2011

RADIATION ONCOLOGY PRACTICE STANDARDS

Supplementary **Guide**

A TRIPARTITE INITIATIVE

The Royal Australian and New Zealand College of Radiologists
The Faculty of Radiation Oncology

Australian Institute of Radiography

ACPSEM
Australasian College of Physical Scientists & Engineers in Medicine

The Tripartite Committee is a peak group in Radiation Oncology, representing the three key professions involved in radiotherapy:

- The Faculty of Radiation Oncology (FRO), The Royal Australian and New Zealand College of Radiologists (RANZCR).
- Australian Institute of Radiography (AIR).
- The Australasian College of Physical Scientists and Engineers in Medicine (ASPSEM).

As a key forum for collaboration between the radiotherapy professions, the main objectives of the Tripartite Committee are:

- To represent a key forum for collaboration between the radiotherapy professions in the areas of quality, standards, workforce and public interest.
- To act as an important liaison point for the Department of Health and Ageing, and its committees and working groups.
- To communicate key sector priorities to the Government and to the public.
- To maintain good communication between FRO, AIR, ACPSEM.

The Royal Australian and New Zealand College of Radiologists, the Faculty of Radiation Oncology, Australian Institute of Radiography and the Australasian College of Physical Scientists and Engineers in Medicine, have received Australian Government funding support for the development and publication of the Radiation Oncology Practice Standards and Supplementary Guide.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

In 2002 the report *A Vision for Radiotherapy* by Professor Peter Baume [1] identified a number of national safety and quality issues relating to radiation oncology. The Radiation Oncology Jurisdictional Implementation Group (ROJIG) was established to develop a response to the Baume enquiry. In 2003 it produced a report recommending the development of a quality program to be implemented as a priority. The Radiation Oncology Reform Implementation Committee (RORIC) was then established and tasked with the development and implementation of a quality program. The Quality Working Group was set up as a sub-committee of RORIC. It identified the need for profession agreed practice standards as a key component of a quality system.

The main professionals providing radiation treatment are radiation oncologists, radiation therapists and radiation oncology medical physicists. These professions are represented by the following organisations:

- Royal Australian and New Zealand College of Radiologists (RANZCR), Faculty of Radiation Oncology (FRO).
- Australian Institute of Radiography (AIR).
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).

Nominees from these professional bodies constitute the Tripartite Committee.

The Tripartite Committee – funded by the Department of Health and Ageing (DoHA) through RANZCR – commenced work to develop radiation oncology practice standards. Draft Standards were developed and reviewed by the Tripartite Committee along with numerous volunteers from the three professions and submitted to DoHA in early 2007. These Standards were edited by members of the professions in consultation with quality standards experts (Tripartite Standards Working Group) under the auspices of the Tripartite Committee. The resultant 16 basic Standards were published in draft form as *Radiation Oncology Practice Standards* in 2008. DoHA and the professions believed it to be essential to pilot the acceptance of and ability to implement these standards. A number of public and private facilities volunteered to trial them. The National Association of Testing Authorities (NATA) was contracted to assist the facilities with the trial and to provide feedback to the Tripartite Committee and to the Quality Working Group. Overall the feedback has been positive and the use of the *Radiation Oncology Practice Standards* is likely to underpin reform in the sector.

THE CURRENT SITUATION

As mentioned above, the 16 Standards were distilled from the original draft standards that were presented to DoHA in 2007. The latter were extremely detailed and expansive and have undergone fine-tuning by members of the editing group with review by the three professions culminating in this document. It is anticipated that radiation oncology facilities, in particular new centres, will find it a valuable resource supporting the *Radiation Oncology Practice Standards* thereby assisting in the provision of safe and effective radiation therapy to oncology patient.

SCOPE

The *Radiation Oncology Practice Standards* are considered to be essential to the delivery of safe quality care to radiation oncology patients. This document provides additional material in support of the Standards and may be used to complement them. The two documents are linked by identical headings and descriptors for each individual standard and criterion. Support for individual criteria is enhanced by additional commentaries and supplementary evidence. As the Standards are interrelated inevitably there will be some duplication both within and between the two documents.

The Standards are compliant with the Australian Commission on Safety and Quality in Healthcare draft National Safety and Quality Health Service Standards.

ACRONYMS AND ABBREVIATIONS

ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
ACSQHC	Australian Commission on Safety and Quality in Healthcare
AIR	Australian Institute of Radiography
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
DICOM	Digital Imaging and Communications in Medicine
DoHA	Department of Health and Ageing
FRO	Faculty of Radiation Oncology, the Royal Australian and New Zealand College of Radiologists
MU	Monitor units
OH&S	Occupational health and safety
QA	Quality assurance
RANZCR	Royal Australian and New Zealand College of Radiologists
RO	Radiation oncologist
ROJIG	Radiation Oncology Jurisdictional Implementation Group
ROMP	Radiation oncology medical physicist
RORIC	Radiation Oncology Reform Implementation Committee
RSO	Radiation safety officer
RT	Radiation therapist

STANDARDS

FACILITY MANAGEMENT

STANDARD 1 – STAFF

Staff competence is ensured by recruitment and selection procedures and maintained by staff development and a performance review system.

CRITERION 1.1

There are registers of current registration/licence to practise for all applicable staff.

SUPPLEMENTARY COMMENTARY

All Radiation Oncologists (ROs), Radiation Therapists (RTs) and Radiation Oncology Medical Physicists (ROMPs) are appropriately qualified and maintain their eligibility to their professional associations and meet requirements of regulatory bodies.

Staff members who work with ionising radiation or radioactive substances in states with radiation licensing may be required to record induction and continuing radiation safety training. Practitioners in other states are monitored by their state registration board or radiation safety committee.

A competency is defined as proficiency, ability or a skill set based on a complex range of knowledge, skills and attitudes [2]. Clinical competencies will develop from “learning in context” [3].

Advances in radiation oncology technology and its application in clinical practice require on-going training and education programs [4]. Training in clinical centres forms a significant component of qualification and professional accreditation as an RO, ROMP and RT.

ROs achieve Fellowship through training at facilities accredited by the Royal Australian and New Zealand College of Radiologists (RANZCR) and supervised by the RANZCR Faculty Education Board [5]. Overseas trained specialists who wish to have their specialist medical qualifications recognised in Australia initially apply to the Australian Medical Council for registration to practise as ROs. Both an assessment of their training and experience and a formal examination conducted under the auspices of the RANZCR are required prior to their eligibility for recognition as a specialist in radiation oncology and for Fellowship of the College [6].

RTs must complete either an undergraduate degree or a graduate entry degree from an accredited university. In both streams, radiation therapists are required to undertake supervised clinical practice to ensure they are safe and competent practitioners. Both groups are then eligible for recommendation for a ‘Statement of Accreditation’ from the Australian Institute of Radiology (AIR) [7]. Resumption of Professional Practice candidates and overseas graduates with qualifications from institutions with programs that have not been approved by the AIR must undertake a Competency Based Assessment to demonstrate skills and knowledge of modern radiotherapy practice [8] including technology applications and treatment techniques.

The accreditation process for ROMPs is coordinated by the ACPSEM. All ROMPs must complete the Training, Education and Accreditation Program (TEAP) as well as undertake study for a higher degree in medical physics from an accredited university. Attainment of the clinical experience required for TEAP can take up to 5 years. Accreditation in radiotherapy equipment commissioning and quality assurance is achieved after examination by the ACPSEM. Medical physicists who have achieved competency in radiation oncology by alternative means or who have overseas qualifications are considered for accreditation on an individual basis.

CRITERION 1.2

Performance review systems supported by staff development programs are in place and current.

SUPPLEMENTARY COMMENTARY

A professional development program at each facility is recommended for all staff. In addition, performance review can have a significant effect on skill development and practice [9].

The range of competencies required in radiotherapy can be divided into three areas: clinical expertise, risk management and professional responsibilities.

The competencies needed by medical specialists include the roles of medical expert, clinical decision maker, communicator, collaborator, health advocate, manager, scholar and professional [10]. Similar competencies are required by RTs. The ROMP competencies span across all aspects of dosimetry in the areas of radiation oncology equipment commissioning, accuracy, reliability and quality assurance, radiology physics and radiation safety and emerging technologies related to medical physics and biomedical engineering.

To support these competencies, participation in education and continuing professional development (CPD) is recommended. Continuing education (CE) is shown to improve the knowledge, skills and behaviour of health professionals as well as enhancing patient health outcomes. CE is most effective when it is ongoing, interactive, and contextually relevant and based on needs assessment [11]. The supervision of staff is enhanced when mentorship is provided by staff with skills and training as an educator [12].

To reduce adverse clinical incidents, staffing levels and non-clinical time for training and development should be reviewed regularly to take account of the facility's current workload, research and development activities, maintenance of quality systems and pressures associated with commissioning new equipment or systems [13].

Participation in CPD is mandatory for RO RANZCR Fellows and RT members of the AIR.

The ACPSEM provides a CPD register for its members to facilitate professional responsibilities in maintaining professional standards of practice.

SUPPLEMENTARY EVIDENCE

- Staff members have documented current position descriptions that describe their required skills and knowledge.
- Documentation of orientation provided for all new staff.
- There is a CPD policy that describes the support for participation in continuing professional development such as in-house programs, mentorship, study leave, conferences and workshops.
- Access to other facilities for training is available where relevant.
- Staff members responsible for the education, training and supervision of fellow colleagues have access to further instruction and support.

STANDARD 2 – WORKFORCE PROFILE

The workforce is managed to ensure delivery of safe quality care.

CRITERION 2.1

Staffing numbers are established to safely meet planned patient care capacity.

SUPPLEMENTARY COMMENTARY

The mix of skill and experience within the workforce should be evaluated and managed according to service, safety and quality objectives and facility operation.

Health care systems that have similar resource levels to Australia provide points of reference for workforce profiles for ROs, RTs and ROMPs [14-19].

CRITERION 2.2

Rosters and schedules incorporate time for non-direct patient care activities applicable to the facility's service delivery profile.

SUPPLEMENTARY COMMENTARY

Rosters and scheduling should be considered in terms of the availability of skilled and experienced staff. Rostering should facilitate skill development, maintenance and continuing education with the support of management through the provision of financial and non-financial resources.

SUPPLEMENTARY EVIDENCE

- There is a protocol that describes the process and frequency for workforce evaluation and management activities consistent with the recommendations of the respective professional bodies.
- Data are collected and monitored to support workforce planning.
- Records of financial and non-financial support provided to allow staff to participate in non-direct patient care activities.
- There are policies to facilitate recruitment and retention of skilled staff.
- Records are kept of staff turnover.
- There is a system for managing the availability of staff, whether directly employed by the facility or providing services under contractual arrangements.
- Rosters show protected non-patient care time is available to assist all staff to undertake continuing education.

STANDARD 3 – MANAGEMENT OF RADIATION ONCOLOGY PATIENT RECORDS

Management of the radiation oncology patient record supports safe, quality care.

CRITERION 3.1

The radiation oncology patient record is the primary, comprehensive source of information for the delivery of patient care and complies with jurisdictional legislation and follows RANZCR guidelines.

SUPPLEMENTARY COMMENTARY

Records, administrative and recording practices are structured to provide a relevant, accurate and retrievable description of the patient's progress through their treatment. Records may be a composite of paper and electronic systems.

The precise detail, timing and location of any previous and current radiation treatment, including site, technique, verification procedures, delivered dose and number of fractions should be obtained and clearly recorded in the individual patient health record.

Staff responsible for radiation treatment of an individual patient should be identified in the radiation treatment record.

CRITERION 3.2

The radiation oncology patient record and databases containing patient information are logged, secure, accessible by authorised personnel and are retained according to jurisdictional requirements.

SUPPLEMENTARY COMMENTARY

The individual patient health record should be structured to allow sufficient access to necessary information by all health professionals involved in providing care.

Data have a role as a clinical and legal record and as a planning tool. Information relating to a patient's treatment is important for evaluating outcomes and can affect future treatment for that patient.

Records should be stored securely and the data retrievable through explicit privacy and confidentiality procedures.

Record-keepers in possession or control of a record that contains personal information must ensure that it is protected by security safeguards against theft, loss, unauthorised access, use, modifications or disclosures, and against other misuse.

The duration of storage recommended by the RANZCR [20] suggests that facilities design and plan systems that can retain information permanently. The ability to retrieve electronic information at a later date will require additional planning in relation to upgrade and obsolescence of any electronic systems.

SUPPLEMENTARY EVIDENCE

- The patient ID is recorded on each page of the treatment chart, whether paper or electronic format.
- Specific treatment related data are recorded at each treatment session, including the identity of at least two (2) accredited persons delivering treatment.
- There is a policy defining the levels of physical and electronic restriction of access to facility records.
- There are documented procedures for storage of electronic information when systems are upgraded or changed. (Examples include the ability to access information from previous electronic systems, and the existence of a DICOM archive for radiation therapy images, plans and dose distributions.)
- Tenders relating to the upgrade or replacement of system components that hold electronic data include specifications for comprehensive data migration to ensure that previous data is still accessible.

STANDARD 4 – DATA MANAGEMENT

The management of data supports clinical activities and reporting requirements.

CRITERION 4.1

The management of clinical data is planned, systematic and supports clinical audit, clinical trials, outcomes analysis and cancer registry requirements.

SUPPLEMENTARY COMMENTARY

Data items and definitions should be based on national data dictionaries to facilitate comparisons of outcomes, choices and treatment. There is agreement in principle between Australian jurisdictions to adopt a nationwide core clinical data set and dictionary [5, 21]. In any radiation oncology facility, the data to be collected will need to consider the requirements of a national data set as well as those of other reporting bodies. For example, professional bodies and statutory authorities require monitoring and audit of specific aspects of radiation oncology practice for quality assurance activities.

In each facility and jurisdiction there is a wide variety of stakeholders with differing data requirements. These may include clinicians, administrators and research groups and it is useful to consult these groups when planning or reviewing data collection [21, 22].

Strategic planning for data collection should include a multidisciplinary data management team led by an appointed data custodian. Understanding user needs is imperative to maintain the relevance and accuracy of data and ongoing support for its collection [23, 24]. Periodic audit of databases helps to ensure data integrity and improve patient management and organisation planning. Reporting the outcomes of data audits can improve staff communication, professional satisfaction and confidence in data collection activities. Any resulting improvements in data quality and integrity are then likely to contribute to improved management of cancer patients [13, 25].

CRITERION 4.2

Disease/diagnosis and staging data conform to recognised classification systems in accordance with facility policies.

SUPPLEMENTARY COMMENTARY

Data collections within radiation oncology facilities are used for the assessment of care of patients, health policy development, clinical research, clinical improvement and health service provision so it is important that the data are accurate and current [25-28].

Accurate reporting of cancer incidence, cancer management, facility activities and treatment outcomes are dependent on reliable and comprehensive data [20, 24, 28, 29]. Accordingly, data collection processes need to consider the reliability of data sources and timeliness of data entry [30-32].

The accuracy of data collection and data transcription depends on appropriate training for staff in current data collection practices and recognised classification systems.

CRITERION 4.3

There is a facility-agreed minimum data set used for each patient that meets the facility's clinical decision making and reporting responsibilities.

SUPPLEMENTARY COMMENTARY

Epidemiological research relies upon verifiable source data [28].

Data collected should be sufficient to allow care delivery to be tracked, monitored and evaluated. Provision of training in data entry, adequate staffing levels and resources are important to achieve compliance [24, 30, 33].

Monitoring demographic trends in cancer incidence, clinical practice trends and clinical outcomes may assist in forward planning for resources, facilities and infrastructure.

SUPPLEMENTARY EVIDENCE

- Toxicity detail provided by clinicians is consistent with the definitions specified in the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE v4.0) or a recognised equivalent.
- There is an appointed data custodian who has responsibility for the control and security of data collection and accuracy of entry.
- The data management plan should address:
  - consistency and continuity between electronic and paper records;
  - accountabilities;
  - data collection;
  - data storage needs of the organisation at all levels;
  - timeliness of data entry;
  - date stamping of events; and
  - management of events that are not date-stamped.
- The data management plan should include guidelines for ROs, RTs and ROMPs about the format of data provision and entry.
- There are scheduled reviews of the needs of staff for data resources, particularly with respect to identifying deficits, the use of available resources and prioritising strategies for improvement.
- There is a policy relating to facility response to data requests from professional and statutory bodies for identified clinical indicators.

STANDARD 5 – FACILITY INFRASTRUCTURE

The facility infrastructure promotes safe quality care and accountability in the delivery of radiation treatment services.

CRITERION 5.1

The strategic planning process addresses the operational and physical organisation of the facility and takes account of changing needs.

SUPPLEMENTARY COMMENTARY

A rational estimate of the number of megavoltage treatment units required is dependent on a number of factors. These include: the proportion of patients with given cancer type with indication for radiation treatment; the incidence of these cancer types; radiation re-treatment rates; and the machine throughput in terms of number of treatment courses per year for a linear accelerator.

Long term planning and investment is needed: to train the highly specialised staff required to prescribe, plan and deliver radiotherapy; provide treatment units and equipment; and build the facilities for them [34].

The facility's strategic plan should consider:

- the patient pathway;
- communication and information systems;
- measurement, quality assurance (QA) and quality improvement (QI) programs and process control systems;
- waste management;
- emergency and disaster management;
- security and safety management;
- risk, incident and complaints management;
- Occupational Health and Safety (OH&S);
- processes for addressing codes of ethics, conduct;
- processes for strategic alignment with local environmental needs, state and national directives, benchmarks or guidelines;
- processes for assessing, evaluating, and adapting to emergent technologies and techniques; and
- resources, financial, accounting, governance, and asset processes [35].

The process of strategic planning should also identify when, where and how to provide allied health services, as access to these services and care is essential to the delivery of quality radiotherapy services [36].

Staff involvement is crucial to organisational success. A participative culture involving all stakeholders, including patients and consumers will encourage individuals to work together in adapting and meeting new challenges, reshaping work patterns and redesigning job roles [37].

CRITERION 5.2

Facility management and performance are based on a multidisciplinary approach to ensure accountability and safety in the delivery of radiation treatment services.

SUPPLEMENTARY COMMENTARY

Operational infrastructure design addresses: resources, reward systems, physical work environment and job design; staff training and development; staff well-being; processes for monitoring and managing change; and processes for ensuring alignment with the overall strategic design [35].

The most important component in safe practice is qualified personnel. The safe and efficient operation of each item of equipment requires equipment system specific training [38].

Radiation oncology requires a multidisciplinary approach to the justification, adoption and implementation of new processes, technologies and techniques, as changes in the operational design and performance in one area may increase or decrease workloads in others.

Clearly defined leadership and organisational arrangements help ensure radiotherapy services are of a high quality [27].

CRITERION 5.3

The physical infrastructure and environment including patient, staff and public amenities are designed, managed and maintained to support safe practice in the delivery of radiation therapy.

SUPPLEMENTARY COMMENTARY

The physical infrastructure and environment of facilities must reflect their strategic objectives and operational infrastructure. These are important safety and quality considerations in facility design.

The facility should employ staff or contracted services with appropriate qualifications in room design, shielding and radiation safety.

The functional performance specifications for all equipment need to meet local requirements and relevant standards, and any deviations identified, documented and justified [38, 39, 40].

Life-cycle management includes upgrade and replacement planning, failure contingency planning, repairs, modifications, maintenance and calibration programs, service and operations logbook systems [41]. Adherence to manufacturer's specifications for life-span limits on equipment and systems will also ensure patient and staff safety and continuity of service.

The facility should comply with radiation protection legislation, including shielding requirements and equipment. When designing radiation shielding for a treatment room, factors that need to be considered include: workload of the equipment and the way it will be used; and the intended use and occupancy of adjacent rooms.

When purchasing new or replacement equipment, radiation protection requirements for shielding design, interlocks, control rooms etc should be considered. All differences should be identified, and any additional works specified by qualified expert(s), and included in the equipment purchase process. These would include changes in external beam energy; for example, by replacement of cobalt unit with linear accelerator of higher beam energy, requiring additional bunker shielding; installation of HDR unit and required control area and interlock systems.

The IAEA [42] stipulates the requirements for dedicated 'hot laboratories' for the use of unsealed sources. This includes the provisions for storage, shielding fume cupboards and support services.

IAEA [42] states that any modifications to building design subsequent to initial approval will be subject to a new approval process.

IAEA [42] states that relevant areas in the facility should be classified as controlled or supervised when specific protection measures and safety procedures are needed to control normal exposure and to prevent potential exposure.

SUPPLEMENTARY EVIDENCE

- The facility, its services and amenities are easily located, suitably signposted and have access for the disabled.
- Annual workloads and equipment performance, including comparisons to published and local benchmarks, are measured, monitored and documented.
- There is a structured system of communication and reporting processes across the facility.
- Records of the life-cycle management for all equipment and systems (maintenance programs, upgrade paths, end-of life projections, replacement programs) are maintained.
- Records of resource allocation (financial, personnel, time) for systems commissioning and implementation; support equipment and accessories to meet optimal QA, safety, dosimetry and calibration requirements are maintained.
- Records of shielding designs, calculations for radiotherapy equipment and details of measurements to verify shielding designs are maintained.

STANDARD 6 – FACILITY PROCESS MANAGEMENT

The provision of radiation treatment services is timely, coordinated and equitable to ensure optimal patient outcomes.

CRITERION 6.1

The patient pathway is co-ordinated to provide optimal patient outcomes within available resources.

SUPPLEMENTARY COMMENTARY

A patient's progress through a care facility is often referred to as the patient pathway. Fully understanding this pathway by mapping the processes is a key element for organising patient flow; ensuring that diagnosis, referral, treatment planning, treatment delivery, supplementary care and review are as efficient and patient-friendly as possible.

Other factors may impact on facility process management, for example staffing and equipment resources. Monitoring and benchmarking suitable indicators will highlight issues that need addressing.

CRITERION 6.2

Care is provided in a timely manner according to patient need.

SUPPLEMENTARY COMMENTARY

Waiting time is one indicator of quality of care. It is defined as "the time elapsed between the radiation oncologist's decision that treatment should commence (ready for care) to the first treatment being delivered". That decision is influenced by post-operative healing phase, post-chemotherapy recovery phase, patient requested delay, time for treatment of intercurrent morbidities that make the patient unfit to start treatment and any other delay beyond the control of the facility. These delays should be separately recorded [43, 44].

Clinical need and resource availability affect waiting list management. Undue delay, treatment interruption and unplanned treatment prolongation may result in adverse clinical outcomes and/or patient harm, reduction in patient satisfaction, negative impact on relatives and carers, negative impact on staff morale and increased demand for labour resources.

The Board of the Faculty of Clinical Oncology [45] list the five major causes of unscheduled interruptions to radical radiotherapy:

- machine and staff availability;
- public holidays/statutory days;
- patient transport problems;
- medical problems; and
- social circumstances that lead to a patient's failure to attend for treatment as scheduled.

Measures to address delay, treatment interruption or prolongation include:

- Adjusted working hours but this practice is not recommended as a long-term solution [44];
- Provision and maintenance of adequate resources;
- Avoidance of the adverse effects of prolonged breaks over public holidays by appropriate treatment scheduling;
- Planned scheduling of machine downtime to avoid treatment interruptions; and
- Compensation measures, including:
  - twice daily fractionation, minimum 6 hour interval;
  - weekend treatment;
  - use of biologically equivalent dose in fewer fractions to achieve planned overall time, where risks of normal tissue complication allow; and
  - additional fractions where compensation cannot be achieved within the original planned time [46].

Benchmarking through the regular monitoring of equipment capacity helps identify future planning and resource needs [44, 47].

SUPPLEMENTARY EVIDENCE

- There is a written protocol that describes the principles of the patient pathway.
- Minutes and records from multidisciplinary team meetings that address the patient pathway and facility needs.
- There is a protocol for prioritising patients based on clinical need.
- Data on process indicators are provided to authorised organisations on request to allow benchmarking against other facilities.
- Audits of compliance with patient pathway policies and protocols.
- There is a policy for the transfer of patients to other facilities when treatment is extended, machine downtime or when patients cannot be accommodated in the facility.
- There are reporting mechanisms adhering to nationally agreed standards enabling comparisons of waiting times.

STANDARD 7 – RADIATION THERAPY EQUIPMENT

Radiation therapy equipment performs to specifications that ensure accurate and safe clinical treatment.

CRITERION 7.1

Qualified, trained and experienced staff specify requirements of new radiation therapy equipment.

SUPPLEMENTARY COMMENTARY

All radiation therapy equipment including software supports the clinical application, safety and accuracy of treatment planning and delivery.

The acquisition of new radiation therapy equipment should follow a needs analysis with input from a multidisciplinary team.

Compliance to relevant Australian and New Zealand Standards encompasses environmental conditions, protection against abnormal operation and fault conditions including electric shock hazards and mechanical hazards, as well as protection against hazards from unwanted or excessive radiation, and the accuracy of operating data.

It is the responsibility of the manufacturer to provide all relevant documentation for equipment function and maintenance.

CRITERION 7.2

New radiation therapy equipment, and any modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel.

SUPPLEMENTARY COMMENTARY

The equipment commissioning and QA records constitute the primary sources of information to support the accuracy and safety of radiation delivery

It is essential that installation of equipment – or modification to existing equipment – is performed only by suitably trained staff. Before modifications are made to existing equipment, staff should consult the manufacturer to establish if the planned modifications will affect performance of the equipment.

Acceptance testing is done to ensure that equipment performs to the specifications agreed in the purchase contract. Qualified staff should perform acceptance testing in conjunction with the manufacturer or their agent. Where particular local needs have been identified in the purchasing process, these should be tested with reference to the specified requirements. The warranty period commences when the equipment is accepted.

Data obtained during acceptance testing provides the information on which to base decision about the life-cycle of the equipment.

Equipment commissioning can be divided into three phases – verification of adherence to specifications, data acquisition and beam modelling. The baseline information obtained during this process provides the foundation for the future QA program.

It is essential to include software in all QA considerations. All changes to software should be subject to stringent acceptance, commissioning and QA checks as for initial commissioning.

Software changes from manufacturers may be mandatory, to fix a known problem, or may be elective; for example, to acquire increased functionality. In advance of proposed changes, release notes should be obtained from the manufacturers and the scope of the changes and implications for clinical use discussed with them.

Any software change should be scheduled to minimise disruption to clinical treatments, and to allow sufficient time for checking and QA before release for clinical use. Some checking programs are extensive, such as treatment planning system upgrades to the software.

All staff using software should be trained.

If any of the specifications are not met, it is essential the vendor, all affected staff and the regulatory authority (where applicable) be notified.

CRITERION 7.3

There is a preventative maintenance program for radiation therapy equipment that ensures safety, reliability, reproducibility and accuracy.

SUPPLEMENTARY COMMENTARY

The functional performance of radiation therapy equipment may be affected by breakdown, ageing or deterioration of any component. The output, laser checks and isocentre of the treatment machine need to be verified daily.

Maintenance may be carried out by the manufacturer's representative, or by in-house staff who are trained and qualified.

CRITERION 7.4

There is a quality assurance program to assess the ongoing performance of all radiation therapy equipment used in treatment planning and delivery.

SUPPLEMENTARY COMMENTARY

Equipment commissioning and QA records provide evidence that all radiation devices, both software and hardware, are maintained and monitored to ensure that the accuracy of dose delivery and imaging meets national and international standards. These provide the basis of an audit trail.

QA procedures may involve all members of the multidisciplinary team, depending on the equipment. These processes may be managed by a QA committee and should be approached from an organisational viewpoint and not be patient specific.

ROMPs are responsible for withdrawal of or restrictions to clinical use of equipment, when performance does not comply with stated baselines and tolerances or is not fit for clinical purpose as determined by the multidisciplinary team [48]. After any upgrade or modification of equipment by the manufacturer, the ROMP is responsible for ensuring appropriate checks are performed [48] and QA procedures put in place.

All staff performing equipment QA procedures must be trained and be familiar with local practices. The QA committee is responsible for local guidelines on the introduction of new equipment or techniques.

The QA program should have planned periodic reviews – and should also be reviewed consequent to the publication of new or revised national or international guidelines – to ensure that it continues to cover all aspects of treatment techniques in use.

SUPPLEMENTARY EVIDENCE

- There are guidelines to describe the procedure for determining equipment specification. These guidelines include advice on ensuring compliance with statutory regulation and safety requirements. These guidelines address occupational health and safety, clinical requirements and training needs.
- There is a documented strategy for the purchase and replacement of equipment, which includes consideration of budgetary measures.
- User manuals and equipment documentation and/or specification are available including notifications and alerts from manufacturers. The method of dissemination of this material to all users is defined.
- Vendor equipment documentation demonstrates that equipment requirements comply with Australian and New Zealand Standards.
- Records are maintained as documented evidence of equipment and safety training, and evidence is provided that these are reviewed prior to staff/operator rotation on to equipment.
- Registration documents are available in accordance with appropriate legislation.
- Logs of all service reports are maintained for both planned and corrective maintenance activities. Service reports contain detailed information on work completed and the performance of equipment with reference to manufacturer's specifications.
- All staff and contractors who perform maintenance work on equipment have appropriate training and qualifications and can be identified.

STANDARD 8 – THE RADIATION TREATMENT PRESCRIPTION

The radiation treatment prescription documents the intended course of treatment for the individual patient.

CRITERION 8.1

Patients are informed of the benefits and risks of the proposed radiation treatment and their consent is documented by the consenting clinician.

SUPPLEMENTARY COMMENTARY

Informed decision-making is an important component of high quality health care.

Patients are entitled to make their own decisions about whether to undergo proposed radiation treatment and need information to make these decisions [49]. The information should be provided in a format and manner that helps patients understand their diagnosis and the proposed radiation treatment. Patient involvement in the development of written information makes it more relevant, easier to read and more understandable, without increasing their anxiety [50]. It needs to be appropriate to the patient's circumstances, personality, expectations, fears, beliefs, values and cultural background [5, 51].

Written information is a source of information that complements the information provided verbally by the consulting radiation oncologist. Written information should be offered to patients rather than expecting them to find it [41]. This should include information that is anatomical-site specific and information about radiation treatment issues in general, including the use of permanent skin marks.

Information should describe the potential side effects for each individual patient. Advice for dealing with and managing side effects should also be included and there should be an identified point of contact for patient queries.

Written information for patients should be evidence based and reviewed regularly to ensure it remains current [52].

It is important to tailor written information to the local population, which includes providing it in the major languages spoken within the area.

CRITERION 8.2

The radiation treatment prescription conforms to legislation, licensing regulations, policies and clinical protocols and guidelines.

SUPPLEMENTARY COMMENTARY

The radiation treatment prescription is the primary source of information for the planning and delivery of safe radiation treatment and documents the intended course of treatment.

Data items essential to prescribing radiation treatment are documented in the radiation treatment prescription by the radiation oncologist. The use of consistent and common datasets and terminology known by all staff enables the prescribed treatment to be accurately interpreted.

The use of prescription templates is common practice in Australia. Templates may be pre-printed prescription sheets or in electronic form. Their use enables all prescriptions for radiation treatment within a facility to conform to a common format and provide consistent information.

National and international disease related protocols and treatment guidelines are useful evidence-based tools that contribute to consistency in the prescribing of treatment.

Reports from the International Commission on Radiation Units and Measurements [53-58] provide recommendations for the prescribing, recording, and reporting of radiation treatment. Use of these internationally recognised guidelines allows comparison between facilities.

CRITERION 8.3

Radiation treatment prescriptions are regularly audited by peer review.

SUPPLEMENTARY COMMENTARY

There is evidence that ongoing audits of treatment contribute to the continuing quality improvement of radiation oncology practice and staff education [3, 9].

SUPPLEMENTARY EVIDENCE

- The staff education program includes the principles of informed consent and their application.
- There is a procedure for involvement of professional interpreter services.
- Evidence-based written information, including the potential side effects, is available to patients about anatomical-site specific treatment and radiation treatment issues.
- Information for patients is written in the main languages spoken in the local population and contains contact details for patient queries.
- Written information for patients is regularly reviewed and includes input from patients.
- There is a policy that states the requirements and definitions to be used for prescribing radiation treatment.
- Nationally and internationally endorsed disease-related protocols for the prescription of radiation treatment are available.
- There is a documented policy for the conduct of radiation treatment prescription audits that describes:
  - the frequency of audits;
  - the number of records to be audited;
  - the personnel to be involved in the audit; and
  - the reporting requirements after the audit; for example, compliance with protocols.

STANDARD 9 – PLANNING PROCEDURES

Comprehensive, safe and consistent planning procedures promote optimal treatment outcomes.

CRITERION 9.1

Treatment planning protocols are documented, accessible to staff and endorse evidence-based best practice.

SUPPLEMENTARY COMMENTARY

Uniformity of treatment planning protocols is desirable so as to enable evaluation of treatment outcome. Regular auditing of treatment planning protocols is an important quality assurance initiative [59, 60].

Treatment planning protocols encompass: patient positioning, immobilisation and monitoring, simulation and imaging, contouring and target definition, suggested beam positioning, plan development and evaluation.

The contouring procedure, which encompasses the treatment voluming process, delineates all relevant regions of interest including, external contour, gross tumour volume (GTV) or clinical target volume (CTV) or planning target volume (PTV), organs at risk (OAR), air cavities, bolus, artifacts and fiducial markers, using manual and/or computer-assisted methods [55, 57, 60].

Quantitative data displays encompassing dose statistics, dose volume histograms and biological modelling – tumour control probability (TCP) and normal tissue complication probability (NTCP) – can be utilised to obtain quantitative information about an isodose distribution [61, 62].

Checking the record of radiation treatment – including the developed, evaluated and approved isodose plan – before a patient commences treatment, minimises the risk of planning-induced treatment errors [5, 63].

Treatment planning system software requires a comprehensive quality control procedure to ensure that the plan development and evaluation are accurate [38, 60, 64-67].

CRITERION 9.2

External and internal immobilisation methods and equipment are fit for purpose.

SUPPLEMENTARY COMMENTARY

A comfortable, stable and reproducible patient position is essential for the delivery of consistent and accurate radiation therapy and can be achieved using an immobilisation device/method [38, 60, 68-71].

All staff who use immobilisation devices should have relevant technical knowledge, and be aware of the usefulness, limitation/s and application of each immobilisation device.

All immobilisation devices should undergo a risk assessment and comprehensive clinical evaluation – including the effect on dose delivery – so that both patient safety and treatment outcomes are not compromised [48, 59, 72-74].

To determine the most appropriate immobilisation device for each patient and promote optimal treatment outcomes it is essential to consider the principles of stability and reproducibility, comfort, individual needs, organ motion and the complexity of the proposed radiation therapy technique [75-79].

The optimal treatment position is achieved and reproducibility errors are minimised by comprehensive documentation that itemises patient immobilisation and set-up details [63, 80-82].

Every personalised immobilisation device should be labelled to avoid incorrect use [5]. It is important to check that the correct device is used for each patient and there is visual verification by a second person.

It is necessary that all patients requiring an internal immobilisation method are given adequate instructions to maximise stability and reproducibility of patient position, as well as ensuring patient safety [75].

Where external immobilisation devices restrain patients, it is essential to have an action plan for rapid release to minimise patient distress [64].

Access to mould room facilities is required for the manufacture of custom immobilisation devices and additional treatment requirements,

CRITERION 9.3

Planning and imaging procedures localise, delineate and define target volumes and organs at risk, as well as enabling treatment verification.

SUPPLEMENTARY COMMENTARY

The pre-simulation process is important to promote accuracy and efficiency [60, 69]. Timely information for patients helps reduce anxiety, increases willingness to comply with treatment, and promotes reproducibility of patient position [70, 71, 83].

Patient position and immobilisation is determined at simulation. The simulation procedure combines the planning imaging process with the technical and clinical planning process.

Ensuring patient privacy, dignity and comfort is essential at all times.

Implementing an infection control policy minimises the harm that can arise from the transmission of health care associated infections, thereby ensuring patient and staff safety, and improving quality of care [84, 85].

Virtual simulation permits the radiation oncologist and radiation therapist to access a computed tomography (CT) data set to define a volume, treatment field and the isocentre.

Pre-treatment verification allows the radiation oncologist and radiation therapist to evaluate the feasibility of a proposed treatment plan, acquire verification images or re-evaluate a previously defined treatment field [69].

Planning and imaging equipment should be compatible with other equipment used in the facility to enable accurate and timely communication of digital images.

The dose a patient receives while undergoing planning and imaging procedures should be ‘as low as reasonably achievable’ (ALARA) to promote patient safety.

Comprehensive and accurate labeling of all planning images ensures image data can be used for quality improvement, education and research activities, and also as an important quality assurance procedure to minimise reproducibility errors and avoid incorrect use [38, 59, 86].

All planning images and planning data need to be durable, confidential, stored securely and easily accessible.

SUPPLEMENTARY EVIDENCE

- Records from multidisciplinary working parties established to develop treatment planning protocols for new techniques.
- All treatment planning procedures including imaging, contouring (manual or computer-assisted) and target definition are documented in the patient's record.
- Treatment planning protocols are accessible in designated work areas used by ROs, RTs and ROMPs.
- There is a policy for the review of treatment planning protocols.
- There is a policy for checking the accuracy of all volumes, including manual contours, 3D-generated volumes, automatically rendered volumes and interpolated volumes.
- Treatment plans and isodose distributions are compliant with treatment protocols.
- The chosen immobilisation device, with settings where applicable and patient set-up information are accurately documented and verified by another staff member during simulation.
- Procedures are monitored and evaluated to ensure that all data required for simulation, including images are requested, collated and reviewed prior to the patient's simulation appointment.
- There is a documented policy for checking of all simulation data.
- Verbal and written information explaining simulation and treatment is given to all patients prior to the simulation procedure.
- There are instructions available for patients on how to signal for help if they experience distress during the planning procedure.
- Documented quality assurance activities that monitor, evaluate and address:
    - image quality, including issues of noise, distortion, artefacts, contrast, resolution, compression and reconstruction;
    - image communication and integrity, including the conformance of planning equipment with DICOM; and
    - image systems, including transfer between hardware and software systems.
- There is a policy that describes the best practice procedures for imaging each region of the body in relation to the: size of the imaged area or upper and lower scanning levels; type of views imaged per technique or the thickness of slices; and the standard exposures or recommended settings.

STANDARD 10 – DOSIMETRY

A dosimetry system, consistent with national and/or international standards ensures the safety and accuracy of the prescribed radiation dose for all clinical treatments.

CRITERION 10.1

Dose measurement ensures compliance of the dose delivery with the treatment prescription.

SUPPLEMENTARY COMMENTARY

Accurate dosimetry can only be attained by strictly following a specific protocol that defines the method and appropriate correction factors to determine absorbed does at the reference point (formalism). In Australia dosimetry formalism is determined by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) [68].

ROMPs are responsible for the calibration of dosimetry equipment and must ensure that it is fit for the purpose of accurately measuring dose.

CRITERION 10.2

The calibration of the radiation dose delivered by all clinical treatment units is consistent with dosimetry codes of practice recommended by national regulatory authorities.

SUPPLEMENTARY COMMENTARY

Accuracy in the dose delivery of treatment equipment is verified through periodic independent dosimetry audit [87].

Treatment delivery equipment must be calibrated using dosimetry equipment with calibrations traceable to the national dose standard kept by a national standards laboratory [60, 88].

CRITERION 10.3

A system for the calculation of dose distributions in the patient ensures that all doses can be directly related to the absolute dose determined for the treatment equipment under reference conditions.

SUPPLEMENTARY COMMENTARY

The purpose of the treatment planning data must be identified, as well as the date of issue, document name and number. The data must have clear guidance for its use and its limitations specified [38, 68, 87].

For purpose of audit, the data sources must be traceable with details of measurement conditions [87, 88]. Inaugural data collection at new treatment units should be verified with relevant published reference data as endorsed by the ACPSEM [89].

For purposes of on-going quality assurance, all dosimetry data should be saved as reference data in a suitable format [68] and all superseded data must be withdrawn from clinical use to prevent accidental use of outdated data.

CRITERION 10.4

Calculation of monitor units (MU), exposure times or dwell times required to deliver each prescribed dose are independently checked.

SUPPLEMENTARY COMMENTARY

Treatment planning systems (TPS) and independent dose calculations systems should be commissioned according to international best practice and national ACPSEM recommendations [68, 86, 90].

All calculations of dose to a patient must be independently checked by a second authorised RT or ROMP before treatment is delivered. This check should be performed using an independent dosimetry system to verify the calculation process and that the appropriate dosimetry data have been applied. Software or processes to perform the monitor unit check calculation should be independent of the primary calculation; for example, software and machine data files should not be shared in the calculations.

If there are changes to the treatment plan or monitor units, any new calculated dosimetric data, including monitor units are to be subject to the same calculation and checking processes as the initial calculation process.

To verify the entire dose calculation chain, the dosimetry for any new treatment delivery equipment, TPS (including changes to algorithms) and new treatment technique should be verified by a ROMP by dose measurement in a phantom before clinical implementation [68, 91, 92].

CRITERION 10.5

There is a system for independent verification of dose delivery to individual patients.

SUPPLEMENTARY COMMENTARY

In-vivo dosimetry should be used to verify new methods of dose calculations, including new treatment planning systems; new treatment techniques or modalities, when new beam modifiers are introduced; and to assess dose to critical organs or structures [91-93].

The ROMP is responsible for establishing and maintaining the accuracy of in-vivo dosimeters according to ACPSEM recommendations.

In-vivo dosimeters may perturb the incident radiation beam, which means that the effect of the in-vivo dosimeter on the dose distribution should be assessed by a ROMP and approved by the prescribing RO.

SUPPLEMENTARY EVIDENCE

- There is documentation that dosimetry equipment is checked at least at the frequency recommended by the ACPSEM.
- Documentation of actions taken to re-calibrate equipment following independent and internal audit processes.
- Documented systems for control of all data used in patient dose calculations are available.
- There are documented pre-defined or set action levels to determine if independent dose calculations are outside tolerance limits.
- There is access to in-vivo dosimetry equipment for patient dose monitoring.
- The procedure for in-vivo dosimetry is based on national and international recommendations.
- Patient in-vivo dosimetry records or reports are available as part of the medical record of treatment.

STANDARD 11 – RADIATION TREATMENT DELIVERY

Treatment is delivered correctly, accurately, safely and consistently with due consideration of the patient's rights and responsibilities.

CRITERION 11.1

Verification procedures are used that minimise the risk of incorrect patient, incorrect dose and anatomical treatment misplacement.

SUPPLEMENTARY COMMENTARY

It is important to treat a patient with the correct treatment to the correct site otherwise a misadministration occurs. The *Draft National Safety and Quality Health Service Standards*, standard 5 (Patient Identification, A) requires "At least three approved patient identifiers are used when providing care, therapy or services" [94].

The site to be treated should be verified at the first treatment episode with the patient. This may be done by: asking the patient to state the site (including laterality) to be treated; using a photograph of the treatment site or field marks; or using an anatomical diagram displaying the location of treatment fields.

Patient confidentiality should be protected in the identification process.

Accredited or credentialed persons delivering the first treatment should use more than one source of information to crosscheck data in the electronic record and verify (RV) system; for example, treatment plan, patient's health record, set-up, and isocentre heights. Regular checks of the RV system should be undertaken to monitor the integrity of these data.

Any changes to treatment should be recorded in the patient's treatment chart or electronic record with the identification of the person making the change and the recorded date of the changes.

A position verification process is used to monitor patient positional differences and uncertainties and facilitate accurate treatment delivery through the adoption of appropriate action levels and clearly specified interventions. The frequency of verification images depends on the site treated, treatment intent, the immobilisation device used, an individual patient's condition and the intended degree of reproducibility sought.

Checks of the source/focus to surface distance (SSD/FSD) before the first treatment and at regular intervals verify that the patient geometry is as expected in the treatment plan. They also detect changes in patient shape over time; for example, due to weight loss. Day to day variations in patient set up are likely to be random and smaller in magnitude than first day variations. Other influences in positioning accuracy include disease change and modification to set up or shielding.

Verification of the treatment isocentre and field position is done prior to the first treatment and re-evaluated at regular intervals during the course of treatment. This may be done by comparing it to the digitally reconstructed radiograph (DRR), simulator film or other localisation methods such as fiducial markers.

Orthovoltage, superficial x-ray and electron treatments should have the field position verified visually at the treatment unit at the time of each treatment to decrease the incidence of field placement errors.

CRITERION 11.2

Patients are observed during radiation delivery and monitored according to need.

SUPPLEMENTARY COMMENTARY

A visual monitoring system promotes patient safety. In instances where patients may require assistance, or in an emergency; for example, if a patient vomits, treatment can be suspended immediately.

CRITERION 11.3

Patients are reviewed for their fitness to continue and for their psychosocial needs throughout a course of treatment.

SUPPLEMENTARY COMMENTARY

Weekly review should include documentation of any radiation-induced side effects (preferably using a recognised acute toxicity scale) and document any interventions provided or recommended.

Progress reviews allow the patient's psychosocial wellbeing to be monitored and any issues managed in an appropriate and timely manner.

Patients should be given the opportunity to discuss any relevant issues with staff throughout their treatment course.

SUPPLEMENTARY EVIDENCE

- There is a system to cross-check specific data prior to the first treatment episode, including:
  - that the treatment plan has been signed by the treating radiation oncologist;
  - that the treatment plan, chart and/or electronic record and verify (RV) system have been checked at least once;
  - that digitally reconstructed radiographs (DRR) or simulation radiographs have been checked at least once; and
  - that an independent monitor unit calculation has been performed, or for intensity modulated radiation therapy (IMRT) treatments, that an independent dose measurement check has been performed.
- Treatment parameter data are crosschecked to the treatment plan and set-up at the first treatment session and whenever there is any modification of the treatment plan. These parameters include:
  - gantry angle;
  - collimator angle;
  - machine;
  - modality;
  - energy;
  - aperture;
  - beam modifiers (wedge size and direction, shielding, Multileaf Collimator (MLC), compensator, electron cut out, bolus, HVL, applicator);
  - monitor units / treatment time;
  - couch positions;
  - landmarks;
  - SSD/FSD or SAD/FAD;
  - accessory equipment (immobilisation devices); and
  - additional instructions (rectal emptying, bladder filling, pre-medication).

- There is a written protocol on verification imaging requirements, which includes frequency of imaging for various sites, radiographic technique, radiation exposure, acceptable variation from isocentre and the process of review.
- Specialised staff and ancillary support equipment are available to deliver radiation treatment safely to: patients undergoing chemotherapy concurrently with radiotherapy, paediatric patients, patients with cardiac pacemakers or implanted defibrillators, and patients with other special needs.

STANDARD 12 – SAFETY, QUALITY AND IMPROVEMENT PROCESSES

Safety and quality processes ensure safe, quality patient care with a commitment to quality improvement.

CRITERION 12.1

Facility governance acknowledges and supports safe practice, quality improvement, innovation and the safe and considered introduction of new technologies.

SUPPLEMENTARY COMMENTARY

Risk management proactively reduces identified risk to an acceptable level with preventative measures rather than reactive remedies. It plays a vital role in supporting and informing decision-making in providing a safe and secure environment for patients, staff and the public [95].

CRITERION 12.2

Risk to patients, staff and the public is managed in accordance with OH&S, national standards and the principles of safe practice.

SUPPLEMENTARY COMMENTARY

Risk Management and the Guidelines for Managing Risk in the Healthcare Sector (AS/NZS 4360: 2004) describe a coordinated approach to clinical risk management. Two Australian bodies provide direction on safe working practices and environments.

Safe Work Australia requires that facilities provide a safe environment for all employees in compliance with relevant workplace safety directives. It also requires each facility to have an incident notification, investigation and reporting system for all staff and patient incidents that complies with workplace safety directives. In addition, all staff should be trained in manual handling procedures relevant to their daily duties [96].

The National Occupational Health and Safety Commission, requires all facilities to meet all building regulations contained in the Occupational Health and Safety Act. It also requires each facility to ensure that all chemical use and chemical storage meets relevant Occupational Health and Safety Acts. Risk assessments on all equipment and chemical use should be undertaken and reviewed on an annual basis.

Similar information is available from the New Zealand Department of Labour.

Good cleaning practices help to reduce infection hazards and have a direct influence on the quality of care. The cleanliness of the facility should be maintained and monitored.

CRITERION 12.3

Facility governance, policies and procedures incorporate the intents of The Australian Charter of Healthcare Rights.

SUPPLEMENTARY COMMENTARY

There are procedures to address patients' rights and needs.

Feedback on patient satisfaction is regularly obtained, analysed, reported and responded to. 'Complaint' handling procedures should be readily available to any individual about whom a participating organisation holds personal information. The facility is required to promote this process and ensure that it is easy to use and free of charge [94].

There are ten underlying principles in the Australian Privacy Act (1988): collection, use and disclosure, data quality, data security, openness, access and correction, identifiers, anonymity, trans-border data flows and sensitive information [97].

The Australian Privacy Act (1988) and the Australian Freedom of Information Act (1982) outline processes for sharing of relevant patient information between health professionals [98, 99].

CRITERION 12.4

The technical quality of care and patient outcome is evaluated, compared to benchmarks for best practice, and acted upon accordingly.

SUPPLEMENTARY COMMENTARY

Quality audit entails systematic and independent evaluation of the quality system or its components to assess performance and to identify areas that need updating or improvement. A quality audit documents current practice, and can lead to improved service delivery [5, 100].

Chart rounds or clinical audits provide a useful forum for in-house peer review, education and effective real-time communication among all members of the multidisciplinary team responsible for delivering radiation treatment [101]. It is paramount to good patient care for this communication to be clear, precise and accurate in detail. A regular chart audit should be a part of the quality assurance program of every radiation oncology facility [102].

SUPPLEMENTARY EVIDENCE

- A designated multidisciplinary committee oversees all quality improvement activities.
- Risk management strategies are used to overcome potential threats and weaknesses in the provision of radiotherapy treatment services.
- There are programs to educate all staff on quality improvement processes.
- There is an elected occupational health and safety officer responsible for liaising between with management and staff about safe work conditions and compliance with the relevant OH&S Act.
- There is an up to date 'hazardous chemical database' and relevant 'material safety data sheets' available at the point of storage of hazardous chemicals.
- There is protective equipment, including gloves, goggles, aprons and adequate fume cupboards available for staff when working with chemical hazards.
- Equipment safety notes are available to all staff expected to use clinical equipment.

- There is a fire and emergency evacuation plan with which all staff are familiar. All staff should attend an orientation program about the plan and annual training updates.
- Manual handling refresher training is conducted by clinical staff on an annual basis.
- There is correct signage to alert staff, patients and the public of all potential hazards, including flammable chemicals, radiation warnings and electrical hazards.
- There is an infection control policy that includes procedures and equipment consistent with national minimum standards and infection control principles that identifies the potential health risks and safety precautions, specifies action plans and documentation procedures, and describes routine work and cleaning practices. This policy is revised and updated regularly.
- There is a manual of standard operating procedures and protocols that is readily accessible to all staff employed or contracted to provide services.
- There is a formal complaint handling procedure.
- There is a policy for the provision of patient information to other health care providers.
- Professional interpreters are provided for patients from culturally diverse backgrounds who have difficulty understanding the English language.
- The physical environment is conducive to maintaining patient dignity and privacy.
- There are regular patient chart rounds or clinical audits.
- The treatment chart is checked upon completion of a course of radiation treatment for concordance with the prescribed treatment.

STANDARD 13 – RADIATION SAFETY

All radiation exposures are managed to minimise risk to patients, staff and the public.

CRITERION 13.1

The management plan for radiation safety defines responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety.

SUPPLEMENTARY COMMENTARY

The responsible person has the overall management responsibility and control of the radioactive source, radiation-producing equipment or medical practice. It may be a natural person, a corporation, chief executive officer or director of medical services for example [103].

Each facility that uses radiation is legally required to appoint a natural person as a radiation safety officer (RSO) to manage radiation safety. In radiation oncology facilities that person will generally be a senior physicist.

The radiation safety management plan must comply with jurisdictional legislative requirements. Sufficient resources are needed to support its practical application. The plan needs to address areas relevant to radiation safety (current IAEA BSS standards):

- work practices for managing medical exposures including the management of pregnant patients;
- roles and responsibilities in the facility, including reporting and delegation;
- staff training and resource allocation;
- protection and monitoring of staff, patients and areas accessible by the public, quality assurance procedures and records for all equipment used in the treatment delivery pathway;
- incident and accident reporting;
- maintenance of records as required by regulatory authority, for workers, radiation sources and apparatus, and premises; and
- emergency procedures.

The multidisciplinary radiation safety committee should monitor compliance with legislative requirements, and make recommendations to the facility.

The main duty holders under safety regulations for radiation oncology facilities must be qualified and one or more must be closely involved in every radiation oncology practice or procedure [48]. As the radiation treatment prescription provides the justification for the exposure of the patient, the radiation oncologist maintains responsibility for overall radiation protection of the patient (IAEA BSS).

CRITERION 13.2

The radiation oncology facility maintains a register of equipment, staff and safety notifications relating to radiation safety and ensures notification and communication as required by the regulatory authority.

SUPPLEMENTARY COMMENTARY

The information required on radiation equipment includes treatment room location, beam energy and modality. Radiation source information required includes the source type, its strength and location. The location of radioactive sources should be easy to access by all emergency staff, including fire fighters and police.

Licences are required to acquire, transport and dispose of sealed and unsealed sources for diagnostic and therapeutic use. The RSO must ensure that there is safe storage accessible only by qualified staff and that, sources are handled only by qualified staff. Safety procedures will include: measures to prevent theft, damage and unauthorised use or disposal; processes to ensure radioactive sources are under control at all times; procedures to ensure that receivers possess valid authorisation; and periodic inventory.

Legislation in each jurisdiction specifies the acceptable dose limits around premises and in controlled areas. The RSO must ensure there is compliance with these dose limits and that interlocks and warning signals are as specified by the legislation.

The Code of Practice states that the responsible person has accountability for the movement, management and safe discharge of brachytherapy patients Furthermore, the responsible person must minimise the risk of contamination from accidental spill or the loss of sources, and ensure the safe movement and removal of radioactive sources.

In the event of a patient death while undergoing treatment with radioactive substances, whether sealed or unsealed, and if the deceased still retains, in or on the body, significant amounts of radioactivity the RSO must detail administrative procedures and instruct all persons who have a risk of exposure to the deceased.

CRITERION 13.3

Appropriate equipment and resources are available for radiation survey measurement in both routine checks and emergency situations.

SUPPLEMENTARY COMMENTARY

Radiation oncology facilities must protect the health and safety of staff from the harmful effects of radiation by personal monitoring, protective equipment and training.

All staff with access to controlled areas, including administrative, nursing and cleaning staff need personal monitoring devices [99]. Records of personal monitoring must be regularly checked by the RSO or delegate. Unusual doses, including doses in excess of the norm but not necessarily in excess of prescribed limits, need to be investigated and, if necessary, remedial action taken. Staff must be advised of their radiation assessment results.

Defence-in-depth principles are applied to procedures and processes involving radiation. These refer to the use of sufficient layers of physical or procedural measures in the facility design and operating procedures to prevent accidents, minimise harm from error and restore safety should an accident occur [99].

Equipment for monitoring radiation and for use in responding to emergency situations includes a calibrated survey meter that is traceable to a national standard, electronic personal dosimeters, spill kit, source handing devices, protective clothing. In the selection of equipment available and used for the measurement of radiation dose or radioactive contamination, there should be surplus equipment, which ensures backup.

The radiation safety committee should ensure that people in a facility know their role and the procedures to be followed in the event of a radiation accident or unplanned exposure. Specific equipment is required to assess the scope of a radiation emergency or accident and it is the legal responsibility of the facility to ensure these resources are available. The RSO must ensure its availability and current calibrations. In the event of an emergency the RSO must ensure that a system is in place to contact the appropriate staff qualified to deal with the emergency.

CRITERION 13.4

There is regular review of all radiation safety procedures and physical verification to confirm continuing radiation safety.

SUPPLEMENTARY COMMENTARY

The radiation management plan should include a review of any changes in techniques and equipment for radiation safety; identify and address any failures and shortcomings; and maintain the cooperation of all staff, who should be consulted and informed about radiation safety management.

SUPPLEMENTARY EVIDENCE

- Working conditions in respect to occupational exposure to radiation are adapted for female workers who notify their employer should they become pregnant.
- There are protocols, conforming to respective state, national and international regulations, for the handling and management of brachytherapy and unsealed sources.
- There are protocols based on defence-in-depth principles for radiation emergency situations that include communication with all qualified staff.
- Records of the calibration of all radiation survey measurement devices are maintained.

STANDARD 14 – INCIDENT MONITORING PROGRAM

Participation in incident monitoring programs provides confidence that radiation is safely delivered in a radiotherapy facility with a safety-conscious culture focused on learning and prevention of error.

CRITERION 14.1

The radiotherapy facility participates in an incident monitoring program.

SUPPLEMENTARY COMMENTARY

Governance ensures accountability of clinical performance and the delivery of safe treatment.

All incidents and adverse events that occur within the facility must be recorded. Not all will be directly related to the physical delivery of radiation therapy. The RSO must ensure immediate internal reporting of any radiation incident or unplanned exposure, including assessments of significance, results of investigation and any corrective action taken.

Incident reporting mechanisms such as root cause analysis, micro systems analysis and failure mode and effects analysis are methods of documenting and analysing errors and may be used to audit risk management interventions. A register of all incidents and errors occurring in a radiation oncology practice is an essential part of a quality program [6].

Documentation and records of clinical data should be detailed enough to enable reconstruction of events in the future [5, 38, 60, 101, 104, 105].

An open disclosure policy is supported by management. The staff members are trained in open disclosure processes.

SUPPLEMENTARY EVIDENCE

- There is a non-punitive reporting system that encourages feedback on safety issues that includes clinical performance.
- In the event of unintended dose being delivered there are copies of reports to the relevant authority and any subsequent advice received from the authority.
- There is evidence of open disclosure practice.
- There is a process that enables the sharing of information on lessons learned from adverse events with other parts of the health system and other facilities.

STANDARD 15 – DOSIMETRIC INTERCOMPARISON

Successful regular participation in dosimetric intercomparisions provides confidence that radiation dose is accurately delivered in a radiotherapy facility.

CRITERION 15.1

The radiotherapy facility participates in dosimetric intercomparisons of at least one photon beam and one electron beam every two years.

CRITERION 15.2

Intercomparisons include at least one level III dosimetric intercomparison every five years using a treatment scenario relevant for the particular centre.

SUPPLEMENTARY COMMENTARY

The IAEA recommends that all teletherapy equipment outputs are compared at least once every two years in a regional, national or international program for independent dose verification [42]. Dosimetric intercomparison is necessary to independently verify the performance of the radiation equipment and should ideally be performed by an independent centre. Examples for this are the Radiological Physics Centre in Houston (http://rpc.mdanderson.org/RPC/home.htm) or the EQUAL network in Europe (EQUAL via http://www.estro.be/) and now the Australian Clinical Dosimetry Service (ACDS).

Three different levels of complexity are defined for dosimetric intercomparisons [106]:

- Level I: This constitutes an independent check of beam calibration under reference conditions in a physical phantom, usually water. It typically consists of only one measurement point. Such services are offered; for example by the ACDS, Radiological Physics Center (Houston) and the IAEA.
- Level II: A level II intercomparison verifies not only the dose under reference conditions but also the accuracy of some other factors required for treatment planning. As electron dosimetry intrinsically requires a verification of depth dose to determine the appropriate point of measurement and the electron energy, electron intercomparisons are necessarily a level II dosimetric exercise [107]. The measurements in level II dosimetric intercomparisons are done in a physical phantom, however, this may include inhomogeneities and/or surface contour changes [108].
- Level III: A level III intercomparison requires the use of an anthropomorphic phantom which is planned and treated as similar to a patient as possible. This can be a full anthropomorphic phantom [109] or a semi-anatomical phantom [110-112].

The advantage of a level III dosimetric intercomparison is that the entire treatment chain from the acquisition of diagnostic images to the treatment set-up and delivery can be verified. The disadvantage of verifying many steps in one procedure is that it is often difficult to identify which step has contributed to a particular outcome. As such it is required to repeat measurements and check smaller segments of the treatment chain if the overall level III check identifies a problem.

A level III dosimetric intercomparison also records the influences of differences in treatment technique and equipment available in participating centers.

Intercomparisons are also useful to verify other aspects of the radiotherapy delivery. Examples are brachytherapy [113] and electron irradiation [107].

Participation in clinical trials requires rigorous quality assurance. Dosimetric intercomparisons constitute an important part of the process ensuring that treatment in all centres participating in a multicentre trial is performed in a similar way.

Dosimetric intercomparisons reduce the risk of a serious error. Many of the incidences reported in IAEA safety report series 17 [91] could have been prevented if regular dosimetric intercomparisons were performed.

Participation in dosimetric intercomparisons itself improves performance – centres who have previously participated in an external dosimetric audit are less likely to be outside of an accepted limit on further dosimetric audits than centres that never participated in an intercomparisons [114].

SUPPLEMENTARY EVIDENCE

- The radiotherapy facility also participates in dosimetric intercomparisons of at least one kilovoltage (kV) beam every two years.

STANDARD 16 – CLINICIAL TRIALS PARTICIPATION

Any participation in human clinical trials is supported by governance and infrastructure to ensure quality care.

CRITERION 16.1

Participation in clinical trials conforms to international guidelines of good clinical practice.

SUPPLEMENTARY COMMENTARY

Optimal models of cancer care describe improvements in quality that occur through participation in clinical trials, based on better outcomes for trial participants and changes in culture that arise from clinical research. These include changes in attitude to reviewing the evidence base of treatment, compliance with protocols, and an improvement in evidence-based practice.

The infrastructure required for participation in clinical trials is dependent on factors related to the individual trial. This means that the indicators used by most multi-centre trials groups relate to accrual, and data completeness and accuracy [99]; for further information refer appendices A & B.

A multidisciplinary model of care is believed to provide the best outcomes and participation by the following groups should be considered: ROs, ROMPs, RTs, physicians, surgeons, radiologists, pathologists, pharmacists, nurses, data managers and clinical trial coordinators.

As part of research governance, centres should have a research review meeting as a quality process to review the operational aspects of research, including infrastructure, feasibility, accrual, protocol compliance, and other technical issues; for example, dosimetric aspects of compliance.

The Code of Practice for Exposure of Humans to Ionizing Radiation for Research purposes requires all research involving the use of ionising radiation conducted in facilities shall be in accordance with legislation as described in the Radiation Protection Series No. 8 [115].

SUPPLEMENTARY EVIDENCE

- The governance of clinical trial research is consistent with national and international standards, in particular those related to informed patient consent.
- Infrastructure is sufficient for clinical trials. This includes staffing, data management resources and facilities for file storage.
- Regular research review meetings occur.

DEFINITIONS

Acceptance testing	The process of verifying that equipment (both hardware and software) operates to performance specifications agreed between the vendor and customer according to a mutually agreed acceptance protocol.
Accuracy	Closeness of the agreement between the result of a measurement and a true value of the measurand (International vocabulary of basic and general terms in Metrology (VIM) draft 2004 revision, definition 3.5). If the true value cannot be determined, then an accepted value may be used as a substitute.
Brachytherapy	Radiation treatment using radioactive material (mostly an encapsulated source) brought into close contact with the treatment area (often by surgical means).
Bolus	Material (typically equivalent in density to normal tissue) placed directly on the patient in order to alter the dose distribution within the patient.
Commissioning	The process of acquiring all the data from a piece of equipment that is required to make it clinically useable in a specific department. Therefore, the commissioning procedure will depend on clinical requirements in a particular centre and other equipment available. For radiation delivery devices commissioning can be divided into three phases: • data acquisition • beam modelling • verification.
Contouring	A procedure that involves outlining regions and anatomical structures of interest including, but not limited to external patient contour, GTV/CTV/PTV, OAR, air cavities, bolus, artefacts and fiducial markers – using manual and/or computer-assisted methods.
Dosimetry	The measurement of absorbed dose in matter resulting from exposure to ionising radiations. In the context of the standards 'Dosimetry' refers to the measurement of physical dose and the provision of these dose measurements for the purpose of treatment planning. Dosimetry can be classified as relative or absolute dosimetry.
Equipment	In the context of the standards, the term equipment applies to all hardware and software used in a radiotherapy department.
Facility	A real entity that provides radiotherapy services.
Facility infrastructure	The framework of the amenities, both physical and operational, that support an organisational unit's operation and function. This basic architecture and its 'fit' with the environment determine how well the unit functions and how adaptive it is to change and future requirements.
Incident	An error, a near miss or any adverse event relating to patient care or patient, visitor and staff safety.
Intensity modulated radiation therapy	This term is used to describe the attempt to optimise the dose distribution during external beam radiotherapy delivery. Each radiation field is divided into small segments with varying radiation intensity which allows for target shape, location and the geometry of overlaying tissues. IMRT fields are typically designed using computer driven (or aided) optimisation. This is often referred to as 'inverse treatment planning'.

Interlock	A device which can inhibit radiation from commencing or terminate an irradiation process when a certain condition occurs (e.g. someone entering the treatment room).
In-vivo dosimetry	The measurement of absorbed dose to the patient at the time of treatment. The measured dose is compared with the planned dose to verify dose delivery. Doses are commonly measured with small detectors which will not affect the therapeutic dose distribution. These detectors may be diodes, thermoluminescent dosimeters (TLDs) or similar devices.
Isocentre	A point at the intersection of the rotational axes of gantry, collimator and treatment couch.
Monitor units	A MU corresponds to a known amount of charge collected on the internal ion chamber of a linear accelerator. The ion chamber can be calibrated so that the number of MUs relates to the absorbed dose of radiation delivered to the reference point under reference conditions. A MU is a measure of linear accelerator output. Commonly, linear accelerators are calibrated for a specific energy such that 100 MU gives an absorbed dose of 1 Gy under reference conditions.
Multileaf collimator	A device that is mounted in the collimator or replaces one of the collimator pairs. It consists of movable leaves which can be positioned freely to allow conformal shielding of organs at risk.
Organisation	The legal entity to which a radiation oncology service is affiliated.
Operational infrastructure	The management and business systems, structure and processes of the unit, the unit's services and staff.
Patient pathway	A patient's progress through a facility.
Phantom	In radiotherapy, the term 'phantom' is used to describe a material and structure which models the radiation absorption and scattering properties of human tissues of interest.
Quality assurance	All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.
Quality care	Care based on commonly accepted best practice and the associated patient outcomes.
Quality control	The techniques and methods built into an organisation's operations to control individual processes.
Quality improvement	Actions taken to review and enhance the quality of a process and/or service.
Quality program	Encompasses all quality activities as listed.
Radiation Oncology Medical Physicist	A person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring. A suitable person will either be on the register of ROMPs held by ACPSEM or have an equivalent level of training, skills, knowledge and experience.
Radiation Oncologist	A person who is registered as a medical practitioner by the relevant Medical Board and is a fellow of the RANZCR or equivalent and is licensed to prescribe radiation therapy.

Radiation oncology patient record	The primary source of information and includes the treatment chart (prescription and treatment sheet; paper based or electronic), all dosimetry and calculation data, as well as localisation and position verification data and images.
Radiation oncology service	The sum total of all affiliated radiation oncology facilities.
Radiation Therapist	A person who is qualified to standards set by the AIR or registered to practise according to jurisdictional requirements.
Radiation therapy equipment	For the purposes of the standards such equipment is defined as all hardware and software relevant to: • patient imaging whether radiation emitting or not • the planning and calculation of radiation dose to a patient • the delivery of radiation treatment to a patient • monitoring, measuring and/or otherwise controlling radiation dose
Radiation Safety Officer	A suitably qualified and experienced person who oversees all activities involving ionising radiation in a workplace. As such, the RSO is also responsible for training of others. Consequently, some of the duties may be delegated. The role and responsibilities of an RSO are defined by national standards.
Ready for care	Is when the patient is ready to commence radiation treatment as agreed between the patient and the radiation oncologist. Patients are not considered to be ready for care if: • the radiation oncologist considers treatment should not commence because the patient is in a postoperative healing phase and/or a post chemotherapy phase; • any existing morbidities require prior therapy; or • a delay is requested by the patient.
Responsible person	The person who has the overall management responsibility and control of the radioactive source, radiation-producing equipment or medical practice. It may be a natural person, a corporation, chief executive officer or director of medical services for example [104].
Service	See radiation oncology service.
Technical quality of care	Refers to the delivery of correct dose to the correct patient to the correct anatomical site as prescribed.
Treatment planning system	The computer hardware and software (including dose calculation algorithms) used to develop, evaluate and display a radiation treatment plan.
Treatment verification	The process of imaging and evaluating the position of the treatment isocentre, radiation treatment field and/or its shape, or anatomical volume against that determined in the treatment planning process.
Verification	Sometimes referred to as Record and Verify or R&V, commonly refers to the matching of a simulated or planned treatment parameter with that set on the treatment unit for treatment delivery.
Waiting time	The interval between the ready for care date and first radiation treatment being delivered.

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APPENDICES

APPENDIX A

- Knowledge and experience of conducting and managing patients in a clinical trial
- Adequate funding and infrastructure support for clinical trials activity, particularly with the appointment of a local data manager/clinical trial coordinator, file storage space, and technology requirements
- Systems in place to ensure staff work to appropriate guidelines and standards
- Systems in place to provide training, education and development
- Ability to work within ethical and legal framework, such as International Committee on Harmonisation, Good Clinical Practice, Therapeutic Goods Administration.

(National Cancer Research Institute, 2006)

APPENDIX B

	Acceptable minimum %
Eligibility and percent of patients evaluable	80
Percent complete forms – no additional inquiries	80
Timeliness of forms submissionw (including pathology and chemotherapy flow sheets)	80
Submission of initial treatment planning data	80
Responsiveness to additional inquiries	80
Submission of treatment data on completed cases	80

(RTOG 2005: Appendix IV)

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