



APEX[®] Program Standards

Level 1 standards are indicated in bold.

Standard 1: Patient Evaluation, Care Coordination and Follow-up

The radiation oncologist is accountable for patient evaluation, ongoing assessment and follow-up, as well as for coordinating and communicating with other providers involved in the patient's care.

1.1 A comprehensive patient evaluation prior to initiation of treatment should include documentation of the following elements:

- 1.1.1 Patient history including, as applicable: current medications, cardiac implantable electronic device, pregnancy status, allergies and previous radiation therapy.**
- 1.1.2 Review of systems.**
- 1.1.3 Physical examination findings.**
- 1.1.4 Pathology review, when applicable.**
- 1.1.5 Staging or documentation of metastatic disease, when applicable.**
- 1.1.6 Laboratory findings, when applicable.**
- 1.1.7 Imaging studies, when applicable.**
- 1.1.8 Pain Intensity assessment; including a pain management plan when applicable.**
- 1.1.9 Initial plan or recommendation of care.**
- 1.1.10 Radiation oncologist's signature and date.**

1.2 The radiation oncologist performs a direct patient evaluation as part of on-treatment management occurs at least once every five treatments, should include documentation of the following elements:

- 1.2.1 Review of cumulative interim dose delivered to date.
- 1.2.2 Patient examination.
- 1.2.3 Assessment of tolerance to treatment.
- 1.2.4 Pain assessment including, as applicable: pain intensity assessment and pain management plan.
- 1.2.5 Radiation oncologist's signature and date.

1.3 A post-treatment summary by the radiation oncologist should include documentation of the following elements:

- 1.3.1 Site of treatment (including laterality, as appropriate).
- 1.3.2 Dose per fraction or number of fractions.
- 1.3.3 Cumulative total dose delivered.
- 1.3.4 Treatment date range (start and end dates).
- 1.3.5 Concurrent systemic therapy.
- 1.3.6 Assessment of tolerance to treatment and, if appropriate, an assessment of disease response to treatment.
- 1.3.7 Pain management plan for patients with unresolved pain.
- 1.3.8 Follow-up plan.
- 1.3.9 Radiation oncologist's signature and date within one month of the patient's completion of care.



- 1.4 Care coordination: Communication.
 - 1.4.1 The ROP transmits a copy of the comprehensive patient evaluation to other involved providers (including the referring provider and/or primary care provider as appropriate) within one month of the initial consultation.
 - 1.4.2 The ROP transmits a copy of the post-treatment summary to other involved providers (including the referring provider and/or primary care provider as appropriate) within one month of treatment completion.
- 1.5 Care coordination: Patient follow-up.
 - 1.5.1 Patient follow-up occurs within four months of treatment completion.
- 1.6 Transfer of previous radiation treatment data.
 - 1.6.1 The ROP defines a process and timeline for transmitting previous radiation treatment details to new providers when requested.

Standard 2: Treatment Planning

Pretreatment processes are documented and communicated prior to the simulation and treatment planning. The ROP uses a written notes and directives resulting in a patient-specific treatment plans and calculations.

- 2.1 Simulation.
 - 2.1.1 The simulation (or pre-treatment) process is conducted according to a written directive/order from a radiation oncologist.**
 - 2.1.2 The simulation (or pre-treatment) process includes documentation of patient positioning, immobilization devices and localization information.
 - 2.1.3 Planning staff verify the accurate DICOM transfer from simulation to treatment planning system.
- 2.2 Treatment planning directive.**
 - 2.2.1 A documented patient-specific planning directive guides treatment planning staff and defines target and normal tissue volume goals.**
- 2.3 A formal treatment prescription includes the physician's order for the following elements in radiation therapy:**
 - 2.3.1 Anatomic treatment site; including laterality where applicable.**
 - 2.3.2 Type and method of radiation treatment delivery.**
 - 2.3.3 Energy or radioisotope used.**
 - 2.3.4 Total dose.**
 - 2.3.5 Normalization/calculation method.**
 - 2.3.6 Dose per fraction.**
 - 2.3.7 Number of fractions.**
 - 2.3.8 Frequency of treatment.**
 - 2.3.9 Imaging guidance**
 - 2.3.10 Radiation oncologist's (or authorized user's) signature and date prior to initiation of treatment.**



- 2.4 A patient-specific treatment plan or calculation includes the following elements:**
- 2.4.1 Anatomic treatment site; including laterality where applicable.**
 - 2.4.2 Type and method of delivery.**
 - 2.4.3 Energy or radioisotope used.**
 - 2.4.4 Total dose.**
 - 2.4.5 Dose per fraction.**
 - 2.4.6 Number of fractions.**
 - 2.4.7 Normalization/calculation method.**
 - 2.4.8 Documentation of doses to target(s) and normal tissue(s).**
 - 2.4.9 Radiation oncologist's (or authorized user's) signature and date prior to initiation of treatment.**

Standard 3: Patient-specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery

The radiation oncology team follows standard operating procedures (SOPs) to ensure patient safety and consistent high-quality care prior to and during radiation therapy.

- 3.1 Patient verification during data transfer includes:**
- 3.1.1 Verifying the patient identity (using two patient-specific identifiers) for every patient at each point in which patient-specific information is electronically transferred from one information system to another or when manually entered.**
- 3.2 For each patient, a timeout is performed prior to all procedures and treatments, which is then documented in the medical record and includes:**
- 3.2.1 Verification of patient identity using at least two patient-specific identifiers.**
 - 3.2.2 Verification of patient treatment site, when applicable.**
 - 3.2.3 Verification of correct patient positioning, when applicable.**
 - 3.2.4 Verification of treatment delivery parameters at the treatment console, when applicable.**
- 3.3 Clinical SOPs.**
- 3.3.1 External beam radiation therapy (EBRT), including 2-D, 3-D, and 4-D; photons and electrons.**
 - 3.3.2 Intensity-modulated radiation therapy (IMRT), including volumetric modulated arc therapy (VMAT).**
 - 3.3.3 Stereotactic radiosurgery including a qualified radiation oncologist (RO) and a qualified medical physicist (QMP) present during treatment.**
 - 3.3.4 Stereotactic body radiation therapy/ Stereotactic ablative radiotherapy, including RO and a QMP supervision requirement during treatment.**
 - 3.3.5 Particle Beam therapy: including protons, neutrons and carbon ions.**
 - 3.3.6 Intra-operative radiation therapy/Electronic brachytherapy.**
 - 3.3.7 Brachytherapy, including low dose rate, high dose rate, and pulse dose rate, including a qualified RO and a QMP present during treatment.**
 - 3.3.8 Unsealed radioactive source, including a qualified RO and a QMP present during treatment.**
 - 3.3.9 Other techniques: including any techniques not already identified in 3.3.1-3.3.8 such as superficial, hyperthermia, microspheres, etc.**
 - 3.3.10 Imaging and motion management procedures.**



- 3.4 Patient-specific plan checks. For non-emergent cases, qualified ROP staff, under supervision of a QMP, verify the following elements:**
- 3.4.1 Treatment plan or calculation compared to treatment prescription prior to treatment implementation.**
 - 3.4.2 Independent dose check of the calculation prior to treatment implementation.**
 - 3.4.3 Patient-specific plan quality assurance (QA) prior to treatment implementation.**
- 3.5 On-treatment checks. A medical physics staff member, under the supervision of a QMP, perform periodic checks of the medical record for:**
- 3.5.1 Accuracy of treatment delivery in relation to both the formal treatment prescription and treatment plan at least every five treatment fractions.**
 - 3.5.2 Accuracy of treatment set-up parameters in relation to both the formal treatment prescription and treatment plan at least once every five treatment fractions.**
- 3.6 End-of-treatment checks.**
- 3.6.1 For each patient, a QMP performs an end-of-treatment review of the medical record within one week of the completion of treatment.**

Standard 4: Staff Roles and Responsibilities

The ROP defines the roles and responsibilities of each member of the team and consistently implements procedures according to these definitions. The team is defined as all personnel involved with patient care.

- 4.1 The ROP has a job description that list requirements for scope and responsibilities within the clinical practice, supervision requirements, certification and/or eligibility and, where applicable, state licensure.**
- 4.1.1 Radiation oncologist.**
 - 4.1.2 Medical physicist.**
 - 4.1.3 Radiation therapist.**
 - 4.1.4 Medical dosimetrist.**
 - 4.1.5 Radiation oncology nurse.**
 - 4.1.6 Non-physician providers.**
- 4.2 A designated medical director for the ROP who, in addition to the job requirements for the radiation oncologist:**
- 4.2.1 Has oversight of SOPs for the practice.**
 - 4.2.2 Is accountable for the quality of patient care.**

Standard 5: Qualifications and Ongoing Training of Staff

The ROP establishes and monitors qualifications and training requirements for all personnel to ensure initial and continuous competency in job requirements.

- 5.1 For each professional discipline, the ROP defines requirements for certification that are consistent with ASTRO's Safety is No Accident for the following:**
- 5.1.1 All radiation oncologists are certified or board eligible for the American Board of Radiology (ABR) in radiation oncology, therapeutic radiology, or equivalent certification and possess state licensure.**



- 5.1.2 All medical physicists are certified or board eligible for certification in medical physicist by the ABR, the American Board of Medical Physicist, or the Canadian College of Physicists in Medicine and possess state licensure, where applicable.
- 5.1.3 All radiation therapists are certified or board eligible for certification by the American Registry for Radiologic Technologists in therapeutic and possess state licensure, where applicable.
- 5.1.4 All medical dosimetrists are certified or board eligible for certification as a Certified Medical Dosimetrist through the Medical Dosimetrist Certification Board.
- 5.1.5 Nurses have licensures, certifications, additional experience and/or educational preparation in radiation oncology.
- 5.1.6 Nurse practitioners, clinical nurse specialists, advanced practice nurses or physician assistants have licensures, certifications, additional experience and/or educational preparation in radiation oncology.

5.2 Board eligibility requirements.

- 5.2.1 For each professional discipline, the ROP defines a process and a timeline for employed individuals who are eligible, but were not board-certified when employment commenced, to achieve that certification.**

5.3 For each professional discipline, the ROP defines the requirement for:

- 5.3.1 Primary source verification for licensure and certification, as part of initial credentialing.
- 5.3.2 Obtaining new licensure and certification during employment.
- 5.3.3 Annual compliance monitoring for each licensed/certified staff member.

5.4 New staff on-boarding.

- 5.4.1 The ROP defines and completes an initial training, orientation and job-specific competency assessment process for each new team member.**

5.5 Staff training and competency requirements include:

- 5.5.1 Annual or on-going staff training and competency assessment program for organizational procedures, including SOPs.
- 5.5.2 Annual or on-going staff training on the Health Insurance Portability and Accountability Act (HIPAA).
- 5.5.3 Initial training and competency assessment of new equipment and/or procedures before either are put into clinical use.
- 5.5.4 Staff competency assessment before they are permitted to use the treatment machine(s) without direct supervision.
- 5.5.5 Specific training, precautions and/or other requirements for patients with special needs including pediatrics, patient undergoing sedation, use of intravenous contrast and/or other special procedures.

5.6 Annual radiation training.

- 5.6.1 The ROP provides annual radiation safety training to all staff assigned radiation exposure monitors.**

5.7 Annual infection control training.

- 5.7.1 The ROP provides annual training for the infection control program.**



Standard 6: Safe Staffing Plan

The ROP establishes, measures and maintains staffing requirements for safe operations in clinical radiation therapy.

- 6.1 Staffing levels.
 - 6.1.1 The ROP's documentation of staffing requirements for each professional discipline that is derived from measurable criteria.
 - 6.1.2 The ROP specifies the number of each professional discipline required to be on-site, directly involved in patient treatment.**
 - 6.1.3 The ROP requires a qualified RO to be on-call 24 hours a day and seven days a week to address patient needs and/or emergency treatments.
 - 6.1.4 The ROP describes how it will provide coverage during planned and unplanned absences of professional staff.
- 6.2 Personnel supervision.
 - 6.2.1 The ROP identifies supervision requirements for non-certified or non-licensed personnel and assistants participating in treatment process.
- 6.3 Temporary staffing (e.g. locum tenens, per diem, etc.) process includes:
 - 6.3.1 Credentialing.
 - 6.3.2 Background checks.
 - 6.3.3 Orientation and training on the practice's SOPs.
 - 6.3.4 Successful completion of competency assessment before temporary personnel may function without direct supervision.

Standard 7: Culture of Safety

The ROP fosters a culture of safety in which all team members participate in assuring safety, the practice capitalizes on opportunities to improve safety and no reprisals are taken for staff that report safety concerns.

- 7.1 **Culture of Safety SOP:**
 - 7.1.1 **Articulates the ROPs approach to patient safety.**
 - 7.1.2 **States that all patient safety events are to be reported and tracked within the ROP.**
 - 7.1.3 **States that near misses are to be reported and tracked within the ROP.**
 - 7.1.4 **Includes a method for staff to report a safety event with an option to report anonymously.**
 - 7.1.5 **Has a timeline for reporting all patient safety events by all staff.**
 - 7.1.6 **Includes a periodic reporting back to staff on activities and findings from the Culture of Safety program.**
 - 7.1.7 **States that procedures are not started until all questions and/or concerns are resolved.**
 - 7.1.8 **Provides assurance that there will be no reprisals based on reporting of patient safety events.**
 - 7.1.9 **Identifies a method for patients to report safety events.**
- 7.2 **Culture of Safety Leadership, designated from the ROP, is responsible for:**
 - 7.2.1 **Implementing and providing leadership to the program.**
 - 7.2.2 **Collecting information and investigating patient safety events.**
 - 7.2.3 **Convening and leading the interdisciplinary safety meetings.**
 - 7.2.4 **Implementing follow-up or education after the event and investigation.**



7.3 Culture of Safety event reporting.

- 7.3.1 The ROP has a method for undertaking an immediate review, with the goal of understanding underlying factors and taking action to prevent future occurrences.**
- 7.3.2 The ROP has a method for formally reporting patient safety events that complies with institutional, state, local and national requirements.**

7.4 Culture of Safety interdisciplinary meetings:

- 7.4.1 Promote an interdisciplinary team-based approach to safety.
- 7.4.2 Review all patient safety events and unsafe condition data from patient, staff and equipment events.
- 7.4.3 Proactively assess the ROP's structure and processes that promote safety.
- 7.4.5 Develop, implement, and assess the progress of action plans to improve safety.

7.5 Patient Safety Organization (PSO).

- 7.5.1 The ROP participates with a PSO.

Standard 8: Radiation Safety

The ROP establishes safe radiation practices for all patients and staff to keep radiation exposure As Low As Reasonably Achievable (ALARA).

8.1 Facility licenses:

- 8.1.1 Complies with requirements of the Nuclear Regulatory Commission (NRC), Agreement State and/or locality.**

8.2 Personnel radiation monitoring.

- 8.2.1 The ROP utilizes radiation exposure monitoring systems for staff consistent with NRC, Agreement State or local requirements.**

8.3 Radiation surveys of the room and patient are performed pre- and post-treatment for:

- 8.3.1 Brachytherapy procedures.**
- 8.3.2 Radiopharmaceutical procedures.**

8.4 Imaging protocols for:

- 8.4.1 Simulation.
- 8.4.2 Treatment.

Standard 9: Emergency Preparation and Planning

The ROP has procedures and training for emergency contingencies that address short- and long-term patient and staff safety.

9.1 Clinical emergency procedures address:

- 9.1.1 Falls.
- 9.1.2 Cardiac events.
- 9.1.3 Threats of violence.
- 9.1.4 Anesthesia or other medication adverse reactions.
- 9.1.5 Allergic events (e.g. contrast media).



- 9.1.6 Other emergencies (e.g. fire).
 - 9.1.7 Radiation equipment failure while a patient is undergoing treatment.
 - 9.1.8 Maintaining clinical continuity.
 - 9.1.9 Evidence of annual training for staff in emergency procedures.
- 9.2 Emergency response, in which the ROP identifies and plans for emergencies or disasters based on a formal disaster analysis or other assessment and prepares for applicable potential events, including:
- 9.2.1 Power failure.
 - 9.2.2 Information system failure, with preparation and back-up plan that addresses business continuity, including data redundancy and recovery plan.
 - 9.2.3 Radioactive material release.
 - 9.2.4 External threats including natural disasters.
- 9.3 Radiation therapy emergency procedures.
- 9.3.1 The ROP follows written SOPs for treating emergency/urgent radiation therapy treatments occurring after normal working hours, including required staff, roles and responsibilities, and QA activities.
 - 9.3.2 The ROP has a process for referring patients to emergency care from radiation oncology department during operating hours and a process for addressing an emergency during non-operating hours.

Standard 10: Facility and Equipment

The ROP has the facility and equipment to support the delivery of safe, high-quality care.

- 10.1 The ROP provides radiation shielding for each radiation area that is:
- 10.1.1 Consistent with workload.
 - 10.1.2 Based on shielding calculations performed by a QMP.
 - 10.1.3 Validated with radiation surveys performed by a QMP.
 - 10.1.4 Monitored by a QMP with updates to ensure ongoing compliance when there are changes in workload, utilization and/or equipment.
- 10.2 Audio Visual (AV) equipment.**
- 10.2.1 The ROP provides functional AV patient monitoring systems in all treatment rooms.**
- 10.3 Simulation SOPs include:
- 10.3.1 Patient-specific considerations are taken into account before the simulation commences.
 - 10.3.2 Trained radiation therapists conduct the simulations according to the written directive, including a minimum requirement of CT simulation when appropriate.
 - 10.3.3 Documentation that enables the reproducibility of patient positioning and set-up during treatment.
- 10.4 ROP equipment infection control procedures for disinfection and/or sterilization of radiation oncology specific items including:**
- 10.4.1 Simulation, treatment and clinic room equipment.**
 - 10.4.2 Non-custom positioning devices and accessories.**
 - 10.4.3 Immobilization devices.**



10.5 Infection control program that includes:

- 10.5.1 Infection control risks.**
- 10.5.2 Communicable diseases.**
- 10.5.3 Handwashing.**
- 10.5.4 Personal Protection Equipment.**
- 10.5.5 Disposal of sharps.**

Standard 11: Information Management and Integration of Systems

The ROP maintains information management systems to support patient care, planning and documentation and assures safety and interoperability of the systems. Information management systems used in radiation oncology come under many different names; examples include electronic health record (EHR), treatment planning systems (TPS), treatment management systems (TMS), oncology information systems (OIS), record and verify equipment, patient positioning systems, treatment delivery systems and simulation and imaging systems.

- 11.1 Information system(s) components.
 - 11.1.1 The ROP defines and maps components of the information management system(s) that impact patient care.
- 11.2 Information system(s) management:
 - 11.2.1 Limits access to information based on the user's job function and need for that information.
 - 11.2.2 Designates authorized users for each type of system that use individualized passwords or other methods to prevent unauthorized access.
 - 11.2.3 Uses the ability to track changes made to the electronic patient records or system specifications.
- 11.3 Treatment planning system(s) QA includes:
 - 11.3.1 Acceptance testing of TPS prior to clinical use.
 - 11.3.2 Commissioning on TPS prior to clinical use and verification of beam models and TPS parameters following service of upgrades, as necessary.
 - 11.3.3 Ongoing QA of TPS.
 - 11.3.4 Verifying the fidelity of information transferred between the TPS and OIS.
- 11.4 Information system(s) training.
 - 11.4.1 The ROP ensures that staff receive training on system functionality and safety features of each information management system and combination of systems prior to clinical use.
- 11.5 Information system(s) support.
 - 11.5.1 The ROP ensures that staff have ongoing access to support for each information management system, including retraining as necessary.
- 11.6 Information system(s) safety options.
 - 11.6.1 The ROP enables software features that improve quality and/or safety.



Standard 12: Quality Management of Treatment Procedures and Modalities

The ROP operates a comprehensive quality management program and safe practices for each treatment procedure and modality.

12.1 Machine QA:

- 12.1.1 **EBRT equipment QA program(s) are consistent with AAPM, or equivalent body, guidance on dosimetry, mechanical and safety checks for daily, monthly and annual checks, including motion management equipment review.**
- 12.1.2 **Brachytherapy equipment QA program(s) are consistent with AAPM, or equivalent body, guidance on dosimetry, mechanical and safety checks during day of treatment, source exchange, and annual QA.**
- 12.1.3 Simulation equipment QA program(s) are consistent with AAPM, or equivalent body, guidance on image quality, mechanical and safety checks for daily, monthly and annual review, including motion management equipment review.
- 12.1.4 Comprehensive quality management program includes a process for performing QA activities (daily, monthly and annual) for treatment techniques/modalities that, in addition to policies and procedures, address the roles and responsibilities of staff.

12.2 Physics QA checks includes:

- 12.2.1 Acceptance testing, clinical commissioning, and clinical release of new equipment.
- 12.2.2 Annual QA of measurements equipment.
- 12.2.3 Annual end-to-end dosimetric system testing.
- 12.2.4 Routine preventative maintenance inspection.

12.3 The ROP has a process for:

- 12.3.1 Reinstating equipment for clinical use following repair, upgrade or maintenance.
- 12.3.2 Taking action on data deviation from expected findings.

12.4 The ROP's comprehensive quality management program includes a review of trend analysis on:

- 12.4.1 Machine calibration.
- 12.4.2 QA results.
- 12.4.3 Downtime.
- 12.4.4 Service Reports.

12.5 External validation of machine output:

- 12.5.1 **Prior to clinical use of new external beam equipment.**
- 12.5.2 **Annually for photons.**
- 12.5.3 **Biennially for electrons.**
- 12.5.4 **Annually for protons.**



Standard 13: Peer Review of Clinical Processes

The ROP implements a robust program to provide peer-to-peer learning that promotes continuous quality improvement in treatment practices.

13.1 The ROP defines and implements a peer review process for each professional discipline providing patient care including:

- 13.1.1 Radiation oncologist.**
- 13.1.2 Medical physicist.**
- 13.1.3 Radiation therapist.**
- 13.1.4 Dosimetrist or other staff members (e.g. nurses).**

13.2 Multidisciplinary peer review.

- 13.2.1 The ROP participates periodically in multidisciplinary review programs, such as tumor board, with other members of the patient's care team (medical oncologist, surgeon, and other specialists), either remotely or on-site.

Standard 14: Patient Consent

The ROP implements a written procedure regarding education of patients on the risks and benefits of radiation therapy treatment and includes documentation of consent for treatment.

14.1 The ROP secures informed consent by:

- 14.1.1 Providing information regarding risks and benefits of radiation therapy from the radiation oncologist.**
- 14.1.2 Obtaining consent before the simulation phase of treatment begins.**
- 14.1.3 Verifying consent is current (within 60 days prior to treatment).**
- 14.1.4 Requiring a date and signature from the patient (or authorized legal representative) and the RO (or their designee).**

14.2 Translation services.

- 14.2.1 The ROP has a process for communication with patients who do not speak English fluently or have other communication barriers.

Standard 15: Patient Education and Patient Health Management

The ROP educates the patient regarding radiation therapy and assists the patient in managing side effects.

15.1 Frequency of patient education.

- 15.1.1 The ROP staff reviews treatment related side effects with the patient before treatment begins and at least one time during the course of treatment.

15.2 Patient Education includes:

- 15.2.1 Options for treatment and the rationale for each option (e.g. surgical, chemotherapy, or choices of radiation modality/techniques).
- 15.2.2 Intent of treatment (curative/palliative).
- 15.2.3 What to expect during the treatment process.
- 15.2.4 Management of treatment related side effects (e.g. skin care, nutrition support, and other side-effects suitable for self-care), as applicable.



- 15.3 Financial Cost of treatment.
 - 15.3.1 The ROP offers information on the cost of treatment to patients, including an assessment of the financial toxicity related to costs.
- 15.4 Education materials.
 - 15.4.1 The ROP provides written or online materials in addition to verbal communication to educate patients.
- 15.5 The ROP offers patient referrals to:
 - 15.5.1 Therapeutic interventions to assist the patient.
 - 15.5.2 Specialized radiation therapy and/or techniques not provided by the ROP.

Standard 16: Performance Measurement and Outcomes Reporting

The ROP measures and evaluates the patient experience and takes actions to improve performance.

- 16.1 The patient experience is:
 - 16.1.1 Measured and evaluated, at least annually, using a survey and/or other tools.
- 16.2 Patient complaints are:
 - 16.2.1 Accepted.
 - 16.2.2 Evaluated and responded to.