUALITY CONTROL PROCEDURES FOR RADIATION THERAPISTS (cont.)

 QC procedures in brachytherapy: Are there QC procedures for the: — Remote afterloading brachytherapy units? — Manual afterloading intracavitary/interstitial sources, surface applicators? 	
Comments:	
OC procedures at the treatment units:	
Is the consistency of all table tops, laser lights and field sizes checked?	
Are door interlocks checked?	
Are room monitors checked?	
Are quality checks carried out on accessory equipment at the point of use?	
Are regular quality checks carried out on immobilization and positioning devices, including how they are stored and if they are in need of replacement?	
Comments:	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	3 4 □ □

Note: CT – computed tomography, QC – quality control.

6. QUALITY AND SAFETY MANAGEMENT

Several quality management system (QMS) related items will be considered when reviewing quality management and safety aspects of departmental operations. They are listed in Checklist 38 below.

CHECKLIST 38. QUALITY AND SAFETY MANAGEMENT

Items to be reviewed by auditors	Response	
	YES	NO
Is a QMS in place?		
Is there a quality management committee?		
Is there a quality manager (responsible for QMS)?		
Does the radiotherapy department have a quality policy?		
Is there a quality manual describing the infrastructure, organization, staffing, processes and procedures of the radiotherapy department?		
Is a departmental organizational chart defined within the QMS?		
Are the job descriptions of radiation oncologists defined?		
Are the job descriptions of medical physicists defined?		
Are the job descriptions of RTTs defined?		
Are the job descriptions of other staff (e.g. nurses, administrative staff, technical support, IT support, clinical engineers) defined?		
Is quality documentation available for all patient related and equipment related procedures, such as standard operating procedures?		
Are there QC procedures for each machine?		
Are there QC records, including calibration records?		
Is there a directive of actions, and are the triggers defined?		
Is there documentation of the actions taken when checks are out-of-tolerance?		
Are quality audits carried out (internally/externally)?		
Comments:		

CHECKLIST 38. QUALITY AND SAFETY MANAGEMENT (cont.)

Frequency: 1-None of the time, $2-Some$ of the time, $3-Most$ of the time, 4-All of the time	1	2	3	4
Are quality review meetings in place?				
Are written minutes prepared?				
Is the introduction of new technologies and techniques properly planned, documented and communicated?				
Is QMS documentation regularly updated/revised?				
Is training of personnel in the use of equipment carried out, and are the training records available/retrievable?				
Are the recommendations resulting from internal/external audits acted upon?				
Comments:				
	Y	ΈS	N	0
Is relevant documentation illustrating the processes of dissemination of information throughout the radiotherapy programme: Prepared by the department? Made available to auditors on-site?	[]
Comment on record keeping and documentation:				
Do radiation protection and safety aspects of departmental operations include the following? Records of the regulatory authorizations for the use of radiation sources and/or equipment Radiation protection committee Radiation protection officer Radiation protection programme Manuals for radiation protection Records of personnel monitoring and feedback to staff Radiation protection training and certification Contingency plans (e.g. handling of incidents, deviations) Patient protection policy and procedures (i.e. justification and optimization)))))))

CHECKLIST 38. QUALITY AND SAFETY MANAGEMENT (cont.)

Comments:				
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	1	2 □	3	4

Note: IT – information technology, QC – quality control, QMS – quality management system, RTT – radiation therapist.

The auditors will also review various aspects of activities at the radiotherapy department related to radiation protection and the safety of patients, staff and the public. Checklist 39 is intended to guide them through the review process.

CHECKLIST 39. RADIATION PROTECTION AND SAFETY

Items to be reviewed by auditors	Response	
	YES NO	
 Responsibilities for radiation protection: Radiological medical practitioner has overall responsibility Radiation protection officer appointed: Oversees the application of regulatory requirements for occupational and public radiation protection Awareness of these roles in the department Radiation safety officer appointed (if applicable): 		
 Responsibilities defined and reflected in the job description Awareness of these roles in the department Radiation safety committee Radiation safety policy documented 		
Licensing to conform to national requirements: Licensing/authorization requirements fulfilled: — For use of ionizing radiation — For facilities — For storage or disposal of radioactive material Inspections by national authorities in place		

CHECKLIST 39. RADIATION PROTECTION AND SAFETY (cont.)

Risk assessment and management: Prospective risk and hazard evaluations undertaken Range of possible incidents, near incidents and accident scenarios considered	
Introduction of safety barriers Active promotion of a safety culture Contingency planning in place for predictable events (actions, instructions, investigations, reporting)	
Radiological incidents, near incidents and accidents (reporting, analysing, learning and feedback)	
Consideration of radiation protection in planning of facilities and procedures	
Local rules for pregnant workers	
Local rules for pregnant patients	
Local rules for visitors, comforters and caregivers, and for discharge of patients, etc.	
Procedures for transport of sources to/from the centre and within the centre	
Classification and identification of areas (e.g. criteria, signs, control)	
Local rules for radiation protection in different areas (e.g. cobalt	
Local supervision of these rules Staff are aware of these rules	
Radiation protection equipment: Equipment availability Acceptance, calibration and QC	
Radiation surveys, for example: What is done? Frequency of surveys Methods used Records kept Corrective actions	

CHECKLIST 39. RADIATION PROTECTION AND SAFETY (cont.)

Practical procedures for personnel monitoring and investigation of sig records kept:	nificant doses,			
Radioactive sources: Storage				
Security				
Handling				
Disposal				
Leak testing				
Records kept				
Procedures for identification of authorized practitioners and operators				
Procedures for ensuring justification and optimization ^a				
Comments:				
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate	$\begin{array}{cccccccccccccccccccccccccccccccccccc$			

Note: QC – quality control.

^a See Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3 [20].

7. EDUCATION AND TRAINING PROGRAMMES

The auditors are required to review the qualifications, education and experience of staff in the radiotherapy department and to check for consistency with the IAEA curricula for the different professional disciplines (radiation oncologists, medical physicists and RTTs) or compare them with national requirements, where such requirements exist. The purpose is to obtain an overview of the background and competencies of radiotherapy staff in relation to the roles and responsibilities expected of professionals operating in the radiotherapy department and to record the education and training activities undertaken.

7.1. EDUCATION PROGRAMMES

Questions to review education programmes are given in Checklist 40. Tables 2–4 list the main subjects included in the IAEA syllabi and/or curricula for radiation oncologists [21], medical physicists [22, 23] and RTTs [24], respectively. The subjects listed may be used to review the content of the training programmes being audited.

CHECKLIST 40. QUALIFICATIONS

Items to be reviewed by auditors	Response		
	Comments		
What qualification is required for the following professionals to work in radiotherapy? RO: MP: RTT:			
What is the officially recognized professional title? RO: MP: RTT:			
What is the minimum entry requirement for academic education in radiotherapy? RO: MP: RTT:			
What is the duration in academic years of the education programme? RO: MP: RTT:			
What is the ratio of academic to clinical education/training? RO: MP: RTT:			
What qualifications are required for other professionals? Nurse practitioner (specific for oncology, if applicable): Maintenance engineer (if in-house): Radiation protection officer:			
CHECKLIST 40. QUALIFICATIONS (cont.)

	RO	MP	RTT	
	Y N	Y N	Y N	
Is the education programme university based?				
Is there a certification/registration/licensing requirement?				
Are any of the staff in the radiotherapy department officially involved in supporting an academic programme (e.g. lecturing)?				
If so, comment on the title of the academic program postgraduate), availability of the syllabus, etc. RO: MP: RTT:	nme, its level	(undergradu	ate,	
Continuing professional development: Is there a national policy for CPD? Is CPD funding available? Is CPD a requirement for maintaining certification? Are external activities recognized for CPD?				
Comments:				
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate Assessment by discipline: RO: MP: RTT:			4	

Note: CPD – continuing professional development, MP – medical physicist, RO – radiation oncologist, RTT – radiation therapist.

TABLE 2. IAEA CURRICULUM FOR RADIATION ONCOLOGISTS [21]

Subject	Duration	Appropriateness of indicative content
General knowledge: cancer epidemiology,		

prevention, detection and treatment; structure/ organization of oncology services; multidisciplinary care

Cross-sectional anatomy

Pathology

Biology of cancer; tumour growth and progression

Radiobiology/molecular oncology

Basic radiation physics

Applied medical radiation physics; basic equipment; basic treatment planning and plan interpretation

Principles of radiation protection

Imaging and target volume; image interpretation

Site specific cancer management; side effect evaluation

Measurements of treatment outcomes and clinical research

Research methodology^a

^a In this context, the term 'research methodology' pertains to research skills that enable professionals to critically assess literature and protocols, as well as engage in structured and efficient research and development activities to introduce new technologies and techniques and assess their value.

TABLE 3. IAEA SYLLABUS AND CURRICULUM FOR MEDICAL PHYSICISTS [22, 23]

Subject	Duration	Appropriateness of indicative content

Academic knowledge:

Anatomy and physiology as applied to
medical physics
Radiobiology
Radiation physics
Radiation protection
Medical imaging fundamentals
Radiation dosimetry
Physics of radiation oncology
Physics of nuclear medicine
Physics of diagnostic and interventional radiology
Research methodology ^a and project

Clinical training competencies:

Orientation and introduction to the radiation oncology environment Radiation safety and protection aspects Radiation dosimetry for external beam radiotherapy External beam radiotherapy equipment External beam radiotherapy treatment planning Brachytherapy Professional studies Quality management Research, development and teaching

^a In this context, the term 'research methodology' pertains to research skills that enable professionals to critically assess literature and protocols, as well as engage in structured and efficient research and development activities to introduce new technologies and techniques and assess their value.

TABLE 4. IAEA CURRICULUM FOR RADIATION THERAPISTS [24]

Subject	Duration	Appropriateness of indicative content

Basic sciences:

Biology Chemistry Biochemistry Introduction to physics and mathematics Anatomy and radiographic anatomy Physiology Psychology/sociology Information technology Oncology science Radiobiology and molecular oncology Medical radiation physics

Professional knowledge:

Professionalism and ethics Patient care Patient positioning and immobilization Radiotherapy treatment planning Radiotherapy delivery Quality assurance, quality control and risk management Critical appraisal^a

^a In this context, the term 'critical appraisal' refers to the use of methods to assess the data in published research, applying the rules of evidence to factors such as internal validity, adherence to reporting standards, conclusions and generalizability. Critical appraisal methods are used in evidence based health care training and are increasingly used in social care and education provision.

7.2. TRAINING PROVIDED IN THE DEPARTMENT

One important component of the education of radiotherapy professionals is the training undertaken in a clinical environment. Checklist 41 will guide the auditors through questions to be clarified when assessing any clinical training programme.

CHECKLIST 41. CLINICAL TRAINING

Items to be reviewed by auditors	Response			
	RO	MP	RTT	
	Y N	Y N	Y N	
Is the clinical training programme in the department linked to an academic programme?				
What is the duration of clinical training? RO: MP: RTT:				
Does the department offer clinical training?				
If so, comment on the curriculum followed: RO: MP: RTT:				
Is the department accredited for training?				
What is the name of the accrediting body? RO: MP: RTT:				
Is accreditation locally, nationally or internationally recognized?				
Is there a programme director?				
Who is the programme director for the specific profession RO: MP: RTT:	onal groups?	,		
How many residents are currently enrolled in the clinical many supervisors? RO: MP: RTT:	l training pr	ogramme, a	nd how	

CHECKLIST 41. CLINICAL TRAINING (cont.)

Are trainees undergoing clinical training remunerated?					
Is training limited to a single department?					
Is more than one centre included in the clinical training					
If so, is a standardized portfolio in use?					
Is there access to external training at national or international levels?					
Is external training: Voluntary? Compulsory?					
Is funding available to support external training?					
How is the training assessed/recorded? Give details:					
Can the department accept students from outside the country into its education and training programmes?					
Is there a defined process that needs to be completed by external students?					
Is there a system for the recognition of qualifications?					
Is there an orientation programme for new staff?					
Are there compulsory programmes on health and safety?					
Are there compulsory programmes on radiation protection?					
What is the frequency of health, safety and radiation protection training?					
Comments:				 	

CHECKLIST 41. CLINICAL TRAINING (cont.)

Comment on the contributions of the staff of the radiothe activities:	erapy department to training
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate Assessment by discipline:	1 2 3 4
KO: MP: RTT:	

Note: MP – medical physicist, RO – radiation oncologist, RTT – radiation therapist.

7.3. RESEARCH

Questions listed in Checklist 42 should clarify any research that is carried out by the radiotherapy department undergoing a QUATRO audit.

CHECKLIST 42. RESEARCH

Items to be reviewed by auditors	Response		
	RO MP		RTT
	Y N	Y N	Y N
Is research included as part of the academic programme?			
Is clinical research supported in the department?			
Is there access to statistical support?			
Are all staff disciplines involved in clinical research in the department?			
Is there a departmental research committee?			

CHECKLIST 42. RESEARCH (cont.)

Are all disciplines represented on the departmental research committee?					
Is ethical approval required for research protocols?					
Is there an ethics committee in the hospital?					
Is ethical approval required from more than one committee (e.g. from the university as well)?					
Comment on the contributions of the staff of the radiothe activities:	erapy depart	ment t	to res	earch	
Overall assessment: 1–Poor, 2–Needs major improvement, 3–Needs minor improvement, 4–Appropriate Assessment by discipline: RO: MP: RTT:			3 4	4	

Note: MP – medical physicist, RO – radiation oncologist, RTT – radiation therapist.

Appendix I

RADIATION ONCOLOGY IN LIMITED RESOURCE SETTINGS

I.1. BACKGROUND

This appendix describes the essential components needed to start a radiotherapy department in a setting with limited resources and illustrates its natural progression to a high level of competence. The key to describing the operation of a radiation oncology facility is the need to consider its three principal components: equipment, human resources and procedures. It is obvious that in order to start operations, a facility has to be equipped. However, the failure of a radiotherapy department to operate efficiently is frequently caused by limited human resources (i.e. insufficient or inadequately educated staff). Another common barrier to operating effectively is a lack of sensible procedures based on an examination of treatment outcomes. In order to operate a radiotherapy department effectively, efficiently and safely, it is necessary to have appropriate equipment, dedicated and properly trained staff, and sensible procedures geared to the economic situation in the region.

This publication does not seek to establish a universal standard in any of the three categories of equipment, staffing or procedures. Judging the service level of a particular facility as basic, competent or excellent would require an examination of the facility's operation by an expert panel, taking into account its economic environment. For example, a modestly equipped radiotherapy department in a limited resource setting but with appropriate staffing and effective procedures might qualify a service as excellent. On the other hand, the limited equipment would relegate such a department to the status of a basic service in a rich resource environment where excellence may be judged entirely on the ability of the department to deal with very rare and special cases. It is important that managers and decision makers in limited resource settings realize that excellence is based on the clinic's procedures and how the centre utilizes its available resources, rather than on the sophistication of its equipment.

The concept of sustainability is important in the process of analysing the level of operation of a particular facility. The term 'basic' implies only that the department has the essential equipment and adequate staffing to treat most tumours with the intent of achieving local control of the disease to the extent possible. In addition, the department's procedures must be reasonable and consistent with basic operation. A department would be classified as 'competent' if it was able to provide clinical training to its entire staff on-site in order to ensure operation in the long term. Such a department would be able to fully train its own RTTs and arrange for specialized academic training for its radiation oncologists and medical physicists at another site. It would have adequate patient follow-up to track treatment outcomes but may not have a national cancer registry. Ideally, a department with a high level of competence also serves the needs of other centres in the region by providing them with a site for clinical training and engaging in clinical research to improve the treatment outcomes for those tumours and stages of disease that are common to its region. In other words, departments operating at a high level of competence should be self-sustainable, and aim to contribute to the sustainability of cancer treatment in the region and have a greater impact when resources allow.

The type, amount and level of sophistication of the equipment available do not determine the competence. Rather, the ability of the radiotherapy department to operate self-sustainably through education and links to other cancer services, address population needs and engage in analysis of its own treatment outcomes, thereby providing guidance for others and creating impact in the region, would be the defining characteristics. It is only when a department is able to provide evidence demonstrating competence capabilities that managers should seek to introduce sophisticated or leading edge technologies that require a much higher level of education and training of staff for implementation to be effective and sustainable.

I.2. THE BASIC RADIATION ONCOLOGY CLINIC

I.2.1. Recommended equipment and staffing levels

The term 'basic radiation oncology clinic' implies that the clinic has the essential equipment and adequate staffing to treat most tumours, with the intent of achieving local control of the disease to the extent possible [8]. The clinic operates a cancer registry and has procedures for the follow-up of treated patients.

Table 5 lists the building, equipment and staffing requirements for a radiotherapy service treating approximately 500 new patients per year with teletherapy (of whom about 50% would be treated with curative intent) and 200 patients per year with brachytherapy. The work is organized into two shifts. Staffing needs are ideally adjusted according to the number of patients treated. The training of staff requires that senior professionals or specialized trainers are available at the clinic.

The basic department is equipped with ⁶⁰Co teletherapy units and/or single photon energy linear accelerators [25]. With the increasing complexity of radiotherapy treatment (e.g. from a simple treatment using standard blocks to conformal radiotherapy with a multimodality linear accelerator), the number of

staff (especially medical physics staff) will need to increase. Consideration needs to be given to maintenance and service contracts and the availability of spare parts for radiotherapy equipment.

TABLE 5. ESSENTIAL EQUIPMENT AND STAFFING FOR A BASIC RADIOTHERAPY CLINIC [8, 25]^a

Set-up	Essential resources
Building	One megavoltage bunker (desirable: two bunkers and a second teletherapy machine) One X ray bunker for an orthovoltage unit, if applicable A simulator room (desirable: two bunkers for fluoroscopic simulation and CT simulation) A dosimetry planning/physics room (equipment storage necessary) One HDR bunker (or LDR room) ^b A dark room (or film/image processing area), if applicable A mould room, if applicable Ample clinical space (with waiting, consulting, changing and examination rooms, and a staff meeting room)
External beam therapy equipment	At least one single photon energy teletherapy unit (desirable: two with multileaf collimator and EPID) One orthovoltage unit, if applicable Beam measurement and QA and radiation protection physics equipment Simulator (desirable: also a CT simulator or access to a CT) A computerized TPS Independent dose/MU verification system Film/image processing equipment, if applicable Record and verify system Patient immobilization devices and mould room equipment
Brachytherapy HDR or LDR equipment ^b	One brachytherapy afterloading unit ^b (two or more if LDR) An X ray C-arm for verification A computerized TPS (if LDR, it can be integrated into the external beam TPS) A full range of applicators QA physics equipment

TABLE 5. ESSENTIAL EQUIPMENT AND STAFFING FOR A BASIC RADIOTHERAPY CLINIC [8, 25]^a (cont.)

Set-up	Essential resources	
Personnel	Four or five radiation oncologists ^c Three or four medical physics staff ^d Seven RTTs Three oncology nurses ^c One maintenance technician/engineer	

^a Reproduced from Ref. [8] and updated [25].

^b HDR vs LDR: An LDR brachytherapy unit can only treat approximately 100 patients per year. Sites with a larger number of cervical cancer cases require HDR brachytherapy.

^c Increase by 50% if the staff are also responsible for chemotherapy; in that case, a chemotherapy suite needs to be available.

^d This requires at least one, and preferably two, senior clinically qualified radiotherapy medical physicists. Other physics staff are clinically qualified radiotherapy medical physicists or residents in medical physics.

I.2.2. Treatment procedures and clinic management

The equipment and staffing indicated above would be sufficient to start operations but certainly would not be sustainable without adding a training component. Therefore, the department will need to provide training to replace its own RTTs. In addition, it should be able to provide financial resources to enable academic education for sustaining the staffing levels of radiation oncologists and medical physicists, as well as on-site clinical training for these professionals. A high level of competence implies that a culture of QA is promoted and practised, as evidenced by written policies and procedures guiding the treatment of its patients, and that regular preventative maintenance of equipment is carried out. In addition, peer review of the clinical procedures, regular evaluation of morbidity and mortality (with special attention to unanticipated adverse events) and regular analysis of short term and long term outcomes with regard to tumour control for the most common types of cancer are essential by regularly following up the treated patients.

In order to increase the level of impact from the local environment to the national or regional level, the department is ideally a resource available to other centres for training. It needs to be continually investigating improved methods of therapy to treat the most common cancers in the region, hopefully contributing to the research literature and thereby providing guidance to other regional centres. To do this, the department will ideally contribute to a cancer registry that is at least hospital based but is ideally a national registry meeting the standards of the International Agency for Research on Cancer (IARC). In addition, the centre will ideally engage in associated cancer control activities, such as cancer prevention (e.g. tobacco control or HPV and hepatitis B vaccination), early diagnosis (e.g. Pap smears) and palliative care (e.g. morphine for pain control).

Appendix II

REMARKS ON THE CONSISTENCY OF THE TERMINOLOGY USED IN RADIOTHERAPY

II.1. INTRODUCTION

In order to avoid misconceptions and misunderstandings in the use of terminology at various radiotherapy departments worldwide, auditors are encouraged to make themselves familiar with the explanations given in this appendix. These have been devised for the purpose of consistency. However, this does not constitute an intention to exclude other definitions of these various terms.

II.2. PATIENT

The patient is an individual with one or more cancers or benign conditions.

II.3. CANCER CASE

A cancer case is a new cancer registered. There may be several different cancers in a single individual (synchronous or metachronous cancers).

II.4. TREATMENT OR COURSE OF TREATMENT

A treatment is a course of radiotherapy consisting of a number of sessions to treat a given disease. Whether the disease is in one or several different target volumes (T and N), the treatment is still considered as one treatment. An additional irradiation at a distance from the primary (e.g. prophylactic cranial irradiation in small cell lung cancer) could be considered a different course of treatment, since the additional workload linked to it might amount to a new treatment (with a different simulation, a different set-up at the treatment machine and a different dose calculation).

The auditors will note in their report what comprises a treatment at the audited department and give examples.

II.5. TREATMENT PLAN

A treatment plan involves at least a 2-D distribution of doses.

II.6. TREATMENT SESSION

A treatment session is synonymous with a fraction. One irradiation session comprises one or more fields on one or more target volumes for the same patient. Sessions are sometimes understood as a time slot at a treatment machine (e.g. ten minutes). A complex treatment might use more than one time slot (e.g. treatment of a child with medulloblastoma), and can therefore be registered as one session or as several sessions, depending on the departmental definition. Auditors need to clarify what is understood as a treatment session in an audited department, and the report of the audit needs to be unambiguous in this matter.

II.7. TREATMENT FIELD

A treatment field is a single radiation beam. Each beam orientation may include more than one field size. Auditors need to determine what definition is used.

II.8. SHIFT

A shift is normal working hours for a given professional class. A department might be open for longer daily hours and therefore use successive shifts for its personnel.

II.9. WORKLOAD

The workload of a radiotherapy department is determined by the number of treatments provided.

Appendix III

REMARKS ON THE ENUMERATION OF PATIENTS AND CANCER CASES

III.1. INTRODUCTION

While the concept of a 'patient' is uncontroversial, the number of 'cancer cases' is often recorded and reported differently from institution to institution. The auditors need to establish the basis from which these statistics are derived.

III.2. CATCHMENT AREAS

Are the records of cancer cases an attempt to create a national or a regional cancer registry derived from the entire country, or a region of the country?

Are the numbers of cancer cases derived from patients presenting to all the hospitals affiliated to the major hospital being audited, or only from those presenting to the audited hospital?

III.3. SOURCE OF INFORMATION

Do the cancer cases include both clinical and pathological diagnoses, or only the latter?

III.4. MANAGEMENT

Do the cancer cases include patients who may have simply been sent home for terminal care, or those managed by surgery or chemotherapy in addition to those seen in a combined assessment clinic? Or are the cases recorded only of those patients who have received radiotherapy?

III.5. SKIN CANCER: INCLUSIONS AND EXCLUSIONS

Do the cases recorded include all cases of skin cancer, or only malignant melanomas (in conformity with IARC guidelines for national cancer registries)? Are all cases of Kaposi sarcoma (AIDS and HIV negative) included?

III.6. COUNTING

It is usual to count a patient with a synchronous or metachronous cancer at a second primary site as a second case. In some institutions, the development of metastases subsequent to primary management is recorded as a further case.

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