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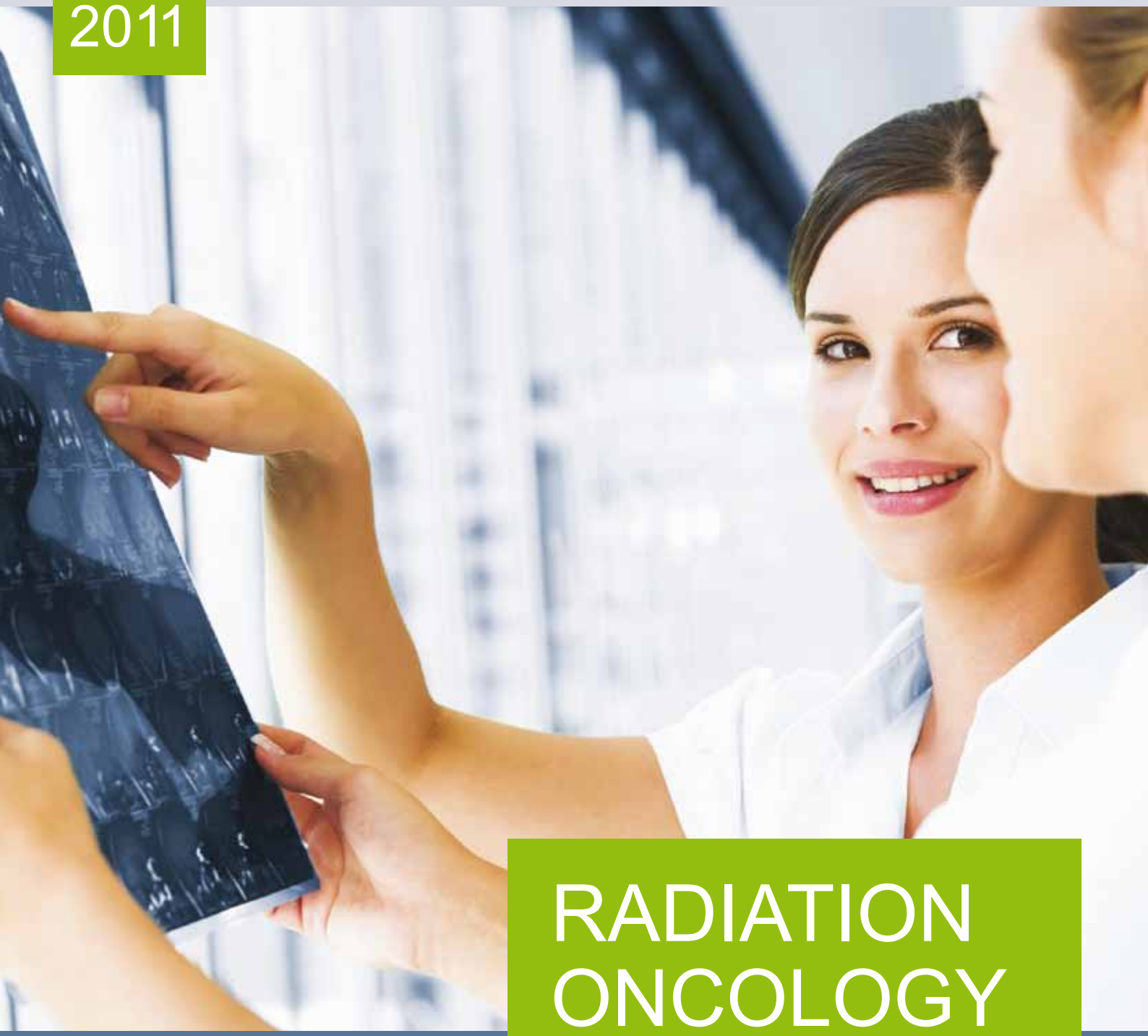

RADIATION ONCOLOGY **PRACTICE STANDARDS**

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.

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INTRODUCTION

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.

In order to establish a quality program, the need for a set of standards became apparent.

The standards in this document have been developed to assist radiation oncology facilities to achieve best practice by providing a framework of requirements. Regard should be given to local needs and these together with clinical judgement should govern how the standards are implemented. Facilities may choose to set additional standards relevant to their individual circumstances. Compliance with legislative and jurisdictional requirements is mandated.

It is expected that radiation oncology facilities will find these standards useful in the establishment and delivery of radiation oncology treatment services. It is also hoped that these standards will allow Australian facilities to be set up in a consistent manner that allows for common data collection and enables participation in national and international trials.

BACKGROUND

As mentioned in the Introduction, the Baume inquiry [1] identified a number of national radiation oncology issues, including quality and safety issues. The Radiation Oncology Jurisdictional Implementation Group (ROJIG) was established to develop a response to the Baume inquiry. It produced a final report in 2003 that recommended a quality program be developed and implemented as a priority. It recommended that such a program should encompass:

- facility accreditation;
- participation in a dosimetry program; and
- participation in an incident monitoring system for radiation oncology.

The Radiation Oncology Reform Implementation Committee (RORIC) was then established by the Australian Health Ministers Advisory Council to implement reforms in the sector. It has a number of working groups to progress sub-discipline issues, including the Quality Working Group. As part of the work of this Group, it was identified that a key component of a quality system is the need for practice standards.

The main health professionals involved in the delivery of radiation treatment are the medical specialist radiation oncologists, radiation therapists and radiation oncology medical physicists. Each of these disciplines works separately but in co-operation, to deliver their component of the radiotherapy process. 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).

Together, these professional bodies are represented by the Tripartite Committee.

In 2005, the Department of Health and Ageing (DoHA) began funding RANZCR to work with the Tripartite Committee to develop radiation oncology standards.

The initial draft standards were submitted to DoHA in April 2007. Since this time, a process of rationalising the standards has been undertaken. The material has been widely disseminated on several occasions and comments have been considered and incorporated as appropriate. This document is the result of the collaborative work.

THE SCOPE OF THE STANDARDS

The Radiation Oncology Practice Standards focus on the radiation treatment pathway and on aspects of the management of the facility considered by the Tripartite Standards Working Group to be of vital importance in the delivery of safe, quality care to radiation oncology patients.

The standards are grouped into three sections:

- Facility Management (Standards 1 to 7)
- Treatment Planning and Delivery (Standards 8 to 11)
- Safety and Quality Management (Standards 12 to 16)

It is important to note that the standards are interrelated and must be considered as a whole. Supporting each standard are a number of criteria and explanatory commentaries to assist with their interpretation. As the standards must be taken in conjunction with each other, it follows that a commentary may relate to more than one standard or criterion within the document. Required evidence does not necessarily relate to a single criterion; it may relate to several criteria in more than one standard

Facilities will note that many of the standards in the sections on Facility Management and Safety and Quality are not exclusive to radiation oncology units and will already be in practice particularly if the facility is participating in a quality or accreditation program. The standards that have been included are considered to be of importance in the current climate of radiation oncology practice in Australia.

Additional guidance is provided in the *Radiation Oncology Practice Standards Supplementary Guide.*

THE STANDARDS FRAMEWORK

The *Acronyms and Abbreviations* use the initial letter of organisations or commonly used phrases.

The *standard* states the goal or outcome, for example, *Management of the radiation oncology patient record supports safe, quality care.*

The *criteria* describe the key processes required to attain the goal, for example, *The radiation oncology patient record and databases containing patient information necessary for safe, quality care are available at all times.*

The *commentary* provides information to assist in incorporating the criteria into everyday practice. Wherever possible, the commentary has been referenced.

The *required evidence* lists the documents or records that the facility needs to be able to provide as evidence to demonstrate how well they have incorporated the Standards into practice, for example, register of equipment.

The *Definitions* explain the meaning of the technical terms used in the Standards.

The *Bibliography* lists all the references used in the Standards in alphabetical order.

Further Reading is suggested to provide more information and context to the Standards.

Appendix 1 contains a list of relevant Australian and New Zealand (AS/NZS) and International Electrotechnical Commission (IEC) standards.

Appendix 2 contains data items that should be collected by radiation oncology facilities as part of the incident reporting and monitoring standard (Standard 16).

Appendix 3 is a practical tool that aggregates the evidence that is required to demonstrate how well the Standards are being incorporated into practice and where relevant documents may be found.

ACRONYMS AND ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACHS	Australian Council on Healthcare Standards
ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
AIR	Australian Institute of Radiography
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
AS/NZS	Australian Standard/ New Zealand Standard
CT	Computed tomography
CTV	Clinical target volume
DH	Department of Health, United Kingdom
DoHA	Department of Health and Ageing
ESTRO	European Society for Therapeutic Radiation Oncology
FRO	Faculty of Radiation Oncology, the Royal Australian and New Zealand College of Radiologists
GTV	Gross tumour volume
ICRU	International Commission on Radiation Units and Measurements
IAEA	International Atomic Energy Agency
IMRT	Intensity modulated radiation therapy
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
IPEM	Institute of Physics and Engineering in Medicine
ISO	International Organisation for Standardisation
MLC	Multileaf collimator
NCCI	National Cancer Control Initiative
NHS	National Health Service, United Kingdom
NHMRC	National Health and Medical Research Council
OH&S	Occupational health and safety
OAR	Organ(s) at risk
PTV	Planning target volume.
QA	Quality assurance
RANZCR	Royal Australian and New Zealand College of Radiologists
RCR	Royal College of Radiologists
RO	Radiation oncologist
ROJIG	Radiation Oncology Jurisdictional Implementation Group
RORIC	Radiation Oncology Reform Implementation Committee
ROMP	Radiation oncology medical physicist
RSO	Radiation safety officer
RT	Radiation therapist
TROG	Trans Tasman Radiation Oncology Group

STANDARDS

FACILITY MANAGEMENT

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.

COMMENTARY 1.1

The qualifications of radiation oncologists, radiation therapists and radiation oncology medical physicists must reflect the skills and competencies required to deliver radiation oncology services safely. Recruitment and selection procedures must ensure that appropriate qualifications are held to enable registration to practice applicable to the jurisdiction [2].

CRITERION 1.2

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

COMMENTARY 1.2

Performance review systems must be in place to ensure that competencies are maintained and keeping pace with developments in radiation oncology. The performance review process should include review of professional responsibilities in terms of continuing professional education [3].

REQUIRED EVIDENCE

1(a) Registers of current registration/licence to practice.

1(b) Attendance records at staff development programs.

1(c) Records of regular performance review in accordance with facility policy.

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.

COMMENTARY 2.1

Radiation oncology is a complex multidisciplinary service that requires interaction between a broad range of professional and non-professional groups. Staffing levels and workforce profiles should ensure a safe and quality service to patients [4]. There is current evidence to support Australian RO, RT and ROMP workforce models and recommendations for workforce profiles that take account of system, professional, organisational and social variables [5-7]. Workforce profile must be considered in terms of risk management and should not be a causal factor in adverse patient care incidents as evidenced by incident analysis data. Data such as those derived from the previous twice yearly RANZCR undue delay surveys or similar data could be used as the basis for workforce needs analysis.

CRITERION 2.2

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

COMMENTARY 2.2

A facility's service profile will reflect the mix of non-patient care workload undertaken and includes but is not limited to clinical and general administration, teaching, training and education.

Workforce profiles must include consideration of both direct and non-direct patient care activities and workloads for all radiation oncology staff. Non-direct patient care workload may relate to clinical and general administration, teaching and education, continuing education, research and development, quality assurance and audit [8].

REQUIRED EVIDENCE

2(a) A documented system for managing workforce in relation to service capacity.

2(b) Evidence to demonstrate funded time within working hours for education, research and development, administration and quality assurance and improvement activities. Evidence may include staffing rosters and schedules and other examples of funded non-patient care time.

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.

COMMENTARY 3.1

Patient records store individual patient information and provide a reference base. The record should include demographic data, medical and social history, assessment, consultation notes and treatment record, clinical correspondence including referrals, the prescription and plan, test results and diagnostic staging studies and other administrative details such as health insurance status, billing, consent and legal correspondence. Other information that assists in safe patient management includes emergency contact, next of kin and required support services.

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.

COMMENTARY 3.2

Security and retention of the patient record and databases are important as there can be adverse consequences if confidentiality, integrity, availability, accountability, authenticity or reliability of information is compromised [9, 10].

REQUIRED EVIDENCE

3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months demonstrates:
- accuracy, comprehensiveness and currency of patient records;
- compliance with legislation and RANZCR guidelines; and
- remedial action where necessary.

Note: records required under 4(a) and 8(b) may be the same as required here.

3(b) Documented contingency plan for ensuring continuing availability of the patient record in the event of a disaster.

3(c) Register for the location of all patient information records and databases.

3(d) Records of action taken to address breakdowns in the procedures for:
- tracing patient records; and
- the security of records.

3(e) Evidence of the retention of records compliant with national and/or local requirements (whichever is the longer).

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.

COMMENTARY 4.1

Successful planning, evaluation and quality assurance of cancer control activities depends on the ability to collect reliable and standardised data sets.

CRITERION 4.2

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

COMMENTARY 4.2

Comparison of radiation outcomes and clinical trials requires the use of equivalent data items and definitions [11, 12].

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.

COMMENTARY 4.3

Gaps or inconsistencies in information may render the data inadequate for reporting, research or audit purposes [13].

REQUIRED EVIDENCE

4(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months includes:

- current versions of ICD and staging systems (or recognised alternatives);
- the facility-agreed minimum patient data set; and
- documented facility policies related to data definitions.

Note: records required under 3(a) and 8(b) may be the same as required here.

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.

COMMENTARY 5.1

The planning, structure and coordination of radiotherapy services are important because they can affect overall access and subsequent health outcomes [1]. The strategic, operational and physical design of radiotherapy services influence each other and should be developed in parallel [14].

The strategic design of an organisation links its objectives and planned outcomes with the environment and external infrastructure [15].

The strategic plan is developed with due consideration of:

- existing national benchmarks for access to radiation treatment [16];
- predicted population changes;
- broader organisational planning, where applicable;
- associated physical infrastructure, equipment, and staffing requirements;
- existing standards;
- multidisciplinary support services; and
- timelines for review and revision.

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.

COMMENTARY 5.2

Facility management includes the effective and efficient management of buildings, plant, equipment, supplies, external service providers, utilities and consumables [17].

The management team has representation from all relevant professions.

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.

COMMENTARY 5.3

Radiation oncology is a specialty that is particularly dependent on the availability of appropriate shielded facilities and equipment. The life-cycle management of buildings, plant, equipment and systems is an important consideration in maintaining quality service delivery.

The design of the environment and the patterns of patient care need to respect the ethnic, cultural and religious practices and beliefs of patients, and yet support a fast throughput of patients [18] while at the same time maintain appropriate hygiene.

REQUIRED EVIDENCE

5(a) A documented strategic plan with a facility agreed timeframe (not greater than 5 years) that identifies the ongoing development needs of the facility in order to maintain or improve the service provided.

5(b) A documented review of the strategic plan as designated by the plan itself.

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.

COMMENTARY 6.1

'How a radiotherapy service is structured, planned and co-ordinated has great effect on health outcomes and overall access to services' [1].

The RANZCR has published guidelines that outline acceptable and best practice for treating radiotherapy emergencies in a timely manner [19]. In addition, minimising disruption to a planned treatment schedule is an important quality initiative if radiation therapy is to achieve optimal outcomes.

CRITERION 6.2

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

COMMENTARY 6.2

Patient prioritisation should be based on the recommendations of the 2005 RANZCR document *Management of Waiting Lists for Radiotherapy* [19]. This advises that:

- priority should be based on medical need;
- emergency and paediatric cases are identified as having special priority;
- the radical/palliative balance should be considered;
- the issue of advanced pre-booking versus new diagnosis requires consideration;
- the priority accorded to inpatients should be considered;
- the objectives of setting priorities should include reduction of stress for both patients and staff;
- any process adopted should be efficient and reproducible; and
- a coordinated and national approach should be encouraged.

The 2005 FRO guidelines [19] from ready for care to first treatment are:

	Radical	Palliative	Emergency
Standard good care	within 14 days	within 2 days	within 24 hours
Maximum acceptable waiting time	within 28 days	within 28 days	within 48 hours

REQUIRED EVIDENCE

6(a) A documented policy for the management of waiting times for treatment that:
- identifies the method used to classify, record and report waiting times; and
- indicates strategies to minimise waiting times.

6(b) Data showing trends in waiting times and documentation of any response to unacceptable delays.

6(c) A documented policy that specifies the management of unscheduled interruptions to treatment and prolongation of a course of radiotherapy.

7. RADIATION THERAPY EQUIPMENT

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

Radiation therapy equipment is defined as:

- radiation emitting and imaging devices;
- dose measuring and monitoring devices; and
- treatment planning systems.

In the context of this Standard, the term equipment applies to all hardware and software used in a radiotherapy department.

CRITERION 7.1

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

COMMENTARY 7.1

Specifications must take relevant standards into account (refer to Appendix 1) and should include the provision of appropriate user training by the manufacturer or vendor.

Specifications should be written in conjunction with the multi-disciplinary team as appropriate to the equipment item.

CRITERION 7.2

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

COMMENTARY 7.2

Radiation oncology medical physicists should take responsibility for the commissioning program [20-22]. The program should clearly define: any baseline values for quality assurance and system operation; the scope of tests to be performed with respect to their intended clinical use; the staff groups to be involved; and the risk assessment for component or system failure.

CRITERION 7.3

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

COMMENTARY 7.3

The preventative maintenance program follows the manufacturer's recommendations. Any variations from the manufacturer's maintenance recommendations should be documented with explanations. All communication from the manufacturers, relevant to safety and operating functionality is kept and disseminated in the facility as appropriate.

A ROMP is responsible for authorising return of the radiation therapy equipment to clinical use following any repair, adjustment, upgrade or modification to the equipment that affects patient safety [20-22].

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.

COMMENTARY 7.4

ROMPs are responsible for establishing and overseeing a quality assurance program to assess the performance of the equipment against baseline values according to national and international guidelines for frequency of testing and for tolerances [23-34].

REQUIRED EVIDENCE

7(a) Records of acceptance tests and commissioning data for all radiotherapy equipment.

7(b) A documented quality assurance program for radiation therapy equipment that includes:
- all tests, their frequency and tolerances;
- a protocol for managing test failures and non-compliances that includes action levels; and
- reporting requirements and action taken.

7(c) Records of delays, unscheduled breaks in treatment and remedial action taken due to equipment failure.

8. 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.

COMMENTARY 8.1

Professional organisations [12, 35, 36] recommend the following guidelines when seeking consent from patients: it must be voluntary and given without coercion, duress, misrepresentation or manipulation. Consent must be specific with information being provided in areas of particular relevance to the patient. A parent or guardian may provide consent [37]. An interpreter should be used when the patient is not fluent in English.

Consent from the patient should be reviewed when there is a delay of months to the start of treatment, the patient's condition has altered or new information has become available which may impact on the patient's consent.

CRITERION 8.2

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

COMMENTARY 8.2

The radiation treatment prescription is a legal record of the radiation treatment to be delivered. This record documents the following mandatory data items:

- identity of the prescribing practitioner;
- unique patient identification, including full name, date of birth, unique identification number and gender;
- treatment intent;
- diagnosis;
- anatomical region to be treated including laterality (in full), where applicable;
- modality;
- radiation dose and prescription point/isodose for each phase of radiation treatment;
- fractionation, including fractions per phase, per week, per day and time interval between fractions where fractionation is not 1 fraction per day; and
- details of any other associated treatment requirements, for example chemotherapy, pacemakers, prostheses.

In addition to legislative and licensing requirements, the information should be readily accessible, legible and in accordance with policy and clinical guidelines [38].

CRITERION 8.3

Radiation treatment prescriptions are regularly audited by peer review.

COMMENTARY 8.3

An audit of radiation treatment prescriptions confirms the degree of compliance with clinical protocols and guidelines [39]. Any detected variances can identify systemic problems in the prescribing process.

REQUIRED EVIDENCE

8(a) Documented consent policies.

8(b) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months includes:

- informed patient consent for radiation treatment, associated procedures and any subsequent review of that consent; and
- all mandatory prescription items.

Note: records required under 3(a) and 4(a) may be the same as required here.

8(c) Documented peer review of radiation treatment prescriptions within a facility agreed timeframe.

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.

COMMENTARY 9.1
Evidence-based treatment planning protocols underpin the treatment technique and reflect the level of contouring, volume delineation and dose reporting required. They ensure a scientific approach to dose optimisation [40-42] and promote safe, accurate and consistent delivery of radiation therapy [4].

Contouring procedures, where necessary, ensure regions of interest and treatment volumes are defined.

Plan development is the process of positioning and modifying beams, manually or by inverse treatment planning methods, to produce an optimal isodose distribution [26, 41, 43, 44].

Plan evaluation is the process of analysing an isodose distribution using visualisation methods and quantitative data displays [26, 41, 43-45].

CRITERION 9.2
External and internal immobilisation methods and equipment are fit for purpose.

COMMENTARY 9.2
An immobilisation device is any external or internal measure, simple or complex, that is used to position and stabilise a patient for radiation therapy. Safe practice involves choice of the most appropriate device, good record keeping, procedures to ensure the optimal and correct device is used for each patient and procedures to ensure equipment is safe to use.

CRITERION 9.3
Planning and imaging procedures localise, delineate and define target volumes and organs at risk, as well as enabling treatment verification.

COMMENTARY 9.3
The planning process involves several key steps including, but not limited to:

- pre planning tasks;
- patient positioning and immobilisation;
- selection and use of optimal imaging modalities;
- delineation of treatment field and isocentre;
- manual measurements and patient contouring;
- additional treatment requirements;
- documentation;
- patient mark-up and education; and
- patient consent to perform permanent skin marking procedures.

REQUIRED EVIDENCE

9(a) Documented protocols or guidelines for treatment planning of common tumour sites including: breast, prostate, lung, head and neck and pelvis that consider the therapeutic decision and evidence-based practice.

9(b) Documented quality control activities that evaluate feasibility and suitablity of the proposed treatment plan.

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.

COMMENTARY 10.1

All radiation dose measurements must be traceable to a national standard if available, otherwise to an internationally recognised standard. Dosimetry equipment that conforms with the requirements of a specified dosimetry code of practice must be used [46].

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.

COMMENTARY 10.2

ROMPs are responsible for the implementation of nationally recommended codes of practice for all aspects of dosimetry for treatment delivery equipment [21].

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.

COMMENTARY 10.3

ROMPs must provide the data required for treatment planning, regularly verify their integrity and define the methodology to be used for patient dose calculations. All new or modified treatment devices that affect dose calculation must have their calibration factors determined by a ROMP [21, 34].

All clinical dosimetric data should be verified by a ROMP and independently checked against existing acceptance and commissioning data.

Quality assurance programs that incorporate the treatment planning system should follow ACPSEM recommendations [21].

CRITERION 10.4

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

COMMENTARY 10.4

All calculations of dose to a patient are performed and independently checked by, or under the supervision of ROMPs [21] or RTs trained and experienced in specific planning calculation methods.

Where independent monitor unit calculation is impractical (e.g. IMRT), due to the complexity of some dose-delivery techniques and associated calculation methods, measurement may replace an independent check.

An independent check is a check performed by a suitably authorised person who did not perform the original task being checked and is not influenced by the person who performed the original task or any of that person's workings.

Ideally the check process should utilise a different method to the original method used.

CRITERION 10.5

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

COMMENTARY 10.5

In-vivo dosimetry is a check of the dose delivered to individual patients independent of the treatment planning system. It should be provided according to protocol or upon the request of the RO, ROMP or RT in consultation with the planning RT.

Non-standard treatment plans, or cases where there may be doubt that the treatment planning system dose calculations are accurate, should be verified by a ROMP.

REQUIRED EVIDENCE

10(a) Documented dosimetry that includes:
- derivation of all factors; and
- an independent check of clinical dosimetric data by a ROMP.

10(b) Records of traceability of all radiation equipment calibrations including documentation of independent checking.

10(c) Records of validation where new methods of dose calculations are introduced, including new:
- treatment planning systems;
- treatment techniques or modalities; and
- beam modifiers.

10(d) Documentation of at least one independent check of all MU, exposure time or dwell time calculations for each treatment plan.

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.

COMMENTARY 11.1

To ensure that the right patient receives the correct treatment, more than one form of identification is needed prior to the commencement of each treatment. This may be name, address, telephone number, date of birth, facility identification number or photograph identification [17, 33, 47, 48].

Two major sources of error in radiation treatment are incorrect dose and incorrect geometry. It is important to check these parameters prior to the patient's first treatment [26].

Verification procedures ensure monitor unit settings and all other treatment parameters are correct for every treatment fraction and radiation field delivered.

Routine and timely assessment of verification images by accredited or credentialed personnel minimises the potential harm of geographic miss by identifying the sources and magnitude of field placement errors [21, 49]. Field shape and volumetric assessment should also be considered where relevant.

CRITERION 11.2

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

COMMENTARY 11.2

A visual monitoring system allows observation of the patient during treatment, thereby promoting patient safety [50].

Patients undergoing concurrent chemotherapy, paediatric patients, patients with pacemakers or similar, or other special needs may require more intense observation, ancillary support equipment and trained personnel to be available to ensure their safety during and after radiation treatment.

CRITERION 11.3

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

COMMENTARY 11.3

Weekly progress review will facilitate early detection and management of acute toxicity [51]. Review should also include compliance with delivery of the overall treatment prescription and plan.

Psychosocial care involves a whole-person approach, taking into account the person's past life experience, current situation and quality of life [52].

REQUIRED EVIDENCE

11(a) Identification procedures that verify patient identity and match the patient to their treatment prescription and plan prior to each treatment session.

11(b) A working system for the observation and monitoring of patients during treatment.

11(c) Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters.

11(d) Documented audit in the last 12 months of 10 randomly chosen treatment records demonstrating:

- assessment of image based verification in accordance with facility treatment management guidelines;
- patient progress review in accordance with facility patient management guidelines; and
- remedial action taken.

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.

COMMENTARY 12.1

An appropriate committee/management structure to monitor and manage the quality of health care being delivered should be in place [53].

Quality improvement in health services requires leadership and commitment at all levels [54].

Quality improvement systems and policies assist in providing safe and quality care by continuously monitoring, auditing and measuring the facility's performance [55-57].

Continual improvement results when leaders enable everyone in the organisation to build new knowledge, to test changes in daily work, and to learn from these tests [58].

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.

COMMENTARY 12.2

Governance requires a responsible body, defined risk management strategies, effective clinical audit and incident reporting path, and clear policies and processes [59, 60].

Organisational infection control policies and procedures must be followed.

CRITERION 12.3

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

COMMENTARY 12.3

The Charter specifies the key rights of patients and consumers when seeking and receiving healthcare services. These are Access, Safety, Respect, Communication, Participation, Privacy and Comment. The Charter can be found at: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/com-pubs_ACHR-main (viewed 11 July, 2011).

The manner in which service is provided is as important as the service itself and it follows that quality must to some extent be defined in terms of customer perceptions [61]. Methods of obtaining direct feedback from patients are therefore vital in informing the quality improvement process

CRITERION 12.4

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

COMMENTARY 12.4

Technical quality of care refers to the delivery of correct dose to the correct patient and correct anatomical site as prescribed.

Health care decisions based on evidence-based best practice provide patients with care that most closely meets their individual needs [13, 62, 63].

REQUIRED EVIDENCE

12(a) Relevant committee minutes, quality and risk records.

12(b) Documented patient satisfaction surveys and action taken.

12(c) Documented audits comparing quality and treatment toxicity with benchmarks defined by the service or facility in the last 12 months.

12(d) Documented safe practice and quality improvement initiatives based amongst others on the findings from the above audits and surveys in the last 12 months.

12(e) Documented management decisions, policies and procedures incorporate and support care delivered in accordance with the Australian Charter of Healthcare Rights.

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.

COMMENTARY 13.1

The responsible person must ensure that a radiation safety management plan is in place, in accordance with the legislation for that jurisdiction [64, 65]. The plan needs to address all aspects of radiation protection including roles and responsibilities in the facility.

To function properly, all staff must be aware of their role in radiation protection. The responsible person must ensure that staff know their role and allocate special responsibilities only to appropriately trained and authorised workers [64].

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.

COMMENTARY 13.2

In each jurisdiction there is a regulatory authority to establish and enforce standards for radiation safety [66] and before conducting radiation oncology practice regulators must be notified and give approvals and authorisations. These authorisations include registrations and licences.

Registration with the regulatory authority is required for each radiation emitting device sealed source apparatus and premises in which radiation sources or apparatus are used. The responsible person is required to be licensed to possess radiation emitting devices, sealed source apparatus and unsealed sources used at the facility. All other persons using radiation emitting devices, sealed source apparatus and unsealed sources are also required to hold an appropriate license or to act under the supervision of the license holder.

It is required to maintain a register of all licensed personnel and registered equipment. The regulatory authority must be notified of any proposed changes to licensing and any proposed new premises, buildings or building modifications relevant for radiation safety. The responsible person is to ensure reports are made to the regulatory body within the designated timescales and as described in the management plan.

CRITERION 13.3

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

COMMENTARY 13.3

The facility is required to have access to suitable equipment to allow assessment and survey of the facility's equipment and premises in order to ensure radiation safety for patients, staff and the public.

CRITERION 13.4

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

COMMENTARY 13.4

The radiation management plan must be reviewed periodically to ensure it adequately addresses radiation protection and complies with regulations. Review with input from all professions concerned can promote the maintenance of a safety culture with all staff following safe work practices.

REQUIRED EVIDENCE

13(a) A management plan for radiation safety that complies with the requirements of the Australian Radiation Protection and Nuclear Safety Agency [65], the relevant regulatory authority and the legislation for the jurisdiction that includes:

- a documented policy that describes the management of pregnant patients who are being exposed to radiation;
- a register of all radiation emitting equipment and radioactive sources that records information required by regulatory authorities; and
- a register of all workers that shows the details of their licensed areas of work, specific responsibilities and records of radiation safety training and personal monitoring results.

13(b) Annual audit of compliance with the management plan for radiation safety.

13(c) Equipment for monitoring radiation and for use in responding to emergency situations.

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.

COMMENTARY 14.1

Incident monitoring is an important risk management and quality improvement tool. Promoting open reporting and providing feedback to staff on incident data and investigations are vital components of a successful incident management system. An open disclosure policy is highly recommended [48, 67].

For the purposes of this standard the terms ‘incident’ and ‘event’ are interchangeable. An incident or event includes but is not limited to an error, a near miss or any adverse event relating to patient care or patient, visitor and staff safety. Incidents or events may arise from: equipment, building or systems failure; operating errors; mishaps or other unusual occurrences.

The incident monitoring program will incorporate incidents specific to the radiation oncology setting. Reporting from radiation incident monitoring facilitates classification in terms of event class, dosimetric error level and clinical consequence as specified in Appendix 2. Additional guidance on an extract and reporting framework is also shown at Appendix 2.

By aggregating incidents from multiple facilities it should be possible to provide answers about the circumstances and contributing factors leading to these events, the actions taken by staff and the outcomes.

It is well recognised that narrative descriptions of the events are the richest form of information for finding out the circumstances leading to an event and if and how such an event can be prevented in future [68].

REQUIRED EVIDENCE

14(a) Documentation that the facility records all incidents (including near-misses) and analyses the data, follows up and takes action as appropriate.

14(b) Evidence of feedback to staff.

15. DOSIMETRIC INTERCOMPARISON

Successful regular participation in dosimetric intercomparisons 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.

COMMENTARY 15.1

Dosimetric intercomparisons ensure accurate radiation dose delivery in participating centres by comparing the dose delivered in a particular irradiation scenario with the dose delivered under identical conditions in a different and/or reference dosimetry centre (report *Elvis project* 2006).

CRITERION 15.2

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

COMMENTARY 15.2

Level III dosimetric intercomparisons constitute a check of the overall patient treatment chain from imaging to planning and treatment for one or more clinical scenarios. They typically involve an anthropomorphic phantom that can accommodate suitable radiation detectors relevant to the clinical scenario.

REQUIRED EVIDENCE

15(a) Documentation that the facility has successfully participated in an external dosimetric intercomparison conducted with a non-affiliated organisationally separate service within the last two years and which has been reviewed and actioned as appropriate.

15(b) Documentation that the facility has successfully participated in a level III dosimetric intercomparison within the last five years and which has been reviewed and actioned as appropriate.

16. CLINICAL 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.

COMMENTARY 16.1

This standard does not imply that facility participation in clinical trials is expected. This standard is not intended as a guide to clinical research.

A clinical trial is a planned investigation conducted in human subjects and involves testing and reporting on new therapies or finding ways to improve on existing therapies [69].

The guidelines of the International Conference on Harmonisation/Good Clinical Practice (ICH/GCP) are internationally accepted standards for the ethical conduct of clinical trials to ensure quality and safety [70].

Clinical practice relies on clinical trials for Level 1 and 2 evidence. Quality assurance tailored to the individual trial is an integral part of clinical trial activity [71-77]. Participation in clinical trials has benefits beyond the evidence it gathers as it helps to define high quality care and allows external review of patient care available to health care organisations. The development of treatment guidelines may also be directly affected by evidence obtained from clinical trials. A governance model for participation in clinical trials is outlined in the EQuIP 4 Guide [17].

REQUIRED EVIDENCE

16(a) Ethics approval of all clinical trials from a committee in accordance with NHMRC guidelines.

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.
Bolus	Material (typically equivalent in density to normal tissue) placed directly on the patient in order to alter the dose distribution within the patient.
Brachytherapy	Radiation treatment using radioactive material (mostly an encapsulated source) brought into close contact with the treatment area (often by surgical means).
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.
Common tumour stream	In the context of these standards, common tumour streams refer to the most prevalent tumours seen and treated at a facility, e.g. breast, prostate, lung, rectum.
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 this standard '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 this standard, the term equipment applies to all hardware and software used in a radiotherapy department.
Gray (Gy)	The unit of absorbed radiation dose equivalent to the deposition of 1 joule per kilogram of material (Bureau Internationale de Poids et Mesures, 2006).
Incident	An error, a near miss or any adverse event relating to patient care or patient, visitor and staff safety.
Intensity modulated radiation therapy	The 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).
Inverse treatment planning	Conventional planning defines and manually adjusts the radiation beams used for a particular treatment and calculates the resulting dose distribution. In inverse treatment planning, the clinician defines the target and critical structures and specifies the desired dose distribution and the computer designs the radiation fields required to achieve this.
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.
Image fusion	The act of combining a primary and secondary data set(s) in a 3D treatment planning system.
Image registration	The process of transforming different data sets into one co-ordinate system.
Isocentre	A point at the intersection of the rotational axes of gantry, collimator and treatment couch.
Medical linear accelerator	The most important treatment unit for external beam radiotherapy. Medical linear accelerators can produce electrons and photons with energies between 4 and 25 MeV. They are typically isocentrically mounted (s. 'Isocentre').
Monitor units (MU)	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.
Organisational 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.
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	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	Person who is registered as a medical practitioner by the relevant Medical Board, is a fellow of the RANZCR or equivalent and is licensed to prescribe radiation therapy.
Radiation oncology facility	Any physical location at which radiation therapy is either planned and/or delivered.
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. http://www.air.asn.au
Radiation safety officer (RSO)	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.
Radiation therapy equipment	For the purposes of the standards such equipment is defined as all hardware and software relevant to: • patient imaging for planning and delivery whether radiation emitting or not; • the planning and calculation of radiation dose to a patient; • the delivery of radiation treatment to a patient; and • monitoring, measuring and/or otherwise controlling radiation dose.
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 (ARPANSA, 2008).
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 1 – RELEVANT STANDARDS

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APPENDIX 2 – INCIDENT REPORTING FRAMEWORK

It is recognised that there are a variety of systems for incident monitoring and reporting in use across different jurisdictions and facilities. In the long term interest of moving towards a nationally consistent approach to incident reporting and monitoring this appendix provides a framework of common terminology, language and classification taxonomies for incidents in radiation oncology.

Contained within this framework are items which are considered both mandatory and desirable, consistent with best practice.

SUMMARY:

Mandatory Elements	Description of Element	Sub-Elements	Comments
Narrative	A free text narrative notification of the event	**Desirable Sub-elements:** • Notifier's Description, • Immediate Actions Taken • Contributing Factors • Final Outcomes / Review • Recommendations • Corrective Actions *See below for a description of these sub elements.	The free text fields are usually a combination of those entered at the point of direct notification and those later entered as part of review and evaluation or management of the event
Pathway Classification	Determination of point in patient pathway where the event or circumstance originated	**Mandatory Sub-elements:** • 1-Prescription Related • 2-Simulation Related • 3-Computer Planning Related • 4-Pre-Treatment Related • 5-Treatment Related • 6-Bolus Related • 7-Shielding / MLC Related • 8-Verification Imaging Related • 9-Documentation Related *See below for a description of these sub elements.	Ideally your system would pre-define these. However, if not, this element must be recorded as part of the event record in a manner which can be extracted and reported in accordance with sub-elements listed in column 3
Dosimetric Error Level	Absolute dosimetric error level of the event or circumstance (where dose related).	**Mandatory Sub-elements:** • Level 0: not dose related • Level 1: (Less than 5%) • Level 2: (>5%, <10%) • Level 3: (>10%) *See below for a description of these sub elements.	Ideally your system would pre-define these. However, if not, this element should be recorded as part of the event record in a manner which can be extracted and reported in accordance with sub-elements listed in column 3
Clinical Consequence	A scored assessment of the actual harm or potential harm to the patient, visitor or staff member	**Mandatory Sub-elements:** • Level 1: Extreme • Level 2: Major / High • Level 3: Moderate • Level 4: Minor / Nil *See below for a description of these sub elements.	As a minimum the consequence scoring system must incorporate 4 levels ranging from extreme to minor / nil. The choice of 4 levels reflects the current ACHS Severity Assessment Code (SAC) scoring system.

DESCRIPTION OF NARRATIVE SUB-ELEMENTS

Notifier's description
Description of the event. The event notifier should record the facts relating to the incident or near miss, avoiding any identifying information such as staff and patient names. Position titles are acceptable.

Immediate actions taken
The event notifier should record the details of the immediate actions taken as well as those to be taken to address the contributing factors or other system issues.

Contributing factors
The event notifier would record any details that contributed to the incident. This may assist in the management and follow-up of reports by ensuring that staff are alerted to any significant risks. The notifier to record details and facts relating to the events leading up to, involved with and contributing to the event. The narrative detail will be analysed to determine specific problems and errors. These will be classified by the main contributory factor groups that are of importance in radiotherapy errors.

Final Outcomes / Review
In the follow up and review of the incident after the completion of any course of corrective actions the final review or outcome of the event should be indicated. This narrative information will be used in combination with the severity assessment score for clinical consequence to provide a descriptive final summary of the event's final outcome.

Recommendations
The recommendations and preventative measures should be recorded by the notifier as well as the staff involved with the management and prevention of the error. Recommendations will be something (as a course of action) that is recommended as advisable to address the event specific to the patient in question as well as those that are intended to improve or address the vulnerabilities of the various systems and provide the foundation for safety enhancement and quality improvement.

Corrective actions
As part of the notification narrative or that in the management of the report, corrective actions should be defined if taken or still to be implemented. These corrective actions will assist in the determination of clinical impact, overall outcome to the patient and the resultant severity assessment score of the clinical consequence.

DESCRIPTION OF PATHWAY CLASSIFICATION SUB-ELEMENTS

Prescription related:
This category would apply to errors and near miss events that occur as a result of erroneous practice at the point of radiation oncologist prescription.

Simulation related:
This category would apply to errors and near miss events that occur as a result of errors occurring during the simulation process itself. This group would include events involving contrast, image fusion, CT scanner protocols and those caused by the actual simulation procedure itself.

Computing related:
This category would apply to errors and near miss events that occur as a result of errors attributed to the plan computation process itself, including examples such as incorrect calculation, dose, weight points, incorrect CT-Density file conversions and the like.

Pre-treatment related:
This category would apply to errors and near miss events that occur at the pre-treatment stage and are detected before treatment occurs. This group would include calculation errors, record and verify system errors, QA errors / breaches, ancillary device factors missing etc.

Treatment related:
This category would apply to errors and near miss events that occur during the patient treatment itself. This category by default usually has the highest incidence as it represents the end of the QA line in terms of patient flow. If all systems before treatment itself fail to detect the error, it is usually detected during treatment. This group would include various delivery errors (field missed, incorrect dose/MU delivered, set-up errors etc). While some of these events occur could be attributed to breaches in process at earlier stages it is important that they are first reported from where the event actually occurred, from there the source can be tracked back to its origin but importantly the treatment processes can be improved or enhanced to detect these errors in the future.

Bolus related:
This category would apply to errors and near miss events that relate to the use of patient bolus. These errors may occur at various stages in the process and need to be highlighted separate from the general pre-treatment or treatment. This group would include events where bolus was not used when specified, bolus placement errors, incorrect thickness used etc.

Shielding related:
This category would apply to errors and near miss events that relate to the use of patient shielding (blocks, MLC, patient surface shields etc). These errors may occur at various stages in the process and need to be highlighted separate from the general pre-treatment or treatment. This group would include tray errors, block errors, shielding not applied when prescribed, MLC pattern errors etc.

Verification imaging (on-line / off-line correction related)
This category would apply to errors and near miss events that occur as a result of erroneous practice during the application of either on-line corrections or those made off-line. These corrections may be using the CBCT, EPID or other tertiary devices such as seed implants, ultrasound or patient surface imaging. This group would include images not being taken as required, image matching errors, incorrect shifts, shifts made outside of agreed practice etc.

Documentation related:
This category would apply to errors and near miss events that occur as a result of documentation flaws, errors or omissions. Again these documentation errors may occur at various points in the patient pathway, however it is important to have these reported separate to those categories for further analysis and trending.

DESCRIPTION OF DOSIMETRIC ERROR LEVEL SUB-ELEMENTS

Dosimetric level 0 error:
This would apply to all incidents where a dosimetric error is not applicable or does not exist.

Dosimetric level 1 error:
An error that is detected within the treating department that is determined to be less than 5% from the intended prescribed radiation dose. An error in this range level falls within the clinical prescription limitations and therefore would not have a detectable influence on the treatment outcome, as such they should be considered of limited or no clinical significance. Importantly while being considered as not clinically detectable or significant, these deviations must be collected by the treating radiation oncology department as they will form the basis for ongoing quality improvement and clinical practice refinement with the view to reducing the frequency of these low level deviations which ultimately reduces the risk for the occurrence of the next level of error. This level of error would also be applicable to near miss events which should also be collected with the same rationale as actual incidents falling in this level.

Dosimetric level 2 error:
An error that is detected within the department that is determined to be in the range of greater than 5% error (Level 1), but less than 10% error from the intended prescribed dose. An error in this range falls outside the clinical prescription limitations therefore has the potential to be of clinical relevance, however it is considered still unlikely to result in a detectable result. Being less than 10% variant from the intended prescribed dose this level of error is not considered to warrant reporting to the relevant regulatory authorities. The same culture of collection, audit and quality improvement as for Level 1 error should be applied to this group as these errors may assist in identifying possible shortcomings / inadequacies in the clinical process of the department in question.

Dosimetric level 3 error:
An error detected in the department that is determined to have been in excess of 10% from the intended prescribed dose. Errors in this range fall into the internationally accepted definition of a serious and unacceptable error. This level of error is of clinical significance and may have a detectable result by way of under or over-dosage. These errors must be formally reported to the relevant regulatory authorities and at minimum must have a full internal department review / audit to identify any possible flaws or shortcomings in the applicable policies and procedures linked to the error. In addition to the internal review, external review and / or root cause analysis may be instigated.

DESCRIPTION OF CONSEQUENCE LEVEL SUB-ELEMENTS

The consequence classification would be via a customised radiation oncology specific version of the well recognised Severity Assessment Code (SAC) scoring system. This will provide a simple method by which staff and management could quantify the clinical consequence/ significance of the event from both an actual and potential viewpoint. This system of risk classification combined with the dosimetric level quantification provides a detailed classification of each reported event which would cover all clinical situations.

Level 1 – consequence / risk score extreme
Incidents assigned this level of consequence or risk would include those in which the consequences range from almost certain moderate severity to an unlikely catastrophic outcome. This level of error is of clinical significance and would have a detectable result by way of patient side effects.

Level 2 – consequence / risk score major/high
Incidents assigned this level of consequence or risk would include those with variation from the prescribed treatment that resulted in changed outcomes ranging from an incident with a likelihood that is almost certain but with insignificant consequences to one that is rare but with a major catastrophic outcome. Both normal tissue effects and tumour control probability needs to be considered.

For normal tissues a high risk event would arise when doses to normal tissues exceed specified constraints. Examples would include faults in calibration that lead to a systematic dose increase of 6-10% which would almost certainly lead to increases in some normal tissue reactions in all patients, however with major effects unlikely. Treatment of the wrong body part falls within this category.
For tumours a high risk event would occur when the tumour target is under-dosed by 2-5% less than the planned dose. The effect on the likelihood of cure for an individual depends on the tumour type and stage and needs to be considered – which may change the score for the actual consequence, however the potential consequence in those cases would remain at this level. Note that if the dose decrease is detected and compensated for then the event would revert to a consequence of 4a (see below).

Level 3 – consequence / risk score moderate
Incidents assigned this level of consequence or risk would include those with variations from the prescribed treatment that exceeds the dose constraints for normal tissues, for which the likelihood of increasing normal tissue side effects ranges from rare to likely and the consequence from insignificance to moderate. Examples included in this group would include:

- 5-15% increase in dose for one or more fractions;
- 2-5% increase in dose over the entire treatment course; or
- One which causes a dose increase to normal tissue above the limits specified by the prescribing radiation oncologist, these at a level that is not likely to exceed a moderate consequence.

Level 4 – consequence / risk score low, clinically minor/nil
Incidents assigned this level of consequence or risk would be all those which fall within the clinically accepted dose and tolerance for tumour and normal tissue. The likelihood of any clinical sequel ranges from zero to unlikely and the clinical consequence is minor. Examples would include situations where less than 5% variation in specified tumour dose for one fraction provided also that there is less than 2% variation in tumour dose over the treatment course, and the variation does not exceed the prescribed dose of the normal tissues.

APPENDIX 3 – REQUIRED EVIDENCE CHECKLIST

FACILITY MANAGEMENT (Standards 1-7)		
STAFF	**Y/N**	**X/Y (%)**
1(a) Registers of current registration/licence to practice.		
1(b) Attendance records at staff development programs.		
1(c) Records of regular performance review in accordance with facility policy.		
WORKFORCE PROFILE		
2(a) A documented system for managing workforce in relation to service capacity.		
2(b) Evidence to demonstrate funded time within working hours for education, research and development, administration and quality assurance and improvement activities. Evidence may include staffing rosters and schedules and other examples of funded non-patient care time.		
RADIATION ONCOLOGY RECORD MANAGEMENT		
3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months demonstrates: • accuracy, comprehensiveness and currency of patient records; • compliance with legislation and RANZCR guidelines; and • remedial action where necessary. Note: records required under 4(a) and 8(b) may be the same as required here.		
3(b) Documented contingency plan for ensuring continuing availability of the patient record in the event of a disaster.		
3(c) Register for the location of all patient information records and databases.		
3(d) Records of action taken to address breakdowns in the procedures for: • tracing patient records; and • the security of records.		
3(e) Evidence of the retention of records compliant with national and/or local requirements (whichever is the longer).		
DATA MANAGEMENT		
4(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months includes: • current versions of ICD and staging systems (or recognised alternatives); • the facility-agreed minimum patient data set; and • documented facility policies related to data definitions. Note: records required under 3(a) and 8(b) may be the same as required here.		
FACILITY INFRASTRUCTURE		
5(a) A documented strategic plan with a facility agreed timeframe (not greater than 5 years) that identifies the ongoing development needs of the facility in order to maintain or improve the service provided.		
5(b) A documented review of the strategic plan as designated by the plan itself.		
FACILITY PROCESS MANAGEMENT		
6(a) A documented policy for the management of waiting times for treatment that: • identifies the method used to classify, record and report waiting times; and • indicates strategies to minimise waiting times.		
6(b) Data showing trends in waiting times and documentation of any response to unacceptable delays.		
6(c) A documented policy that specifies the management of unscheduled interruptions to treatment and prolongation of a course of radiotherapy.		

EQUIPMENT		Y/N	X/Y (%)
7(a)	Records of acceptance tests and commissioning data for all radiotherapy equipment.		
7(b)	A documented quality assurance program for radiation therapy equipment that includes: • all tests, their frequency and tolerances; • a protocol for managing test failures and non-compliances that includes action levels; and • reporting requirements and action taken.		
7(c)	Records of delays, unscheduled breaks in treatment and remedial action taken due to equipment failure.		
TREATMENT PLANNING AND DELIVERY (Standards 8-11)			
RADIATION TREATMENT PRESCRIPTION			
8(a)	Documented consent policies.		
8(b)	Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation therapy in the last 12 months includes: • informed patient consent for radiation treatment, associated procedures and any subsequent review of that consent; and • all mandatory prescription items. Note: records required under 3(a) and 4(a) may be the same as required here.		
8(c)	Documented peer review of radiation treatment prescriptions within a facility agreed timeframe.		
PLANNING PROCEDURES			
9(a)	Documented protocols or guidelines for treatment planning of common tumour sites, including: breast, prostate, lung, head and neck and pelvis that consider the therapeutic decision and evidence-based practice.		
9(b)	Documented quality control activities that evaluate feasibility and suitability of the proposed treatment plan.		
DOSIMETRY			
10(a)	Documented dosimetry that includes: • derivation of all factors; and • independent check of clinical dosimetric data by a ROMP.		
10(b)	Records of traceability of all radiation equipment calibrations including documentation of independent checking.		
10(c)	Records of validation where new methods of dose calculations are introduced, including new: • treatment planning systems; • treatment techniques or modalities; and • beam modifiers.		
10(d)	Documentation of at least one independent check of all MU, exposure time or dwell time calculations for each treatment plan.		
RADIATION TREATMENT DELIVERY			
11(a)	Identification procedures that verify patient identity and match the patient to their treatment prescription and plan prior to each treatment session.		
11(b)	A working system for the observation and monitoring of patients during treatment.		
11(c)	Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters.		
11(d)	Documented audit in the last 12 months of 10 randomly chosen treatment records demonstrating: • assessment of image based verification in accordance with facility treatment patient management guidelines; • patient progress review in accordance with facility patient management guidelines; and • remedial action taken.		

SAFETY AND QUALITY MANAGEMENT (Standards 12-16)		
SAFETY, QUALITY AND IMPROVEMENT PROCESSES	**Y/N**	**X/Y (%)**
12(a) Relevant committee minutes, quality and risk records.		
12(b) Documented patient satisfaction surveys and action taken.		
12(c) Documented audits comparing quality and treatment toxicity with benchmarks defined by the service or facility within the last 12 months.		
12(d) Documented safe practice and quality improvement initiatives based amongst others on the findings from the above audits and surveys in the last 12 months.		
12(e) Documented management decisions, policies and procedures incorporate and support care delivered in accordance with the Australian Charter of Healthcare Rights.		
RADIATION SAFETY		
13(a) A management plan for radiation safety that complies with the requirements of the Australian Radiation Protection and Nuclear Safety Agency [65], the relevant regulatory authority and the legislation for the jurisdiction that includes: • a documented policy that describes the management of pregnant patients who are being exposed to radiation; • a register of all radiation emitting equipment and radioactive sources that records information required by regulatory authorities; and • a register of all workers that shows the details of their licensed areas of work, specific responsibilities and maintains a record of radiation safety training and personal monitoring results.		
13(b) Annual audit of compliance with the management plan for radiation safety.		
13(c) Equipment for monitoring radiation and for use in responding to emergency situations.		
INCIDENT MONITORING PROGRAM		
14(a) Documentation that the facility records all incidents (including near-misses) and analyses the data, follows up and takes action as appropriate.		
14(b) Evidence of feedback to staff.		
DOSIMETRIC INTERCOMPARISON		
15(a) Documentation that the facility has successfully participated in an external dosimetric intercomparison conducted with a non-affiliated organisationally separate service within the last two years and which has been reviewed and actioned as appropriate.		
15(b) Documentation that the facility has successfully participated in a level III dosimetric intercomparison within the last five years and which has been reviewed and actioned as appropriate.		
CLINICAL TRIALS PARTICIPATION		
16(a) Ethics approval of all clinical trials from a committee in accordance with NHMRC guidelines.		

NOTES TO THE DATA SHEETS:

- All inquiries demand a Yes/No response.
- Some will need a quantified response eg 3(a) Audit evidence of 10 records from each of three common tumour streams in the last 12 months demonstrating the compliance with legislation and RANZCR guidelines. This would require a denominator of 30, numerator of number that comply, and hence a percentage can be worked out.
- At this stage there are no minimum standards being set. This is a pilot project which will result in the establishment of baselines.

SUGGESTED EVIDENCE LOCATIONS:

STAFF RECORDS AND REGISTERS:

- Recruitment and selection procedure records;
- Attendance records at staff development programs;
- Performance review records;
- Staffing rosters and schedules;
- Register of workers showing licensed areas of work, responsibilities and radiation safety training and personal monitoring results.

PATIENT SYSTEM RECORDS:

- System for analysing waiting times in relation to workforce establishment, for example, twice yearly RANZCR undue delay survey;
- Trended data on waiting times and documentation of response;
- Contingency plan for ensuring continuing availability of the patient record in the event of a disaster;
- Register for the location of all patient information records and databases;
- Records of action taken to address breakdowns in the procedures for security and tracing of patient records.

POLICY DOCUMENTS AND PROTOCOLS:

- Management of waiting times for treatment;
- Strategic plan for the facility;
- Management of unscheduled interruptions to treatment and prolongation of a course of radiotherapy;
- Consent policies;
- Identification procedures;
- Protocols or guidelines for treatment planning of common tumour sites;
- Management plan for radiation safety.

PATIENT RADIOTHERAPY RECORD AUDIT ITEMS:

Documented audit of 10 records from each of three common tumour streams within the last 12 months demonstrating the:

- accuracy, comprehensiveness and currency of patient records;
- compliance with legislation and RANZCR guidelines;
- use of current versions of ICD and staging systems (or internationally recognised alternatives);
- use of facility-agreed minimum patient data set;
- informed patient consent for radiation treatment, associated procedures, and any subsequent review of that consent;
- mandatory data items;
- assessment of image based verification in accordance with facility treatment management guidelines; and
- progress review in accordance with facility patient management guidelines.

EQUIPMENT SYSTEM RECORDS:

- Records of acceptance tests and commissioning data;
- Records of delays and unscheduled breaks in treatment;
- Treatment plan and Immobilisation evaluation activities;
- Documented dosimetry procedure;
- Records of traceability of all radiation equipment calibrations;
- Records of independent verification where new methods of dose calculations are introduced;
- System for visually observing patients during treatment;
- Verification system of treatment delivery;
- Register of all radiation emitting equipment and radioactive sources.

QUALITY RECORDS:

- Relevant committee minutes, quality and risk records;
- Patient satisfaction surveys;
- Technical quality or outcome audits;
- Documented quality improvement initiatives;
- Clinical trial ethics approval;
- External dosimetric intercomparisons documentation;
- Incident monitoring documentation.