RADIATION ONCOLOGY PRACTICE STANDARDS
Part A: Fundamentals

RANZCR ASMIRT ACPSEM CNSA

Part A presents 16 standards developed for radiation oncology practices.

The Tripartite Committee, formed in 1998, is a peak group in radiation oncology, representing the three key professions involved in radiation therapy:

- The Royal Australian and New Zealand College of Radiologists (RANZCR) Faculty of Radiation Oncology (FRO)
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)
- The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).

In 2019, the Tripartite Committee expanded to include radiation oncology nurses represented by the Cancer Nurses Society of Australia (CNSA) and was thus renamed the Radiation Oncology Alliance (ROA). The main objectives of the ROA are to:

- Represent a key forum for collaboration between the radiation therapy professions in the areas of quality and standards for high-level, individualised patient care, workforce and public interest
- Act as an important liaison point for the Department of Health, and its committees and working groups
- Communicate key sector priorities to the Government and to the public
- Maintain good communication between FRO, ASMIRT, ACPSEM, and CNSA.

FRO, ASMIRT and ACPSEM received Australian Government funding support for the development and publication of the original *Radiation Oncology Practice Standards* and *Supplementary Guide*.

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FOREWORD

As Chair of the Radiation Oncology Alliance (ROA), I am extremely pleased to provide the foreword to this third iteration of the Radiation Oncology Practice Standards (ROPS). Working together as the peak group in radiation oncology, the four key professions represented by the ROA have authored a current and meaningful document to encourage the standardisation of patient care across Australia and New Zealand. This refreshed version of the earlier 2017 ROPS reflects progress and change in service delivery to date, along with expanded guidance on evidence-based requirements to support institutional processes and future changes.

Within this current version, ongoing developments in innovative technology including Artificial Intelligence (AI) and the increasing role of imaging in the radiation therapy environment are highlighted. This work provides a valuable resource for the ROPS readership and is aligned with current best practice. The Standards also bring into even sharper focus the importance of the patient experience. Nursing practice principles have been included in this edition for the first time, further consolidating the importance of the multidisciplinary care needed in the delivery of radiation oncology services.

As with earlier versions of the ROPS—Part A: Fundamentals and Part B: Guidelines—these editions must be read in conjunction with each other and will continue to support a culture of ongoing quality improvement in radiation oncology service provision. As with earlier editions, this foreword would be incomplete without thanking all the members of the radiation oncology professional organisations for their time, energy, and expertise in completing this work. In addition to the ROA member organisations, the New Zealand Cancer Nurses College (CNC) made particular contributions to this edition. Specific thanks are extended to the ROPS Working Group whose membership includes Gerard Adams (chair), Andrew Last, Reza Rahbari, Iain Ward, Stephen Manley, Jemma Blyth, Susan Hewitt, Mario Perez, John Shakeshaft, Andy Cousins, Pauline Rose, Margie Hjorth, Natasha Chisholm, Shellye Hanson, and Iona Mcaulay. Sincere thanks are also extended to other members of the community who have supported this work.

Kym Rykers
Chair, Radiation Oncology Alliance
December 2022

CHANGES FROM VERSION 2

Standard / Criterion / Evidence	Version 2, 2017	Version 3, 2022
		In 2019, the Tripartite Committee was replaced by the Radiation Oncology Alliance with the inclusion of radiation oncology nurses supported by the Cancer Nurses Society of Australia (CNSA).
Background	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 work separately but in co-operation, to deliver their component of the radiation therapy process. These professions are represented by the following organisations: • The Royal Australian and New Zealand College of Radiologists (RANZCR), Faculty of Radiation Oncology (FRO) • Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) • Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).	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 work separately but in co-operation, to deliver their component of the radiation therapy process. Radiation oncology nurses work as part of a multidisciplinary team with the radiation oncology professionals and allied health staff to provide safe, supportive, person-centred care to patients undergoing radiation therapy. These professions are represented by the following organisations: • The Royal Australian and New Zealand College of Radiologists (RANZCR), Faculty of Radiation Oncology (FRO) • Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) • Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) • The Cancer Nurses Society of Australia (CNSA) with representation from the New Zealand Nurses Organisation Cancer Nurses College (CNC)
The Scope of the Standards		Radiation oncology has always been at the forefront of the next frontier in medicine as early adopters of new technology. Artificial Intelligence (AI) and Machine Learning are currently rapidly evolving technologies in Radiation Oncology. Therefore, RANZCR is developing AI Standards that will build on its ethical principles and provide doctors, AI developers and healthcare organisations with clear guidelines to deploy machine learning systems and AI tools ensuring patient safety.

		The ethical principles will outline the most appropriate use of AI and machine learning, including how both can successfully help to drive continuing improvements in patient care. The RANZCR AI Standards and the ACPSEM and ASMIRT AI Standards when available should be implemented alongside the Radiation Oncology Practice Standards where AI is a factor or tool.
The Standards Framework		Appendix 3 is the RANZCR Radiation Oncology Telehealth Principles.
Acronyms and Abbreviations		CIED: Cardiac implantable electronic device CNSA: Cancer Nurses Society of Australia ICD: International Classification of Disease ITV: Internal Target Volume CNC: New Zealand Nurses Organisation Cancer Nurses College RON: Radiation oncology nurse ROTC: Radiation Oncology Trainee Committee SABR/SBRT: Stereotactic ablative radiation therapy / stereotactic body radiation therapy SRS: Stereotatic radiosurgery TBI: Total Body Irradiation TSEI: Total Skin Electron Irradiation
Facility Management 1. Staff	Staff competence is ensured by recruitment and selection procedures and maintained by staff development and a performance review system.	Staff qualifications are ensured by recruitment and selection procedures and maintained by staff development and a performance review system.
1. Staff Commentary 1.1	The qualifications of radiation oncologists (ROs), radiation therapists (RTs), radiation oncology medical physicists (ROMPs) must reflect the skills and competencies required to deliver radiation therapy services safely. Recruitment and selection procedures must ensure that appropriate qualifications are held to enable registration to practise applicable to the jurisdiction.[4]	The qualifications of radiation oncologists (ROs), radiation therapists (RTs), radiation oncology medical physicists (ROMPs) and radiation oncology nurses (RON) must reflect the skills and competencies required to deliver radiation therapy services safely. Recruitment and selection procedures must ensure that appropriate qualifications are held to enable registration-to-practise applicable to the jurisdiction.[5]

2. Workforce Profile 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. 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. [7-11] 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 RANZCR workforce census, facility survey, cancer incident project and optimisation rates or similar data, could be used as the basis for workforce needs analysis.	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. It is recommended that the majority of staff reside locally with at least one (1) qualified local full time equivalent from each staff group available to operate a basic service. 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 RANZCR workforce census, facility survey, cancer incidence project and optimisation rates or similar data, could be used as the basis for workforce needs analysis. Regional and rural considerations should be considered.[8]
Facility Management 2. Workplace 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.[12]	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] Regional and rural considerations should be considered.[8]
3. Management of Radiation Oncology Patient Records 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,	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 nursing care plan. As well as the treatment record, clinical correspondence including referrals, the prescription and treatment plan, test results and diagnostic staging studies and other administrative details such as health insurance status, billing, consent

	consent and legal correspondence. Other information that assists in safe patient management includes emergency contact, next of kin and required support services.	and legal correspondence. Other information that assists in safe patient management includes emergency contact, next of kin, language spoken/is a translator required and required support services.
3. Management of Radiation Oncology Patient Records Required Evidence	3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three (3) common tumour streams of patients treated with radiation therapy in the last 12 months that demonstrates: • accuracy, comprehensiveness and currency of patient records; • compliance with legislation; 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 longer).	3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three (3) common tumour streams of patients treated with radiation therapy in the last 12 months that demonstrates: • accuracy, comprehensiveness and currency of patient records; • compliance with legislation; • adherence to professional guidelines for complex* techniques e.g. RANZCR Guidelines for Safe Practice of Stereotactic Body Radiation Therapy; and • remedial action where necessary. Note: records required under 4(a) and 8(b) may be the same as required here. A useful resource is the RANZCR peer review audit tool. 3(b) Documented contingency plan for ensuring continuing availability of the patient record in the event of a catastrophic failure. • Register for the location of all patient information records and databases. 3(c) Records of action taken to address breakdowns in the procedures for: • tracing patient records; and • the security of records. 3(d) Evidence of the retention of records compliant with national and/or local requirements (whichever is longer). *A technique would be considered complex where separate professional guidelines exist, or it is not available at most facilities. Such complex techniques would include (but not be limited to), SABR/SBRT, SRS, brachytherapy, TBI and TSEI.

4. Data Management Criterion 4.2	Disease/diagnosis and staging data conform to recognised classification systems in accordance with facility policies.	Disease/diagnosis and staging data conform to recognised classification systems in accordance with facility policies and any jurisdictional requirements.
5. Facility Infrastructure 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.	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. Centres that cater to Māori, Aboriginal and Torres Strait Islander patients need to assess their physical infrastructure with their patients in mind. For example, an outside waiting area may be appropriate. A Māori or Aboriginal/Torres Strait Islander liaison officer should be consulted to ensure the environment is culturally safe.
5. Facility Infrastructure Commentary 5.3	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 [20] while at the same time maintain appropriate hygiene.	The design of the environment and the patterns of patient care need to respect the sexual identity, ethnic, cultural and religious practices and beliefs of patients, and yet support a timely throughput of patients [16] while at the same time maintaining appropriate safety and hygiene practices.
5. Facility Infrastructure Criterion 5.4		Facility management includes a plan for facility or major equipment failure, up to and including building inaccessibility.
5. Facility Infrastructure Commentary 5.4		Given the known impact of unscheduled treatment interruption,[17] all centres should make a risk assessment covering plausible scenarios of treatment interruption in their circumstances. No centre is immune but smaller and regional centres with potentially lower base staffing levels, less redundancy of equipment, as well as increased distance to alternative centres can be more vulnerable Reasonable steps to mitigate this risk such as beam matched equipment and formal agreements to transfer patients to other facilities should be planned and documented in detail. Issues such as patient and staff transfer, treatment replanning and capacity of alternative facility require formal and detailed agreements in advance.[8] These issues are discussed to some extent in the regional paper.

Required Evidence		5(c) A business continuity plan that has been reviewed for appropriateness within the last two (2) years.
6. Facility Process Management	The provision of radiation therapy treatment services is timely, coordinated and equitable to ensure optimal patient outcomes.	The provision of radiation therapy treatment services is timely, coordinated, patient-centred and equitable to ensure optimal patient outcomes and experience.
6. Facility Process Management Required Evidence		6(d)Evidence that patients have been consulted in the design of institutional processes, such as surveys of patient experience. 6(e)Evidence that the needs of Indigenous and other cultural groups have been consulted regarding institutional processes.
7. Radiation Therapy Treatment	**Radiation therapy equipment performs to specifications that ensure accurate and safe clinical treatment.** 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.	**Radiation therapy equipment performs to specifications that ensure accurate and safe clinical treatment.** For the purposes of the standards such equipment is defined as all hardware and software listed on the Australian Register of Therapeutic Goods" or "The Web Assisted Notification of Devices (WAND)" Database in New Zealand 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.
7. Radiation Therapy Equipment Criterion 7.2	New radiation therapy equipment, and any significant or major modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel. To ensure accurate and safe clinical usage, any newly commissioned equipment requires independent NATA accredited or equivalent recognised by the regulator dosimetric intercomparison, where applicable.	New radiation therapy equipment, and any significant or major modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel. To ensure accurate and safe clinical usage, any newly commissioned equipment requires an independent dosimetric audit performed by an audit body that is independent and without conflict of interest (The minimum audit requirements for new linacs/planning system models are detailed in *Appendix 5.*)
7. Radiation Therapy Equipment	7(e) Documented evidence of independent verification of dose calibration must be carried out on	7(e) Documented evidence of independent dosimetric audit, consistent with the requirements of *Appendix 5* (if

Required Evidence	commissioning of equipment.	applicable).
Treatment Planning Delivery 8. Radiation Treatment Prescription 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.	Patients are informed of the benefits and risks, including the risks both short and long-term side effects resulting from the proposed radiation treatment and their consent is documented by the consenting clinician.
8. Radiation Treatment Prescription Commentary 8.1	Professional organisations [16,36,37] 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.	Professional organisations [32-33] 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.[33] An interpreter should be used when the patient is not fluent in English. Understanding of consent must be confirmed. Consent from the patient should be reviewed when there is a delay of greater than one month to the start of treatment, significant change in treatment management plan, the patient's condition has altered or new information has become available which may impact on the patient's consent.
8. Radiation Treatment Prescription 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;	The radiation treatment prescription is a legal record of the radiation treatment to be delivered. This record documents the following data items: • identity of the prescribing practitioner; • unique patient identification, including full name, date of birth, unique identification number; • treatment intent; • diagnosis; • anatomical region to be treated including laterality (in full), where applicable; • modality; • radiation dose and prescription recorded following internationally recognised standards appropriate for the technique used;

	• fractionation, including fractions per phase, per week, per day and time interval between fractions where fractionation is not one (1) fraction per day; and • details of any other associated treatment requirements, for example chemotherapy, pacemakers, prostheses.	• fractionation, including fractions per phase, per week, per day and time interval between fractions where fractionation is not one (1) fraction per day; and • details of any other associated treatment requirements, for example chemotherapy, CIEDs, prostheses.
8. Radiation Treatment Prescription Required Evidence		8(d) Add documented prescribing practice – i.e. local methodology rather than doses for specific sites.
9. Planning and Procedures 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.	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 utilising appropriate cleaning and sterilisation procedures.
9. Planning Procedures Commentary 9.3		Nursing Practice Principle 1**:** Care delivery is tailored to the specific needs and preferences of each individual**.** Nursing Practice Principle 3: The information and education needs of patients and their carers are identified and met.
9. Planning Procedures Required Evidence	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.	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, these shall explicitly include SBRT and SRS practices if these techniques are performed**.**
10. Dosimetry 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 radiation oncologist, ROMP or RT in consultation with the planning RT. Non-standard treatment plans, or cases where there may be doubt	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 request. 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. Patient-specific QA using planar or 3D detector arrays can be

	that the treatment planning system dose calculations are accurate, should be verified by a ROMP	used to verify the accuracy of delivered dose.
10. Dosimetry Criterion 10.6		For SBRT/SRS treatments where CTV to PTV margins are small and geometric accuracy is critically important, a system shall be in place to ensure that the required geometric accuracy is routinely achievable.
10. Dosimetry Commentary 10.6		There are many points in the treatment chain where small geometrical errors can be introduced. These may combine to give an uncertainty greater than the proposed CTV to PTV margin and so lead to sub-optimal treatment. It is therefore important to ensure the geometrical integrity of the treatment chain.
10. Dosimetry 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. This could be incorporated into the audit of 30 randomly selected records. Note: records required under 3(a) and 4(a) may be the same as required here.	10(a) Documented evidence of: • derivation of all factors; • an independent check of clinical dosimetric data by a ROMP; and • an end-to-end check of the geometrical accuracy. 10(b) Records of traceability of all radiation equipment calibrations including documentation of independent checking. 10(c) Records of validation including results of end-to-end testing 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. This could be incorporated into the audit of 30 randomly selected records. Note: records required under 3(a) and 4(a) may be the same as required here.
11. Radiation Treatment Delivery Commentary	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.	Radiation therapists provide daily online image guidance and assessment to ensure the safe and accurate delivery of highly conformal radiotherapy treatments. Image guidance is an

11.1	This may be name, address, telephone number, date of birth, facility identification number or photograph identification. [20,35,47,48] 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.[28] 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 suitably qualified personnel minimises the potential harm of geographic miss by identifying the sources and magnitude of field placement errors. [24,49] Field shape and volumetric assessment should also be considered where relevant.	integral part of radiation therapy treatment delivery and supports on-line correction and offline review of a patient's treatment. Departmental imaging policies and guidelines are required to match international and published best practice standards relevant to each treatment site and protocol. [16,31,43-44] 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.[24] 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 suitably qualified personnel minimise potential harm of geographic miss and/or unintentional irradiation of healthy tissues by identifying the sources and magnitude of field placement errors.[20,45] Field shape and volumetric assessment should also be considered where relevant.
11. Radiation Treatment Delivery Commentary 11.2	A visual and audio monitoring system allows observation of the patient during treatment, thereby promoting patient safety.[46] Patients undergoing concurrent chemotherapy, paediatric patients, patients with CIEDs or similar or other special needs may require more intensive observation, ancillary support equipment and trained personnel to be available to ensure their safety during and after radiation treatment.	A visual and audio monitoring system allows observation of the patient during treatment, thereby promoting patient safety.[46] Patients undergoing concurrent chemotherapy, paediatric patients, patients with CIEDs or similar or other special needs may require more intensive observation, ancillary support equipment and trained personnel to be available to ensure their safety during and after radiation treatment. RTs must be notified of concurrent chemoradiation for their own personal protection or in the event of a spill (e.g. by dropdown box in a radiation oncology information system).
11. Radiation Treatment Delivery Criterion 11.3	Patients are reviewed for their fitness to continue and for their psychosocial needs throughout a course of treatment. Nursing Practice Principle 2: A consistent approach is used for patient assessment and symptom management.	Nursing Practice Principle 2: A consistent approach is used for patient assessment and symptom management.

11. Radiation Treatment Delivery Commentary 11.3	Weekly progress review will facilitate early detection and management of acute toxicity.[55] Review should also include compliance with delivery of the overall treatment prescription and plan. Psychosocial care involves a whole-person approach, considering the person's past life experience, current situation and quality of life.[52]	Regular progress reviews should consider compliance with the current treatment regimen and can improve the detection and management of acute toxicities.[47] Review should also include compliance with delivery of the overall treatment prescription and plan. This is to be communicated to the patient and can be done as part of a discharge letter that includes appropriate contact details. Nursing Practice Principles 4: Healthcare professionals are skilled in identifying the potential effects of radiation therapy and the treatment on patients. Psychosocial care involves a whole-person approach, considering the person's past life experience, current situation and quality of life.[48] Nursing Practice Principle 5: Optimal patient outcomes are achieved through effective multidisciplinary teamwork.
11. Radiation Treatment Delivery Required Evidence		11 (e) Local protocol based on published evidence for appropriate management and monitoring of CIEDs before commencement of treatment.
Safety and Quality Management 12. Safety, Quality and Improvement Processes Criterion 12.1	Facility governance acknowledges and supports safe practice, quality improvement, innovation and the safe and considered introduction of new technologies.	Safe practice, quality improvement, and the safe and considered introduction of new technologies requires effective facility governance.
12. Safety, Quality and Improvement Processes Commentary 12.2	Governance requires a responsible body, defined risk management strategies, effective clinical audit and incident reporting path, and clear policies and processes. [58,59] Organisational infection control policies and procedures must be followed.	Governance requires a responsible body, defined risk management strategies, effective clinical audit and incident reporting path, and clear policies and processes. [54-55]
12. Safety, Quality and Improvement Processes Commentary 12.4	Technical quality of care refers to the delivery of correct dose to the correct patient and correct anatomical site as prescribed. Healthcare decisions based on evidence-based best practice provide patients with care that most	Technical quality of care refers to the delivery of correct dose to the correct patient and correct anatomical site as prescribed. Healthcare decisions based on evidence-based best practice provide

	closely meets their individual needs. [61-63]	patients with care that most closely meets their individual needs. [57-59] Nursing Practice Principle 6: Patients and their carers have the opportunity to participate in all aspects of care.
12. Safety, Quality and Improvement Processes 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 among others on the findings from the above audits and surveys in the last 12 months.	12(a) Relevant committee minutes, quality and risk records. 12(b) Documented audits comparing quality and treatment toxicity with benchmarks defined by the service or facility in the last 12 months. 12(c) Documented patient satisfaction surveys and action taken. 12(d) Documented safe practice and quality improvement initiatives based among others on the findings from the above audits and surveys in the last 12 months.
13. Radiation Safety 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.	The radiation management plan (Australia) or radiation safety plan (New Zealand) for radiation safety defines responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety.
13. 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]	The responsible person or managing entity (New Zealand) must ensure that a radiation management plan or radiation safety plan is in place, in accordance with the legislation for that jurisdiction. [60-61] 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 or managing entity must ensure that staff know their role and allocate special responsibilities only to appropriately trained and authorised workers.[60]
13. Radiation Safety Commentary 13.2	In each jurisdiction there is a regulatory authority to establish and enforce standards for radiation safety [65,66] and before conducting radiation oncology practice regulators must be notified and give approvals and authorisations. These authorisations include registrations and licenses.	In each jurisdiction there is a regulatory authority to establish and enforce standards for radiation safety [61-62] and, before conducting radiation oncology practice, regulators must be notified and give approvals and authorisations. These authorisations include registrations and licenses.

	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.	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 or managing entity 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 or managing entity is to ensure reports are made to the regulatory body within the designated timescales and as described in the management plan.
13. 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.	The radiation management plan or radiation safety 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 including non-radiation oncology professionals following safe work practices, for example cleaners and ward staff.
15. Dosimetric Intercomparison	Regular participation in dosimetric intercomparisons ensures confidence that radiation dose is accurately delivered in a radiation therapy facility.	Regular participation in dosimetric intercomparisons (such as those offered by the ACDS) ensures confidence that radiation dose is accurately delivered in a radiation therapy facility.
15. Dosimetric Intercomparison Required Evidence	15(a) Documentation that the facility has participated within the last two (2) years – or is participating in – an external dosimetric intercomparison conducted by an independent organisationally separate service, and that the outcomes have been reviewed and actioned as appropriate.	15(a) Documentation that the facility has participated within the last two (2) years or is participating in an external dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5*.

	15(b) Documentation that the facility has participated within the last five (5) years – or is participating in – a level III dosimetric intercomparison by an independent, organizationally separate service, and that the outcomes have been reviewed and actioned as appropriate. Note: in addition to Standard 7, this standard is about ensuring ongoing quality assurance.	15(b) Documentation that the facility has participated within the last four (4) years or is participating in a level III dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5*. Note: in addition to Standard 7, this standard is about ensuring ongoing quality assurance.
Standard 16	16. EVIDENCE-BASED PRACTICE Any participation in human clinical trials is supported by governance and infrastructure to ensure quality care.	16. CLINICAL TRIALS AND EVIDENCE-BASED PRACTICE Any participation in clinical trials is supported by governance and infrastructure to ensure quality care and oversight. Evidence-based practice ensures the integration of the best current evidence with clinical expertise to provide optimal care to each patient.
16. Clinical Trials and Evidence Based 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.[70] 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.[71] Clinical practice relies on clinical trials for Level 1 and 2 evidence. Quality assurance tailored to the individual trial is an integral part	This standard is not intended as a guide to clinical research. This standard does not imply that facility participation in clinical trials is required but it is encouraged. Patients should be informed of any relevant clinical trials and provided with opportunities to participate in them. Participation by telehealth should be explored for patients with limited access to clinical trials (refer to *Appendix 3*). 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.[67] 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.[68] 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.[69-75] Participation in clinical trials has benefits beyond the evidence it

	of clinical trial activity.[72-78] 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.[20] See Further Reading list for additional information.	gathers as it helps to define high quality care and allows external review of patient care available to healthcare 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 6 Guide.[16] See Further Reading list for additional information.
16. Clinical Trials and Evidence Based Practice Criterion 16.2		All clinical services are provided using evidence-based or best practice principles.
16. Clinical Trials and Evidence Based Practice Commentary 16.2		Evidence-based practice underpins the provision of safe, quality care in all aspects of radiation oncology. Evidence-based clinical practice guidelines and recommendations are designed to assist decision-making and guide best practice in the management of cancer. These guidelines are based on the best evidence available at the time of publication and are a guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. As new evidence becomes available, existing resources may be updated or topic-specific updates may be developed to act as supplements to existing documents.[76-78]
16. Clinical Trials and Evidence Based Practice Required Evidence	16 (a) Ethics approval of all clinical trials from a committee in accordance with NHMRC or Health and Disability Ethics Committees (HDEC) guidelines.	(a) Evidence of radiation oncology staff (RO, RT, ROMP, RN, AH) actively providing current, relevant evidence-based information to patients, their families and carers. (b) Evidence of research activities contributing to evidence-based practice. (c) Evidence of best practice in radiation therapy (examples required to guide ROTCs – RANZCR SABR, contouring

		guidelines, relevant department based clinical protocols, link back to patient audit and peer review tool, include all disciplines).

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, in Australia and New Zealand, 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 and New Zealand 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 [2] 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.

Further to that, the Standards also looks to incorporate risk management.

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 work separately but in co-operation, to deliver their component of the radiation therapy process. Radiation oncology nurses work as part of a multidisciplinary team with the radiation oncology professionals and allied health staff to provide safe, supportive, person-centred care to patients undergoing radiation therapy.
These professions are represented by the following organisations:

- The Royal Australian and New Zealand College of Radiologists (RANZCR), Faculty of Radiation Oncology (FRO)
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- The Cancer Nurses Society of Australia (CNSA) with representation from the New Zealand Nurses Organisation Cancer Nurses College (NZNOCNC).

Together, these professional bodies are represented by the Radiation Oncology Alliance (ROA) Committee.

In 2005, the then 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 Radiation Oncology Standards Working Group (sub-group of the ROA Committee) 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 and New Zealand.

The *Radiation Oncology Practice Standards—Part A: Fundamentals* and *Part B: Guidelines* are considered to be essential to the delivery of safe, quality care to radiation oncology patients; as such, both documents shall be read together. Part B provides additional essential material in support of the Standards and shall be used to complement them. The two documents are linked by identical headings and descriptors for each individual standard and criterion. 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 National Safety and Quality Health Service Standards[3] and New Zealand's Health and Disability Services Standard.[4]

Radiation oncology has always been at the forefront of the next frontier in medicine as early adopters of new technology. Artificial Intelligence (AI) and Machine Learning are currently rapidly evolving technologies in Radiation Oncology. Therefore, RANZCR is developing AI Standards that will build on its ethical principles and provide doctors, AI developers and healthcare organisations with clear guidelines to deploy machine learning systems and AI tools ensuring patient safety.

The ethical principles will outline the most appropriate use of AI and machine learning, including how both can successfully help to drive continuing improvements in patient care.

The RANZCR AI Standards and the ACPSEM and ASMIRT AI Standards when available should be implemented alongside the Radiation Oncology Practice Standards where AI is a factor or tool.

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 *References* lists all the references used in the Standards.

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 14).

Appendix 3 is the RANZCR Radiation Oncology Telehealth Principles.

Appendix 4 is a practical tool that allows radiation oncology centres to assess their level of compliance with the Radiation Oncology Practice Standards. The results are purely for internal reflection on quality management processes and are not intended to be shared with any external organisation.

Appendix 5 outlines the frequency of dosimetric audits required in order to be eligible for Radiation Oncology Health Program Grants (ROHPG) payments in Australia.

ACRONYMS AND ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACHS	Australian Council on Healthcare Standards
ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
ACSQHC	Australian Commission on Safety and Quality in Health Care
AI	Artificial Intelligence
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASMIRT	Australian Society of Medical Imaging and Radiation Therapy
AS/NZS	Australian Standard/ New Zealand Standard
CIED	Cardiac Implantable Electronic Device
CBCT	Cone Beam Computed Tomography
CNC	New Zealand Cancer Nurses College
CNSA	Cancer Nurses Society of Australia
CT	Computed tomography
CTV	Clinical target volume
DH	Department of Health, United Kingdom
DoH	Department of Health (formerly Department of Health and Ageing)
EPID	Electronic Portal Imaging Device
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
IAEA	International Atomic Energy Agency
ICD	International Classification of Disease
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
IMRT	Intensity modulated radiation therapy
IPEM	Institute of Physics and Engineering in Medicine
ISO	International Organisation for Standardisation
ITV	Internal Target Volume
MLC	Multileaf collimator
NCCI	National Cancer Control Initiative
NHMRC	National Health and Medical Research Council
NHS	National Health Service, United Kingdom
OAR	Organ(s) at risk
PTV	Planning target volume
QA	Quality assurance
RANZCR	The Royal Australian and New Zealand College of Radiologists
RCR	Royal College of Radiologists
RO	Radiation oncologist
ROJIG	Radiation Oncology Jurisdictional Implementation Group
RON	Radiation oncology nurse
ROMP	Radiation oncology medical physicist
RORIC	Radiation Oncology Reform Implementation Committee
ROTC	Radiation Oncology Trainee Committee
RSO	Radiation safety officer
RT	Radiation therapist
SABR/SBRT	Stereotactic ablative radiation therapy/stereotactic body radiation therapy
SRS	Stereotactic radiosurgery
TBI	Total Body Irradiation
TROG	Trans-Tasman Radiation Oncology Group

TSEI	Total Skin Electron Irradiation
WH&S	Work health and safety

STANDARDS

FACILITY MANAGEMENT

1. STAFF

Staff qualifications are 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 practice for all applicable staff.

COMMENTARY 1.1

The qualifications of radiation oncologists (ROs), radiation therapists (RTs), radiation oncology medical physicists (ROMPs) and radiation oncology nurses (RONs) must reflect the skills and competencies required to deliver radiation therapy services safely. Recruitment and selection procedures must ensure that appropriate qualifications are held to enable registration-to-practice applicable to the jurisdiction.[5]

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 keep pace with developments in radiation therapy. The performance review process should include review of professional responsibilities in terms of continuing professional education.[6]

REQUIRED EVIDENCE

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

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.[7] It is recommended that the majority of staff reside locally with at least one (1) qualified local full time equivalent from each staff group available to operate a basic service. 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 RANZCR workforce census, facility survey, cancer incidence project and optimisation rates or similar data, could be used as the basis for workforce needs analysis. Regional and rural considerations should be considered.[8]

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.[9] Regional and rural considerations should be considered.[8]

REQUIRED EVIDENCE

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

2(b) Evidence to demonstrate funded time within working hours for education, research and development, administration and quality assurance and improvement activities. Evidence must 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.

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 nursing care plan. As well as the treatment record, clinical correspondence including referrals, the prescription and treatment 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, language spoken, whether a translator is required 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 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.[10-11] With the advancements in digital technology, the healthcare industry has begun to shift towards using electronic medical records. Radiation oncology facilitates should give consideration to storing medical records electronically.

REQUIRED EVIDENCE

3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three (3) common tumour streams of patients treated with radiation therapy in the last 12 months that demonstrates:

- accuracy, comprehensiveness and currency of patient records;
- compliance with legislation;
- adherence to professional guidelines for complex* techniques e.g. RANZCR Guidelines for Safe Practice of Stereotactic Body Radiation Therapy; and
- remedial action where necessary.

Note: records required under 4(a) and 8(b) may be the same as required here. A useful resource is the RANZCR peer review audit tool.

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

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 longer).

*A technique would be considered complex where separate professional guidelines exist, or it is not available at most facilities. Such complex techniques would include (but are not limited to), SABR/SBRT, SRS, brachytherapy, TBI and TSEI.

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 existing cancer registry requirements.

COMMENTARY 4.1

Successful planning, evaluation and quality assurance of cancer control activities depend 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 and any jurisdictional requirements.

COMMENTARY 4.2

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

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 that 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 therapy 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 radiation therapy services are important because they can affect overall access and subsequent health outcomes.[1] The strategic, operational and physical design of radiation therapy services influence each other and should be developed in parallel.[13]

The strategic design of an organisation links its objectives and planned outcomes with the environment and external infrastructure.[14]

The strategic plan is developed by a multidisciplinary team, with due consideration of:

- existing national benchmarks for access to radiation therapy treatment;[15]
- 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 therapy treatment services.

COMMENTARY 5.2

Facility management includes the effective and efficient management of buildings, plant, equipment, supplies, external service providers, utilities and consumables.[16]

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. Centres that cater to Māori, Aboriginal and Torres Strait Islander patients need to assess their physical infrastructure with their patients in mind. For example, an outside waiting area may be appropriate. A Māori or Aboriginal/Torres Strait Islander liaison officer should be consulted to ensure the environment is culturally safe.

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 sexual identity, ethnic, cultural and religious practices and beliefs of patients, and yet support a timely throughput of patients [16] while at the same time maintaining appropriate safety and hygiene practices.

CRITERION 5.4

Facility management includes a plan for facility or major equipment failure, up to and including building inaccessibility.

COMMENTARY 5.4

Given the known impact of unscheduled treatment interruption,[17] all centres should make a risk assessment covering plausible scenarios of treatment interruption in their circumstances. No centre is immune but smaller and regional centres with potentially lower base staffing levels, less redundancy of equipment, as well as increased distance to alternative centres can be more vulnerable Reasonable steps to mitigate this risk such as beam matched equipment and formal agreements to transfer patients to other facilities should be planned and documented in detail. Issues such as patient and staff transfer, treatment replanning and capacity of alternative facility require formal and detailed agreements in advance. [8] These issues are discussed to some extent in the regional paper.

REQUIRED EVIDENCE

5(a) A documented strategic plan with a facility-agreed timeframe (not greater than five (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.

5(c) A business continuity plan that has been reviewed for appropriateness within the last two (2) years.

6. FACILITY PROCESS MANAGEMENT

The provision of radiation therapy treatment services is timely, coordinated, patient-centred and equitable to ensure optimal patient outcomes and experience [3].

CRITERION 6.1

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

COMMENTARY 6.1

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

RANZCR has published guidelines that outline acceptable and best practice for treating radiation therapy emergencies in a timely manner.[18] 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 2013 RANZCR document *Management of Waiting Lists in Radiation Oncology: "Quality in the timeliness of patient care"*[18]. 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 2013 FRO guidelines [18] 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 14 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 radiation therapy.

6(d) Evidence that patients have been consulted in the design of institutional processes, such as surveys of patient experience.

6(e) Evidence that the needs of indigenous and other cultural groups have been consulted about institutional processes.

7. RADIATION THERAPY EQUIPMENT

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

For the purposes of the standards such equipment is defined as all hardware and software listed on the Australian Register of Therapeutic Goods" or "The Web Assisted Notification of Devices (WAND)" Database in New Zealand 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.

CRITERION 7.1

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

COMMENTARY 7.1

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

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 significant or major modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel. To ensure accurate and safe clinical usage, any newly commissioned equipment requires an independent dosimetric audit performed by an audit body that is independent and without conflict of interest. (The minimum audit requirements for new linacs/planning system models are detailed in Appendix 5.)

COMMENTARY 7.2

Radiation oncology medical physicists should take responsibility for the commissioning program.[18-20] 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 a 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. [19-21]

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. [7,20,22-31]

REQUIRED EVIDENCE

7(a) Records of acceptance tests and commissioning data for all radiation therapy 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.

7(d) Documented evidence of decision to purchase equipment, such as meeting minutes or business case.

7(e) Documented evidence of independent dosimetric audit, consistent with the requirements of *Appendix 5* (if applicable).

TREATMENT PLANNING AND DELIVERY

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, including the risks both short-term and long-term side-effects resulting from the proposed radiation treatment and their consent is documented by the consenting clinician.

COMMENTARY 8.1

Professional organisations[32-33] 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.[33] An interpreter should be used when the patient is not fluent in English. Understanding of consent must be confirmed.

Consent from the patient should be reviewed when there is a delay of greater than one month to the start of treatment, significant change in treatment management plan, 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 data items:

- identity of the prescribing practitioner;
- unique patient identification, including full name, date of birth, unique identification number ;
- treatment intent;
- diagnosis;
- anatomical region to be treated including laterality (in full), where applicable;
- modality;
- radiation dose and prescription recorded following internationally recognised standards appropriate for the technique used;
- fractionation, including fractions per phase, per week, per day and time interval between fractions where fractionation is not one (1) fraction per day; and
- details of any other associated treatment requirements, for example chemotherapy, CIEDs, prostheses.

In addition to legislative and licensing requirements, the information should be readily accessible, legible and in accordance with policy and clinical guidelines.[34]

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.[35] 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 (3) common tumour streams of patients treated with radiation therapy in the last 12 months that 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.

8(d) Documented prescribing practice – i.e. local methodology (for example [39–40] rather than doses for specific sites.

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. If there is no clinical protocol available for the procedure/treatment, as far as possible, the procedure/treatment should follow the best available evidence with documentation of rationale.

COMMENTARY 9.1

Evidence-based treatment planning protocols (including image registration) underpin the treatment technique and reflect the level of contouring, volume delineation and dose reporting required. They ensure a scientific approach to dose optimisation[36-39] and promote safe, accurate and consistent delivery of radiation therapy.[7]

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. [24,39-40,42]

Plan evaluation is the process of analysing an isodose distribution using visualisation methods and quantitative data displays. [24,38,40-42]

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 utilising appropriate cleaning and sterilisation procedures.

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.

Nursing Practice Principle 1: Care delivery is tailored to the specific needs and preferences of each individual.

Nursing Practice Principle 3: The information and educational needs of patients and their carers are identified and met.

REQUIRED EVIDENCE

9(a) Documented protocols or guidelines for treatment planning (including image registration) of common tumour sites including: breast, prostate, lung, head and neck and pelvis that consider the therapeutic decision and evidence-based practice, these shall explicitly include SBRT and SRS practices if these techniques are performed.

9(b) Documented quality control activities that evaluate feasibility and suitability of the proposed treatment plan, including immobilisation devices used and documented image selection and registration protocols.

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. [42-43]

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. [19]

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. [7,20]

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.

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 and/or international recommendations, where appropriate. [20]

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 [20] or RTs trained and experienced in specific planning calculation methods.

Where independent monitor unit calculation is impractical, 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 request.
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. Patient-specific QA using planar or 3D detector arrays can be used to verify the accuracy of delivered dose.

CRITERION 10.6

For SBRT/SRS treatments where CTV to PTV margins are small and geometric accuracy is critically important, a system shall be in place to ensure that the required geometric accuracy is routinely achievable.

COMMENTARY 10.6

There are many points in the treatment chain where small geometrical errors can be introduced. These may combine to give an uncertainty greater than the proposed CTV to PTV margin and so lead to sub-optimal treatment. It is therefore important to ensure the geometrical integrity of the treatment chain.

REQUIRED EVIDENCE

10(a) Documented evidence of:

- derivation of all factors;
- an independent check of clinical dosimetric data by a ROMP; and
- an end-to-end check of the geometrical accuracy.

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

10(c) Records of validation including results of end-to-end testing 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. This could be incorporated into the audit of 30 randomly selected records.

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

11. RADIATION TREATMENT DELIVERY

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

CRITERION 11.1

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

COMMENTARY 11.1

Radiation therapists provide daily online image guidance and assessment to ensure the safe and accurate delivery of highly conformal radiotherapy treatments. Image guidance is an integral part of radiation therapy treatment delivery and supports on-line correction and offline review of a patient's treatment. Departmental imaging policies and guidelines are required to match international and published best practice standards relevant to each treatment site and protocol.[16,31,43,44]

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.[24]

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 suitably qualified personnel minimise potential harm of geographic miss and/or unintentional irradiation of healthy tissues by identifying the sources and magnitude of field placement errors.[20,45] Field shape and volumetric assessment should also be considered where relevant.

CRITERION 11.2

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

COMMENTARY 11.2

A visual and audio monitoring system allows observation of the patient during treatment, thereby promoting patient safety.[46]

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

RTs must be notified of concurrent chemoradiation for their own personal protection or in the event of a spill (e.g. by dropdown box in a radiation oncology information system).

CRITERION 11.3

Patients are reviewed for their fitness to continue and for their psychosocial needs throughout a course of treatment.
Nursing Practice Principle 2: A consistent approach is used for patient assessment and symptom management.

COMMENTARY 11.3

Regular progress reviews should consider compliance with the current treatment regimen and can improve the detection and management of acute toxicities.[47] Review should also include compliance with delivery of the overall treatment prescription and plan. This is to be communicated to the patient and can be done as part of a discharge letter that includes appropriate contact details.

Nursing Practice Principles 4: Healthcare professionals are skilled in identifying the potential effects of radiation therapy and the treatment on patients.

Psychosocial care involves a whole-person approach, considering the person's past life experience, current situation and quality of life.[48]

Nursing Practice Principle 5: Optimal patient outcomes are achieved through effective multidisciplinary teamwork.

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 30 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.

11 (e) Local protocol based on published evidence for appropriate management and monitoring of CIEDs before commencement of treatment.

SAFETY AND QUALITY MANAGEMENT

12. SAFETY, QUALITY AND IMPROVEMENT PROCESSES

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

CRITERION 12.1

Safe practice, quality improvement, and the safe and considered introduction of new technologies requires effective facility governance.

COMMENTARY 12.1

An appropriate committee/management structure to monitor and manage the safety and quality of health care being delivered should be in place.[49]

Quality improvement in health services requires leadership and commitment at all levels.[49]

Quality improvement systems and policies assist in providing safe and quality care by continuously monitoring, auditing and measuring the facility's performance. [50-52]

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.[53]

CRITERION 12.2

Risk to patients, staff and the public is managed in accordance with the relevant WH&S legislation for the respective jurisdiction, 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. [54-55]

CRITERION 12.3

Facility governance, policies and procedures incorporate the intent of The Australian Charter of Healthcare Rights or the Code of Health and Disability Services Consumers' Rights in New Zealand.

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 Code extends to any person or organisation providing, or holding themselves out as providing, a health service to the public or to a section of the public—whether that service is

paid for or not. The Code therefore covers all registered health professionals, such as doctors, nurses, dentists et cetera.

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.[56] 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.

Healthcare decisions based on evidence-based best practice provide patients with care that most closely meets their individual needs. [57-59]

Nursing Practice Principle 6: Patients and their carers have the opportunity to participate in all aspects of care.

REQUIRED EVIDENCE

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

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

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

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

13. RADIATION SAFETY

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

CRITERION 13.1

The radiation management plan (Australia) or radiation safety plan (New Zealand) 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 or managing entity (New Zealand) must ensure that a radiation management plan or radiation safety plan is in place, in accordance with the legislation for that jurisdiction. [61-63] 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, or managing entity must ensure that staff know their role and allocate special responsibilities only to appropriately trained and authorised workers.[60]

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 [62-64] and, before conducting radiation oncology practice, regulators must be notified and give approvals and authorisations. These authorisations include registrations and licenses.

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, or managing entity 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, or managing entity, 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 including non-radiation oncology professionals following safe work practices, for example, cleaners and ward staff.

REQUIRED EVIDENCE

13(a) A management plan for radiation safety that complies with the requirements of the relevant regulatory authority and the legislation for the jurisdiction.

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 radiation therapy facility with a safety-conscious culture focused on learning and prevention of error.

CRITERION 14.1

The radiation therapy 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. [44,63]

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.[64]

REQUIRED EVIDENCE

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

14(b) Evidence of feedback to staff.

15. DOSIMETRIC INTERCOMPARISON

Regular participation in dosimetric intercomparisons (such as those offered by the ACDS) ensures confidence that radiation dose is accurately delivered in a radiation therapy facility. [65]

CRITERION 15.1

The radiation therapy facility participates in ongoing dosimetric intercomparisons of at least one photon beam and one electron beam every two (2) years, and on commissioning any new equipment.

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 (*Elvis project,* 2006).

CRITERION 15.2

Intercomparisons include at least one level III dosimetric intercomparison every four (4) years using a treatment scenario relevant for the particular centre.[66]

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 participated within the last two (2) years—or is participating in—an external dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5*.

15(b) Documentation that the facility has participated within the last four (4) years—or is participating in—a level III dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5*.

Note: in addition to Standard 7, this standard is about ensuring ongoing quality assurance.

16. CLINICAL TRIALS AND EVIDENCE BASED PRACTICE

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

Evidence-based practice ensures the integration of the best current evidence with clinical expertise to provide optimal care to each patient.

CRITERION 16.1

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

COMMENTARY 16.1

This standard is not intended as a guide to clinical research.

This standard does not imply that facility participation in clinical trials is required but it is encouraged. Patients should be informed of any relevant clinical trials and provided with opportunities to participate in them. Participation by telehealth should be explored for patients with limited access to clinical trials (refer to *Appendix 3*).

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.[67]

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.[68]

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.[69-75] 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 healthcare 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 6 Guide.[16] See Further Reading list for additional information.

CRITERION 16.2

All clinical services are provided using evidence-based or best practice principles.

Commentary 16.2

Evidence-based practice underpins the provision of safe, quality care in all aspects of radiation oncology.
Evidence-based clinical practice guidelines and recommendations are designed to assist decision-making and guide best practice in the management of cancer.

These guidelines are based on the best evidence available at the time of publication and are a guide to appropriate practice, to be followed subject to the clinician's judgement and the

patient's preference in each individual case. As new evidence becomes available, existing resources may be updated or topic-specific updates may be developed to act as supplements to existing documents. [76-78]

REQUIRED EVIDENCE

16 (a) Ethics approval of all clinical trials from a committee in accordance with NHMRC or Health and Disability Ethics Committees (HDEC) guidelines.

16 (b) Evidence of radiation oncology staff (RO, RT, ROMP, RON, Allied Health) actively providing current, relevant evidence-based information to patients, their families and carers.

16 (c) Evidence of research activities contributing to evidence-based practice.

16 (d) Evidence of best practice in radiation therapy (e.g. required to guide ROTCs – RANZCR SABR, contouring guidelines, relevant department based clinical protocols, link back to patient audit and peer review tool, includes all disciplines).

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 radiation therapy 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 radiation therapy 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 radiation therapy. 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 radiation therapy, 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 fulfil 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 in medical physics to perform the necessary dosimetric calculations, measurements and monitoring in radiation oncology. A suitable person will: a) be on the Qualified Medical Physics Specialists (QMPS) Register in Radiation Oncology held by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM); or b) have an equivalent level of training, skills, knowledge and expertise to a person listed on the ACPSEM Qualified Medical

	Physics Specialists (QMPS) Register in Radiation Oncology as determined by a relevant authority.
Radiation oncologist	Person who is registered as a medical practitioner by the relevant Medical Board, is a fellow of 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 ASMIRT or registered to practice 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 or Managing Entity	The person or entity 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.
Suitably qualified	Means registered (for regulated professions) or eligible for registration on the ACPSEM Register of Qualified Medical Physics Specialists (for medical physicists), and licensed (where required) to practice according to relevant jurisdictional legislation and the defined scope of practice for that profession; and within any organisationally defined credentialing requirements applicable to specific aspects of practice.
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

AS/NZS IEC 60601.2.1:2015. Medical electrical equipment – Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV. 2015.

AS/NZS 3200.2.11:1999. Medical electrical equipment – Particular requirements for safety – Gamma beam therapy equipment Identical to IEC 60601-2-11 – Ed. 2.0 – Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment. 1997.

AS/NZS IEC 60601.2.17:2015. Medical electrical equipment – Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment. 2015.

AS/NZS IEC 60601.2.29.2015. Medical electrical equipment – Particular requirements for the basic safety and essential performances of radiotherapy simulators. 2015.

AS/NZS 3824:1998. Guidelines for radiotherapy treatment rooms design – identical to IEC/TR3 61859 – Ed. 1.0 – Guidelines for radiotherapy treatment rooms design. 1997.

AS/NZS 4184.1:1994. Evaluation and routine testing in medical imaging departments – General aspects. 1994.

AS/NZS 4213.1:1994. Radiotherapy simulators – Functional performance characteristics identical to IEC 61168 – Ed. 1.0 – Radiotherapy simulators – Functional performance characteristics. 1993.

AS/NZS 4213.2:1994. Radiotherapy simulators – Guidelines for functional performance characteristics identical to IEC/TR2 61170 – Ed. 1.0 – Radiotherapy simulators – Guidelines for functional performance characteristics. 1993.

AS/NZS 4358:1996. Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics.

AS/NZS 4434.1:1996. Medical electrical equipment – Medical electron accelerators – Functional performance characteristics identical to IEC 60976 – Ed. 1.0 – Medical electrical equipment – Medical electron accelerators – Functional performance characteristics. 198.

AS/NZS 4434.2:1996. Medical electrical equipment – Medical electron accelerators – Periodic function performance testing identical to IEC/TR 60977 – Ed. 1.0 – Medical electrical equipment – Medical electron accelerators in the range of 1 MeV to 50 MeV – Guidelines for functional performance characteristics. 1989.

AS/NZS 4495:1997. Radiotherapy equipment – Coordinates, movements and scales. Identical to IEC 61217 - Consol. Ed. 1.1 (incl. am1) – Radiotherapy equipment – Coordinates, movements and scales. 2002.

AS/NZS 4537:1999. Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy identical to IEC 60731 – Ed. 2.0 Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy. 1997.

AS/NZS 4580:1999 (R2016). Medical electrical equipment – Digital imaging and communications in medicine (DICOM) – radiotherapy objects. 2016.

AS ISO/IEC 27001:2015. Information technology – Security techniques – Information security management systems – Requirements. 2015.

AS/NZS IEC 60601.2.8:2015. Medical electrical equipment – Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV. 2016.

IEC 62083 Ed. 2.0. Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems.

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 following pages 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 following pages 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.

Mandatory Elements	**Description of Element**	**Sub-Elements**	**Comments**
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 following pages 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 following pages for a description of these sub-elements.	As a minimum the consequence scoring system must incorporate four (4) levels ranging from extreme to minor / nil. The choice of four 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, the description should include date of the event, if a patient is involved, if a staff member was affected, and the body region being treated.

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 radiation therapy errors. This record should report where in the process was the incident discovered and the treatment modality (EBRT vs BT). The absolute dosimetric error level, as well as the level according to percentage error, should also be reported.

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. It should be stipulated whether the percentage error applies to the fractional dose or to the whole treatment course. 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 whether 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 *et cetera*.

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 *et cetera*). 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 *et cetera*.

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 *et cetera*). 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 *et cetera*.

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 *et cetera*.

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 separately 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 – RADIATION ONCOLOGY TELEHEALTH PRINCIPLES

Introduction

Technological advances have seen healthcare services provided remotely. The provision of healthcare remotely through telecommunications technology is referred to as 'telehealth'.

Telehealth has been defined by the International Organisation for Standardisation (ISO)[1] and Standards Australia[2] as "information and communication technologies (ICTs) to deliver healthcare services and transmit health information over long and short distances".

Further, telehealth "encompasses a broad variety of technologies including teleconferencing, video conferencing, Internet, store-and-forward devices, streaming media, and terrestrial and wireless communication".[1]

The use of ICTs complements existing services, enabling health services to be offered to areas otherwise out-of-reach and for tertiary level healthcare professionals to service and maintain outreach sites without extensive travel.

In radiation oncology, telehealth offers opportunity to improve professional support to regional services, outreach services and patient follow up[3] as well as offering the opportunity to protect patients at risk from exposure to infection associated with in-person consultation as seen during the COVID-19 pandemic. Telehealth is vital to extending the benefits of multidisciplinary care to regional and rural patients and reducing the associated cost of care.

Key Principles

a) Services provided via telehealth must adhere to reasonable standards of quality and professional healthcare in accordance with each health care discipline's clinical standards[4].
b) Treatment provided to a patient in another location must meet the same required standards as care provided in an in-person consultation,[5] and any requirements in that other location, e.g. around medication prescribing. Be aware that providing telehealth to a patient in a different country may be restricted under your country's regulatory system and subject to that other country's laws and standards. Advice should be sought from your professional college or association, professional indemnity insurer or lawyer.
c) Health professionals must be satisfied that it is clinically appropriate to provide telehealth services to a patient[6].
d) Health professionals must make their identity known to the patient and confirm, to their satisfaction, the identity of each patient and significant other present at each consultation[7].
e) Additional staff are not permitted in the consultation room without patient consent.
f) Consultations must not be recorded by clinical staff without patient consent.
g) The usual principles for obtaining and documenting patient informed consent, protecting patient privacy, and protecting patient rights to confidentiality (including of patient health records) must be applied[7].

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h) The same standards for patient health records apply in both telehealth and in-person consultations. Records must be maintained in accordance with existing legal requirements for record retention and privacy, and professional standards. All patient health records must be up-to-date, clear, accurate and reasonably secure[8]. Generally, there should be sufficient information in the record to allow a colleague to take over the patient's care based on the records alone.
i) If a physical examination is necessary, then either alternative arrangements to take this into account are necessary, or treatment decisions delayed, until a physical examination by a clinician appropriate to the situation can be arranged[5].
j) The integrity and therapeutic value of the relationship between patient and practitioner should be maintained and not diminished through the use of telehealth technology[4].
k) Telehealth must not be used to provide healthcare services that are otherwise not legally or professionally authorised[4]. Ensure your use of telehealth under particular schemes (such as the Medicare Benefits Schedule - MBS) complies with scheme requirements (for MBS, this includes general MBS and specific item number requirements)."
l) The safety of patients and practitioners must be ensured. Safe hardware and software, combined with demonstrated user competence, are essential components of safe telehealth practice[4].

Additional guidance is provided by the Medical Board of Australia[7], the Medical Council of New Zealand[5], the New Zealand Telehealth Forum (https://www.telehealth.org.nz), and peak professional groups.

Standards

Facility Management

Criterion 1

The facility has a documented plan for the use of telehealth.

Commentary 1

A facility plan for telehealth should consider various factors including, but not limited to a cost/benefit analysis; change management and ensuring staff understand any workflow implications; needs assessment of staff (i.e. additional training/professional development requirements); inclusion of telehealth in the facility's quality improvement program

The facility must ensure that the telehealth service is adequately covered by insurance and professional indemnity.

Criterion 2

The rooms being used for telehealth are fit for purpose. The patient has a safe space from which to call from including the option to use a room at a local hospital or health care facility.

Commentary 2

Rooms allocated for telehealth services, must be fit for purpose and consider the needs of both the service and patient. For example, there is adequate space for patients with mobility issues, or for any support. Rooms should maintain an appropriate level of comfort and privacy[9] and allow for the effective use of equipment (e.g. lighting, limited noise, camera use).

Criterion 3

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The facility has procedures for the installation of ICT equipment required for telehealth services.

Commentary 3

The facility ensures procedures are in place for the installation of equipment and devices for telehealth according to the guidelines of the manufacturer or supplier[9] and has assessed whether the equipment or software is appropriate for telehealth services[9] (including with other telehealth services where necessary).

Criterion 4

Information and communication technology (ICT) equipment used in the provision of telehealth services are fit for purpose.

Commentary 4

All ICT equipment used for telehealth should be tested regularly to ensure that they work reliably over the network; support interoperability with other telehealth services[9] where necessary; and meet expected standards for the protection of health records in electronic storage or transmission[9].

Criterion 5

The facility has procedures to support telehealth.

Commentary 5

The facility ensures procedures are in place to support telehealth including, but not limited to, service level agreements specifying the levels of telehealth service required to support the agreed continuity of care[9]; capacity management ensures that IT infrastructure resources are in place to effectively meet planned demand for telehealth[9]; and service continuity management to provide recovery plans for telehealth when there is a significant failure.

Criterion 6

The facility has a system for the coordination of bookings.

Commentary 6

A booking system is in place to ensure that bookings of patients, rooms, and required equipment are coordinated. The room(s) used for telehealth and any required equipment are accessible when needed.

Clinical aspects

Criterion 7

Patients are provided with information about modes of healthcare delivery available.

Commentary 7

Patients should be able to make informed choices for their care, including whether care is delivered in person or through telehealth. Facilities must provide patients with easily accessible information to make their choice. This information should include plain language information about telehealth and other care options available. It must be clear to patients that

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they are free to change their preference and switch to another mode of healthcare delivery[9].

Criterion 8

Patients are informed of the benefits and limitations of telehealth and their consent to care provided by telehealth is documented by the consenting clinician.

Commentary 8

The facility should ensure that any relevant benefits or limitations of telehealth in the context of the patient's care are explained to the patient and any limitations or risks resulting from the use of telehealth are noted and reduced as far as possible[9]. Consent to the use of telehealth may be provided by the patient in writing prior to the telehealth appointment/booking. The consent should confirm[9] that (1) the patient has been informed of relevant benefits or limitations of telehealth in their care; (2) that the patient understood the provided information; and (3) that the patient agrees to care being provided by telehealth. The patient's clinic letter should document that consultations were conducted via telehealth and that the patient consented to this format. Consent should be given in writing.

Criterion 9

The facility maintains a list of criteria that documents suitability for telehealth.

Commentary 9

Both patient and healthcare provider must be able and willing to participate in care delivered by telehealth. Patients being considered for telehealth should meet set criteria for suitability. The key criteria is whether telehealth is clinically appropriate for the patient's condition. Other criteria should include a variety of factors including ability of a patient to travel, their family, work and cultural situation[9]; need for an interpreter; appropriate clinical objectives and model(s) of care or shared care[9]; practical factors such as at what times of day the patient can expect to be able to access the service[9]; appropriateness for the patient based on documented inclusion or exclusion criteria[9].

Criterion 10

Protocols exist about the way healthcare providers collaborate when using telehealth.

Commentary 10

The facility defines the clinical guidelines and protocols that support collaboration among healthcare organisations and health care professionals. Such protocols should describe processes that are part of the care provision; roles and responsibilities of those involved in each process; and which elements of the professional health record are required to support the collaboration.[9]

Evaluation

Criterion 11

An evaluation framework for telehealth should exist, at both the individual patient and the facility levels.

Commentary 11

Patients, following their first use of telehealth, should be invited to complete an evaluation of

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their experience. The healthcare provider should regularly evaluate whether or not the patient and any necessary support person are still able and motivated to engage in telehealth appropriately.[9]

The facility should periodically evaluate the effectiveness/value of telehealth to determine the continuing range and value of telehealth used by the facility.

Required evidence

(a) Documented plan for the use of telehealth services.

(b) Insurance and professional indemnity covering telehealth services.

(c) Documented procedures for the installation and service records.

(d) Documented procedures to support telehealth services.

(e) Booking system for patients/rooms/equipment.

(j) Documented plain language information regarding telehealth for consumers.

(k) Documented consent policies.

(l) Documented set of criteria for patient suitability for telehealth.

(m) Documented protocols supporting collaboration among healthcare providers.

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Related documents

- Radiation Oncology Practice Standards

References

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(3) Sabesan S. et al. What teleoncology models of care are available to health services in Australia and overseas? 2017. Accessed 30 August 2019 from https://wiki.cancer.org.au/australia/Clinical_question:What_teleoncology_models_of_care_are_available_to_health_services_in_Australia_and_overseas%3F
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(9) Standards Australia. Australian Standard. Health informatics—Telehealth services—Quality planning guidelines (AS ISO13131:2017)

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APPENDIX 4 –SELF-AUDIT TOOL

Radiation Oncology Practice Standards

Self-Audit Tool

This document is provided as a tool for radiation oncology centres to assess their compliance with the Tripartite Radiation Oncology Practice Standards.

The results are purely for reflection on quality management processes and are not intended to be shared with any external organisation.

Radiation Oncology Practice Standards—Part A: Fundamentals

Radiation Oncology Practice Standards—Part B: Guidelines

				Date	Click here to enter a date.

Standard	Key Contact	Criterion	Required evidence	Compliant	Evidence sources
1. Staff	Click here to enter text.	1.1 There are registers of current registration/license to practice for all applicable staff. 1.2 Performance review systems supported by staff development programs are in place and current.	1(a) Registers of current registration/license to practice	Yes ☐ Part ☐ No ☐	Click here to enter text.
			1(b) Attendance records at staff development programs	Yes ☐ Part ☐ No ☐	Click here to enter text.
			1(c) Records of regular performance review in accordance with facility policy	Yes ☐ Part ☐ No ☐	Click here to enter text.
2. Workforce profile	Click here to enter text.	2.1 Staffing numbers are established to safely meet planned patient care capacity. 2.2 Rosters and schedules incorporate time for non-direct patient care activities applicable to the facility's service delivery profile.	2(a) A documented system for managing workforce in relation to service requirement	Yes ☐ Part ☐ No ☐	Click here to enter text.
			2(b) Evidence to demonstrate funded time within working hours for education, research and development, administration and quality assurance and improvement activities. Evidence	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
			must include staffing rosters and schedules and other examples of funded non-patient care time		
3.Management of radiation oncology patient records	Click here to enter text.	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. 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.	3(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three (3) common tumour streams of patients treated with radiation therapy in the last 12 months that demonstrates: • accuracy, comprehensiveness and currency of patient records; • compliance with legislation; • adherence to professional guidelines for complex* techniques e.g. RANZCR Guidelines for Safe Practice of Stereotactic Body Radiation Therapy; and • remedial action where necessary Note: records required under 4(a) and 8(b) may be the same as required here *A technique would be considered complex where separate professional guidelines exist, or it is not available at most facilities. Such complex techniques would include (but are not limited to), SABR/SBRT, SRS, brachytherapy, TBI and TSEI.	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
			3(b) Documented contingency plan for ensuring continuing availability of the patient record in the event of a catastrophic failure.	Yes ☐ Part ☐ No ☐	Click here to enter text.
			3(c) Register for the location of all patient information records and databases	Yes ☐ Part ☐ No ☐	Click here to enter text.
			3(d) Records of action taken to address breakdowns in the procedures for: • tracing patient records; and • the security of records	Yes ☐ Part ☐ No ☐	Click here to enter text.
			3(e) Evidence of the retention of records compliant with national and/or local requirements (whichever is longer)	Yes ☐ Part ☐ No ☐	Click here to enter text.
4. Data management	Click here to enter text.	4.1 The management of clinical data is planned, systematic and supports clinical audit, clinical trials, outcomes analysis and cancer registry requirements.	4(a) Audit evidence of at least 30 randomly selected records encompassing a minimum of three common tumour streams of patients treated with radiation	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		4.2 Disease/diagnosis and staging data conform to recognised classification systems in accordance with facility policies and any jurisdictional requirements. 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.	therapy in the last 12 months that 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	Click here to enter text.	5.1 The strategic planning process addresses the operational and physical organisation of the facility and takes account of changing needs. 5.2 Facility management and performance are based on a multidisciplinary approach to ensure accountability and safety in the delivery of radiation therapy treatment services. 5.3 The physical infrastructure and environment including patient, staff and public amenities are	5(a) A documented strategic plan with a facility-agreed timeframe (not greater than five (5) years) that identifies the ongoing development needs of the facility in order to maintain or improve the service provided	Yes ☐ Part ☐ No ☐	Click here to enter text.
			5(b) A documented review of the strategic plan as designated by the plan itself	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		designed, managed and maintained to support safe practice in the delivery of radiation therapy. Centres that cater to Maori, Aboriginal and Torres Strait Islander patients need to assess their physical infrastructure with their patients in mind. For example, an outside waiting area may be appropriate. A Maori or Aboriginal/Torres Strait Islander liaison officer should be consulted to ensure the environment is culturally safe. 5.4 Facility management includes a plan for facility or major equipment failure, up to and including building inaccessibility.	5(c) A business continuity plan that has been reviewed for appropriateness within the last two (2) years	Yes ☐ Part ☐ No ☐	Click here to enter text.
6.Facility process management	Click here to enter text.	6.1 The patient pathway is co-ordinated to provide optimal patient outcomes within available resources. 6.2 Care is provided in a timely manner according to patient need.	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	Yes ☐ Part ☐ No ☐	Click here to enter text.
			6(b) Data showing trends in waiting times and documentation of any response to unacceptable delays	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
				No ☐	
			6(c) A documented policy that specifies the management of unscheduled interruptions to treatment and prolongation of a course of radiation therapy	Yes ☐ Part ☐ No ☐	Click here to enter text.
			6(d) Evidence that patients have been consulted in the design of the institutional processes, such as surveys of patient experience	Yes ☐ Part ☐ No ☐	Click here to enter text.
			6(e) Evidence that the needs of indigenous and other cultural groups have been consulted about institutional processes	Yes ☐ Part ☐ No ☐	Click here to enter text.
7. Radiation therapy equipment	Click here to enter text.	7.1 Qualified, trained and experienced staff specify requirements of new radiation therapy equipment. 7.2 New radiation therapy equipment, and any significant modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel. To ensure accurate and safe	7(a) Records of acceptance tests and commissioning data for all radiation therapy equipment	Yes ☐ Part ☐ No ☐	Click here to enter text.
			7(b) A documented quality assurance program for radiation therapy equipment that includes:	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		clinical usage, any newly commissioned equipment requires independent dosimetric audit performed by an audit body that is independent and without conflict if interest. (The minimum audit requirements for new linacs/planning system models are detailed in Appendix 5.) 7.3 There is a preventative maintenance program for radiation therapy equipment that ensures safety, reliability, reproducibility and accuracy. 7.4 There is a quality assurance program to assess the ongoing performance of all radiation therapy equipment used in treatment planning and delivery.	• all tests, their frequency and tolerances; • a protocol for managing test failures and non-compliance that includes action levels; and • reporting requirements and action taken	No ☐	
			7(c) Records of delays, unscheduled breaks in treatment and remedial action taken due to equipment failure	Yes ☐ Part ☐ No ☐	Click here to enter text.
			7(d) Documented evidence of decision to purchase equipment, such as meeting minutes or business case	Yes ☐ Part ☐ No ☐	Click here to enter text.
			7(e) Documented evidence of independent dosimetric audit, consistent with the requirements of *Appendix 5* (if applicable)	Yes ☐ Part ☐ No ☐	Click here to enter text.
8. Radiation treatment	Click here to enter text.	8.1 Patients are informed of the benefits and risks, including the risks both short-term and long-term side-effects resulting from	8(a) Documented consent policies	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
prescription		the proposed radiation treatment and their consent is documented by the consenting clinician. 8.2 The radiation treatment prescription conforms to legislation, licensing regulation, policies and clinical protocols and guidelines. 8.3 Radiation treatment prescriptions are regularly audited by peer review		No ☐	
			8(b) Audit evidence of at least 30 randomly selected records encompassing a minimum of three (3) common tumour streams of patients treated with radiation therapy in the last 12 months that 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	Yes ☐ Part ☐ No ☐	Click here to enter text.
			8(c) Documented peer review of radiation treatment prescriptions within a facility-agreed timeframe	Yes ☐ Part ☐ No ☐	Click here to enter text.
			8(d) Documented prescribing practice – i.e. local methodology (for example [39-40] rather than doses for specific sites	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.

Standard	Key Contact	Criterion	Required evidence	Compliant	Evidence sources
9. Planning procedures	Click here to enter text.	9.1 Treatment planning protocols are documented, accessible to staff and endorse evidence-based best practice. If there is no clinical protocol available for the procedure/treatment, as far as possible the procedure/treatment should follow the best available evidence with documentation of rationale. 9.2 External and internal immobilisation methods and equipment are fit-for-purpose. 9.3 Planning and imaging procedures localise, delineate and define target volumes and organs at risk, as well as enabling treatment verification.	9(a) Documented protocols or guidelines for treatment planning (including image registration) of common tumour sites including: breast, prostate, lung, head and neck and pelvis that consider the therapeutic decision and evidence-based practice, these shall explicitly include SBRT and SRS practices if these techniques are performed	Yes ☐ Part ☐ No ☐	Click here to enter text.
			9(b) Documented quality control activities that evaluate feasibility and suitability of the proposed treatment plan, including immobilisation devices used and documented image selection and registration protocols	Yes ☐ Part ☐ No ☐	Click here to enter text.
10. Dosimetry	Click here to enter text.	10.1 Dose measurement ensures compliance of the dose delivery with the treatment prescription. 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.	10(a) Documented evidence of: • derivation of all factors; • an independent check of clinical dosimetric data by a ROMP; and • an end-to-end check of the geometrical accuracy	Yes ☐ Part ☐ No ☐	Click here to enter text.
			10(b) Records of traceability of all radiation equipment calibrations including documentation of independent checking	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		10.3 A system for the calculation of dose distributions in the patient ensures that all doses can be directly related to absolute dose determined for the treatment equipment under reference conditions. 10.4 Calculation of MU, exposure times or dwell times required to deliver each prescribe dose are independently checked. 10.5 There is a system for independent verification of dose delivery to individual patients.		No ☐	
			10(c) Records of validation including results of end-to-end testing where new methods of dose calculations are introduced, including new: • treatment planning systems; • treatment techniques or modalities; and • beam modifiers	Yes ☐ Part ☐ No ☐	Click here to enter text.
			10(d) Documentation of at least one independent check of all MU, exposure time or dwell time calculations for each treatment plan. This could be incorporated into the audit of 30 randomly selected records. Note: records required under 3(a) or 4(a) may be the same as required here	Yes ☐ Part ☐ No ☐	Click here to enter text.
11. Radiation treatment delivery	Click here to enter text.	11.1 Verification procedures are used that minimise the risk of incorrect patient, incorrect dose and anatomical treatment misplacement. 11.2 Patients are visually observed during radiation delivery and clinically monitored according to need.	11(a) Identification procedures that verify patient identity and match the patient to their treatment prescription and plan prior to each treatment session	Yes ☐ Part ☐ No ☐	Click here to enter text.
			11(b) A working system for the observation and monitoring of patients during treatment	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		11.3 Patients are reviewed for their fitness to continue and for their psychosocial needs throughout a course of treatment.		No ☐	
			11(c) Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters	Yes ☐ Part ☐ No ☐	Click here to enter text.
			11(d) Documented audit in the last 12 months of 30 randomly chosen treatment records demonstrating: • assessment of image-based verification in accordance with facility treatment management guidelines; • patient progress review in accordance with facility management guidelines; and • remedial action taken	Yes ☐ Part ☐ No ☐	Click here to enter text.
			11(e) Local protocol based on published evidence for appropriate management and monitoring of CIEDS before commencement of treatment		
12. Safety, quality and improvement	Click here to enter text.	12.1 Safe practice, quality improvement, and the safe and considered introduction of new	12(a) Relevant committee minutes, quality and risk records	Yes ☐ Part ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
processes		technologies requires effective facility governance. 12.2 Risk to patients, staff and the public is managed in accordance with the relevant WH&S legislation for the respective jurisdiction, national standards and the principles of safe practice. 12.3 Facility governance, policies and procedures incorporate the intent of The Australian Charter of Healthcare Rights or the Code of Health and Disability Services Consumers' Rights in New Zealand. 12.4 The technical quality of care and patient outcome is evaluated, compared to benchmarks for best practice, and acted upon accordingly.		No ☐	
			12(b) Documented audits comparing quality and treatment toxicity with benchmarks defined by the service or facility in the last 12 months	Yes ☐ Part ☐ No ☐	Click here to enter text.
			12(c) Documented patient satisfaction surveys and action taken	Yes ☐ Part ☐ No ☐	Click here to enter text.
			12(d) Documented safe practice and quality improvement initiatives based among others on the findings from the above audits and surveys in the last 12 months	Yes ☐ Part ☐ No ☐	Click here to enter text.
13. Radiation safety	Click here to enter text.	13.1 The radiation management plan (Australia) or radiation safety plan (New Zealand) for radiation safety defines responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety.	13(a) A management plan for radiation safety that complies with the requirements of the relevant regulatory authority and the legislation for the jurisdiction	Yes ☐ Part ☐ No ☐	Click here to enter text.
			13(b) Annual audit of compliance with the management plan for radiation safety	Yes ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	**Key Contact**	**Criterion**	**Required evidence**	**Compliant**	**Evidence sources**
		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. 13.3 Appropriate equipment and resources are available for radiation survey measurement in both routine checks and emergency situations. 13.4 There is a regular review of all radiation safety procedures and physical verification to confirm continuing radiation safety.		Part ☐ No ☐	
			13(c) Equipment for monitoring radiation and for use in responding to emergency situations	Yes ☐ Part ☐ No ☐	Click here to enter text.
14. Incident monitoring program	Click here to enter text.	14.1 The radiation therapy facility participates in an incident monitoring program.	14(a) Documentation that the facility records all incidents (including near misses) and analyses data, follows up and takes action as appropriate	Yes ☐ Part ☐ No ☐	Click here to enter text.
			14(b) Evidence of feedback to staff	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.

Standard	Key Contact	Criterion	Required evidence	Compliant	Evidence sources
15. Dosimetric inter-comparison	Click here to enter text.	15.1 The radiation therapy facility participates in dosimetry intercomparisons of at least one photon beam and one electron beam every two (2) years and on commissioning any new equipment. 15.2 Intercomparisons include at least one level III dosimetric intercomparison every four (4) years using a treatment scenario relevant for the particular centre.	15(a) Documentation that the facility has participated within the last two (2) years - or is participating in - an external dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5*	Yes ☐ Part ☐ No ☐	Click here to enter text.
			15(b) Documentation that the facility has participated within the last four (4) years - or is participating in - a level III dosimetric audit conducted by an organisation that is independent and without conflict of interest, and that the outcomes have been reviewed and actioned as appropriate. Where applicable, the audit should meet the requirements of *Appendix 5* Note: in addition to Standard 7, this standard is about ensuring ongoing quality assurance	Yes ☐ Part ☐ No ☐	Click here to enter text.
16. Clinical trials and evidence based practice	Click here to enter text.	16.1 Participation in clinical trials conforms to international guidelines of good clinical practice.	16(a) Ethics approval of all clinical trials from a committee in accordance with NHMRC or Health and Disability Ethics Committee (HEDC) guidelines 16(b) Evidence of radiation oncology staff (RO, RT, ROMP, RN, AH)	Yes ☐ Part ☐ No ☐	Click here to enter text.

				Date	Click here to enter a date.
Standard	Key Contact	Criterion	Required evidence	Compliant	Evidence sources
		16.2 All clinical services are provided using evidence based or best practice principles.	actively providing current, relevant evidence-based information to patients, their families and carers 16(c) Evidence of research activities contributing to evidence based practice 16(d) Evidence of best practice in radiotherapy (*examples required to guide ROTCs – RANZCR SABR, contouring guidelines, relevant department based clinical protocols, link back to patient audit and peer review tool, include all disciplines*)		

APPENDIX 5 –FREQUENCY OF DOSIMETRIC AUDITS

In accordance with the requirements set out to be eligible for the Radiation Oncology Health Program Grants (ROHPG) payments in Australia, the ROPS recommend the following audit frequency:

- Level I every 2 years
- Level II every 4 years
- Level III every 4 years
- Every new linac should have an on-site ion chamber TRS-398 (Level Ib) audit prior to treatment. Where a new treatment planning system model is associated with the new linac, a Level III audit should also be performed prior to treatment.
- A new radiation therapy facility should have at a minimum, a Level III audit prior to treatment.
- In Australia these dosimetric audits must be performed by a NATA accredited auditor. In New Zealand, the audits shall be performed in accordance with the Code of Practice for Radiation Therapy ORS C3 (2019).

For example, a new radiation therapy facility would undergo the following rotation of audits each year:

Year	**Number of linacs**	**Scheduled audit**	**Additional audit**
Year 1	1 linac	Level III (on-site)	Level Ib
Year 2	1 linac	Level I (mailed)	
Year 3	2 linacs	Level II (on-site)	Level Ib (on new linac)
Year 4	2 linacs	Level I (mailed)	
Year 5	2 linacs	Level III (on-site)	
Year 6	2 linacs	Level I (mailed)	
Year 7	2 linacs	Level II (on-site)	
Year 8	2 linacs	Level I (mailed)	