



APEX® Program Standards

The following standards are the basis of the APEX program.

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 by the radiation oncologist prior to initiation of treatment that includes documentation of:

1.1.1 Patient history including, as applicable: current medications, implantable cardiac device, pregnancy status, allergies, and previous radiation therapy history.

1.1.2 Review of systems.

1.1.3 Physical examination findings.

1.1.4 Pathology review.

1.1.5 Staging or documentation of metastatic disease.

1.1.6 Laboratory findings.

1.1.7 Imaging studies.

1.1.8 Pain assessment including, as applicable: pain intensity assessment and pain management plan.

1.1.9 Recommendation for care (initial plan).

1.1.10 Physician's signature and date.

1.2 During treatment the physician conducts and documents direct patient evaluation at least once every five patient treatments, which includes:

1.2.1 Review of cumulative interim dose delivered.

1.2.2 Patient examination.

1.2.3 Assessment of tolerance to treatment and, as appropriate, patient reported subjective and physician reported objective assessments of disease response to treatment.

1.2.4 Pain assessment including, as applicable: pain intensity assessment and pain management plan.

1.2.5 Physician's signature and date.

1.3 A documented post-treatment summary by the radiation oncologist that includes the following information:

1.3.1 Site of treatment.

1.3.2 Dose per fraction.

1.3.3 Cumulative 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, as appropriate, patient reported subjective and physician reported objective assessments 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 Physician's signature and date within two weeks of the patient's completion of care.
- 1.4 Coordination of care and communication of information
- 1.4.1 Following the initial patient evaluation, ROP transmits a copy of the comprehensive patient evaluation (Evidence Indicator 1.1) to other involved providers (including the referring provider and primary care provider) within four weeks.
 - 1.4.2 Following treatment completion, the ROP transmits a copy of the post-treatment summary (Evidence Indicator 1.3) to other involved providers (including the referring provider and primary care provider) within four weeks.
 - 1.4.3 The ROP participates periodically in multidisciplinary review programs (such as a Tumor Board), with other members of the patient's care team (medical oncologist, surgeon and other specialists), either remotely or on-site.
- 1.5 Patient follow-up:
- 1.5.1 Occurs within four months of treatment completion.

Standard 2: Treatment Planning

The radiation oncology practice uses a written treatment planning directive resulting in a patient-specific treatment plan.

The planning process:

- 2.1 Is based on data from a simulation procedure that:
 - 2.1.1 Is conducted according to the written simulation direction of a radiation oncologist.
 - 2.1.2 Includes documentation of factors that impact reproducibility including: patient positioning, patient immobilization devices and verification of accurate information transfer from simulation machines to treatment planning systems.
- 2.2 Is based on a documented, patient-specific planning directive that:
 - 2.2.1 Guides treatment planning staff and defines target and normal tissue volume goals.
- 2.3 Culminates in a formal treatment prescription and plan that includes the physician's order for the following elements of radiation therapy:**
 - 2.3.1 Anatomic treatment site.**
 - 2.3.2 Type and method of radiation treatment delivery.**
 - 2.3.3 Energy.**

- 2.3.4 Total dose.**
- 2.3.5 Dose per fraction.**
- 2.3.6 Number of fractions.**
- 2.3.7 Frequency of treatment.**
- 2.3.8 Imaging guidance.**
- 2.3.9 Physician 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 to ensure patient safety and consistent high-quality care prior to and during radiation therapy.

3.1 The ROP verifies patient identity:

3.1.1 For each patient, at each point in which patient-specific information is transferred from one information system to another, using two patient-specific identifiers.

3.2 For each patient, a time out is performed prior to all procedures, including all treatments, to conduct patient-specific quality and safety checks evidenced by documentation of:

3.2.1 Verification of patient identity using at least two patient-specific identifiers.

3.2.2 Verification of patient treatment site.

3.2.3 Verification of correct patient positioning for external beam radiation therapy (EBRT).

3.2.4 Verification of treatment delivery parameters against the approved prescription and plan.

3.3 For each patient:

3.3.1 A medical physicist performs an end-of-treatment review of the medical record within one week of the completion of therapy.

3.4 The ROP follows written standard operating procedures for each treatment modality that address the number of each professional discipline required, roles, responsibilities and QA activities, imaging and motion management(as applicable) in the use of:

3.4.1 External Beam Radiation Therapy (EBRT), including 2-D, 3-D and 4D.

3.4.2 Intensity Modulated Radiation Therapy (IMRT).

3.4.3 Stereotactic Radiosurgery (SRS).

3.4.4 Stereotactic Body Radiation Therapy (SBRT).

3.4.5 Particle beam therapy; including protons, neutrons and carbons.

3.4.6 Intraoperative Radiation Therapy (IORT).

3.4.7 Brachytherapy; including HDR, LDR and electronic.

3.4.8 Unsealed radioactive sources.

3.4.9 All other radiation therapy procedures not already identified in 3.4.1-

3.4.8

3.5 For non-emergency cases, a qualified medical physicist verifies the following elements before treatment implementation and when changes are made to the plan:

3.5.1 Treatment plan compared to treatment prescription.

3.5.2 Dosimetric results.

3.5.3 IMRT quality assurance.

3.6 A qualified medical physicist performs periodic checks of:

3.6.1 The accuracy of treatment delivery in relation to both the formal treatment prescription and plan at least every five treatment fractions.

3.6.2 The accuracy of treatment set up parameters in relation to both the formal treatment prescription and plan at least once every five treatment fractions.

Standard 4: Staff Roles and Accountabilities

The radiation oncology practice defines the roles and responsibilities of each member of the team and consistently implements procedures according to these definitions.

The ROP has:

4.1 Job descriptions that define scope of practice.

4.1.1 For each professional discipline involved in patient care, job descriptions that are consistent with professional standards applicable to the individual.

4.2 A designated Medical Director for the radiation oncology practice who is board certified or board eligible in radiation oncology and:

4.2.1 Has oversight of standard operating procedures for the practice.

4.2.2 Is accountable for quality of patient care.

Standard 5: Qualifications and Ongoing Training of Staff

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

For each professional discipline the ROP defines:

5.1 Requirements for certification, that are consistent with ASTRO's "Safety is No Accident" for the following:

5.1.1 All radiation oncologists possess state licensure and possess or are eligible for American Board of Radiology (ABR) certification in radiation oncology, therapeutic radiology, or equivalent certification.

- 5.1.2 All medical physicists possess state licensure, where applicable, and possess or are eligible for certification in Therapeutic Medical Physics by The American Board of Radiology, The American Board of Medical Physics, or The Canadian College of Physicists in Medicine.
 - 5.1.3 All radiation therapists possess or are eligible for certification as American Registry of Radiologic Technologists (ARRT) in radiation therapy and, where applicable, state licensure.
 - 5.1.4 All medical dosimetrists possess or are eligible for certification as a Qualified Medical Dosimetrist through the Medical Dosimetrist Certification Board (MDCB).
 - 5.1.5 Nurses have licensure, certificates, additional experience and/or educational preparation in radiation oncology.
 - 5.1.6 Nurse practitioners, clinical nurse specialists, advanced practice nurses, physician assistants and other non-physician providers have licensure, certificates, additional experience and/or educational preparation in radiation oncology.
- 5.2 A process and timeline:**
- 5.2.1 For individuals who are eligible but not currently certified to achieve certification that is consistent with the requirements of Evidence Indicator 5.1.**
- 5.3 Requirements for obtaining and maintaining appropriate credentials.
- 5.3.1 Maintaining licensure, obtaining new certifications and maintaining certification on an ongoing basis for each professional discipline.
- 5.4 A process for initial credentialing:
- 5.4.1 Of licensed or certified personnel that includes primary source verification for each professional discipline.
- 5.5 A process for license and certification monitoring of:
- 5.5.1 Annual compliance of licensed and/or certified personnel.
- 5.6 A process for onboarding staff that includes:**
- 5.6.1 Initial training, orientation and job-specific competency testing process for each team member.**
- 5.7 Implements an on-going staff training and competency testing program that includes:
- 5.7.1 Annual staff training and successful completion of competency testing for organizational procedures, including standard operating procedures, infection control, radiation safety and Health Insurance Portability and Accountability Act (HIPAA).
 - 5.7.2 Training and successful completion of competency testing for new equipment and/or procedures before either are put into clinical use.
 - 5.7.3 Training of staff with direct responsibilities on the use of treatment machines and completion of successful competency testing before staff are permitted to use the treatment machine(s) without direct supervision.
 - 5.7.4 Address specific training, precautions and/or other requirements for patients with special needs including pediatrics, patients undergoing conscious sedation, use of intravenous contrast and/or other special procedures.

Standard 6: Safe Staffing Plan

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

The ROP identifies:

- 6.1 Staffing requirements for each professional discipline that:
 - 6.1.1 Are derived from measurable criteria.
 - 6.1.2 Specify the number of each professional discipline required to be on-site, directly involved in patient treatment (including at least two radiation therapists per patient when external beam radiation therapy is being delivered) or available remotely during operating and non-operating hours.
 - 6.1.3 Describe how the practice will provide coverage during planned and unplanned absences of professional staff.
- 6.2 Requirements for supervision of:
 - 6.2.1 Non-certified or non-licensed personnel and assistants participating in treatment processes.
- 6.3 Requirements of availability of:
 - 6.3.1 A qualified radiation oncologist on-call 24 hours a day, seven days a week to address patient needs and/or emergency treatments.
- 6.4 The process for referring patients to emergency care:
 - 6.4.1 During both operating and non-operating hours.
- 6.5 The process for the use of temporary personnel (locum tenens) that includes:
 - 6.5.1 Credentialing, background checks, orientation and training on the ROP's standard operating procedures and successful completion of competency testing before the temporary personnel is allowed to function without direct supervision within the ROP.

Standard 7: Culture of Safety

The radiation oncology practice 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.

The ROP:

- 7.1 Has a policy on patient safety that:**
 - 7.1.1 Articulates the practice's approach to patient safety.**
 - 7.1.2 Specifies that patient safety events, including patient safety incidents and near misses, are to be reported and tracked within the practice.**
 - 7.1.3 Identifies methods for staff to report patient safety events and unsafe conditions, including a method for staff to report anonymously.**
 - 7.1.4 Encourages timely reporting of patient safety events and unsafe conditions by all staff.**
 - 7.1.5 Specifies periodic reporting back to staff on activities and findings of the culture of safety program.**
 - 7.1.6 Specifies that procedures are not started until all questions and/or concerns are resolved.**
 - 7.1.7 Provides assurances that there will be no reprisals based on reporting of patient safety events and unsafe conditions.**

- 7.1.8 Identifies a role for patients in the culture of safety program.**
- 7.1.9 Designates an accountable individual from the practice leadership who is:**
 - 7.1.9a Responsible for implementing the requirements of Standard 7, which states that 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.**
 - 7.1.9b Responsible for collection of information and investigation of patient safety events and unsafe conditions.**
 - 7.1.9c The lead on convening Interdisciplinary Safety Rounds.**
 - 7.1.9d Evaluated in part for providing leadership to the practice's culture of safety program.**
- 7.2 Conducts Interdisciplinary Safety Rounds at least quarterly to:
 - 7.2.1 Promote a team-based approach to safety.
 - 7.2.2 Review all patient safety event and unsafe condition data from patients, staff and equipment.
 - 7.2.3 Proactively assess the ROP's structure and processes that promote safety.
 - 7.2.4 Develop, implement and assess progress of action plans to improve safety.
- 7.3 If a patient safety incident occurs, the ROP:
 - 7.4.1 Undertakes an immediate review, with the goal of understanding underlying factors and taking action to prevent future occurrence.
 - 7.4.2 Complies with institutional, state, local and national requirements for reportable patient safety incidents.
- 7.4 Reports to and participates in:
 - 7.4.1 A Patient Safety Organization (PSO).

Standard 8: Radiation Safety

The radiation oncology practice establishes safe radiation practices for all patients and staff.

- 8.1 The ROP complies with requirements of:**
 - 8.1.1 The Nuclear Regulatory Commission (NRC), Agreement State and/or locality.**
- 8.2 The ROP utilizes:**
 - 8.2.1 A radiation exposure monitoring system for staff consistent with NRC, Agreement State or local requirements.**
- 8.3 The ROP provides:**
 - 8.3.1 Annual radiation safety training to all staff.**
- 8.4 The ROP conducts:**
 - 8.4.1 Radiation surveys pre- and post-treatment for brachytherapy and radiopharmaceutical procedures.**
- 8.5 The ROP utilizes:
 - 8.5.1 Imaging protocols for simulation and treatment to reduce unnecessary radiation

dose to patients.

Standard 9: Emergency Preparation and Planning

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

9.1 The ROP has a written plan for emergencies that pose an immediate threat to patient safety, that addresses:

9.1.1 Patient clinical emergencies such as falls, cardiac events, threats of violence, anesthesia events, allergic events or other emergencies.

9.1.2 Radiation equipment failure while a patient is undergoing treatment.

9.1.3 Clinical continuity.

9.1.4 Evidence of annual training for staff in emergency procedures.

9.2 The ROP identifies and plans for other emergencies or disasters based on a formal disaster analysis or other assessment and prepares for applicable potential events:

9.2.1 Power failure.

9.2.2 Information system failure, with preparation and a 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.

Standard 10: Facility and Equipment

The radiation oncology practice has a facility and equipment to support the delivery of safe, high quality care.

The ROP:

10.1 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 qualified medical physicist.

10.1.3 Validated with radiation surveys performed by a qualified medical physicist.

10.1.4 Monitored by a qualified medical physicist with updates to ensure ongoing compliance when there are changes in workload, utilization and/or equipment.

10.2 Provides monitoring though:

10.2.1 **Functional video and audio patient monitoring systems in all treatment rooms.**

10.3 Performs radiation therapy simulations including, at a minimum, CT simulation and ensures that:

10.3.1 Simulations enable reproducibility of patient positioning during treatment.

10.3.2 Trained radiation therapists conduct the simulations.

10.3.3 Patient-specific considerations are taken into account before simulation begins.

10.4 Has an infection control program that:

10.4.1 Includes procedures for equipment, devices and individuals.

10.4.2 Contains procedures that address infection control risk, communicable disease, sterilization of devices and equipment, hand washing, and disinfection of immobilization devices.

10.4.3 Includes staff training on infection control.

Standard 11: Information Management and Integration of Systems

The radiation oncology practice maintains information management systems to support patient care, planning and documentation, and assures safety and interoperability of the systems.

The ROP:

11.1 Defines and maps:

11.1.1 Components of the information management system that impact patient care.

11.2 Designates authorized users for each type of system that:

11.2.1 Limits access to information based on the user's job function and need for that information.

11.2.2 Uses individualized passwords or other methods to prevent unauthorized access.

11.2.3 Have the ability to track changes made to electronic patient records or system specifications.

11.3 Conducts a quality assurance program for each information management system and combination of systems, including:

11.3.1 System acceptance testing prior to clinical use.

11.3.2 Commissioning prior to clinical use and re-commissioning as necessary.

11.3.3 Ongoing quality assurance of information system performance.

11.3.4 Verifying the fidelity of information transferred between systems.

11.4 Ensures, prior to clinical use, that:

11.4.1 Staff receive training on system functionality and safety features of each information management system and combination of systems.

11.5 Ensures information management system support.

11.5.1 Staff have ongoing access to support for each information management system, including retraining as necessary.

11.6 Enables information management support improvement.

11.6.1 Optional software features that improve quality and/or safety.

Standard 12: Quality Management of Treatment Procedures and Modalities

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

The ROP's comprehensive quality management program for each treatment procedure and modality:

12.1 Is consistent with American Association of Physicists in Medicine (AAPM) or equivalent body standards of practice for:

12.1.1 External beam radiation therapy dosimetry, mechanical, safety and respiratory management checks.

12.1.2 Brachytherapy dosimetry, mechanical and safety checks.

12.1.3 Quality assurance of measurement equipment.

12.1.4 Acceptance testing, clinical commissioning and clinical release.

12.1.5 End to end dosimetric system testing.

12.1.6 Simulation dosimetry, mechanical, safety and respiratory management checks.

12.2 Includes processes for maintaining systems.

12.2.1 Routine Preventive Maintenance Inspection (PMI) of mechanical, electronic and software systems.

12.2.2 Reinstating clinical use status of mechanical, electronic and software systems following repair, upgrade or maintenance.

12.2.3 Taking action on data that deviates from expected findings.

12.3 Maintains and reviews records and trend analysis on machine calibrations, quality assurance results, down time and service reports.

12.4 Includes external validation of machine output accuracy:

12.4.1 Prior to clinical use.

12.4.2 At least annually thereafter for photons and protons, and every two years for electrons.

Standard 13: Peer Review of Clinical Processes

The radiation oncology practice implements a robust program to provide peer to peer learning that promotes continuous quality improvement in treatment practices.

The ROP:

13.1 Defines and implements a process for prospective, concurrent or retrospective peer review for each professional discipline providing patient care that specifies:

13.1.1 Objectives for peer to peer review.

13.1.2 Frequency of peer review activities.

13.1.3 The number, type and frequency of cases for peer review.

13.1.4 How the information obtained from peer review will be used for professional feedback and future learning.

Standard 14: Patient Consent

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

The ROP:

14.1 Secures informed patient consent by:

14.1.1 Providing information regarding risks and benefits of radiation therapy.

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 of the radiation oncologist.

14.2 Addresses a process for communication with patients:

14.2.1 Who do not speak English fluently or who have other communications barriers.

Standard 15: Patient Education and Patient Health Management

The radiation oncology practice educates the patient and assists the patient in managing side effects.

The ROP:

15.1 Assesses patient education needs for:

15.1.1 Self-management of treatment-related side effects before treatment begins and at least one time during the course of treatment.

15.2 Educates patients on:

15.2.1 Options for treatment and the rationale for each option (for example, surgical, chemotherapy or choices of radiation modality).

15.2.2 Intent of treatment (curative / palliative) and what to expect in the treatment process.

15.2.3 Management of treatment-related side effects involving pain, skin care, weight loss (need for nutrition support) and other side effects suitable for self-care, as necessary.

15.2.4 The cost of treatment, on request.

15.3 Uses:

15.3.1 Written or online materials in addition to verbal communication to educate patients.

15.4 Provides:

15.4.1 Therapeutic interventions to manage treatment-related side effects.

15.5 Has a patient referral process for:

15.5.1 Specialized radiation therapy and/or other services not provided by the ROP.

Standard 16: Performance Measurement and Outcomes Reporting

The radiation oncology practice measures and evaluates the patient experience and takes actions to improve performance.

The ROP:

16.1 Measures and evaluates, at least annually:

16.1.1 The patient experience using a survey and/or other tools.

16.2 Response to patient complaints.

16.2.1 Accepts patient complaints.

16.2.2 Evaluates and responds to patient complaints.