

ASTRO'S APEX -  
ACCREDITATION PROGRAM FOR EXCELLENCE®



# APEX® Standards Guide

## **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, including any patient interaction prior to simulation/pre-treatment activities, should include documentation of the following elements:**

- 1.1.1 Patient history.
- 1.1.2 Cardiac implantable electronic device status.
- 1.1.3 Pregnancy status.
- 1.1.4 Allergies, including to contrast.
- 1.1.5 Prior radiation therapy.
- 1.1.6 Physical examination findings.
- 1.1.7 Diagnostic information (e.g., labs, pathology, imaging studies).
- 1.1.8 Staging or documentation of metastatic disease, when applicable.
- 1.1.9 Pain quantification.
- 1.1.10 Pain management plan, when applicable.
- 1.1.11 Initial plan or recommendation of care.
- 1.1.12 Discussion of patient treatment goals.
- 1.1.13 Radiation oncologist's signature and date.

### **1.2 Patient-specific documentation of prior radiation therapy includes the following elements:**

- 1.2.1 Anatomic treatment site; including laterality, where applicable.
- 1.2.2 Cumulative target dose.
- 1.2.3 Dates of treatment.

### **1.3 The ROP's policy on sending prior radiation treatment details to new providers on request includes:**

- 1.3.1 A process for transmitting prior radiation treatment details.
- 1.3.2 A timeline for transmitting prior radiation treatment details.

### **1.4 The radiation oncologist performs a direct patient evaluation as part of on-treatment management occurring at least once every five treatments, and includes documentation of the following elements:**

- 1.4.1 Review of cumulative interim dose delivered to date.
- 1.4.2 Patient assessment (physical, social, etc.)
- 1.4.3 Radiation oncologist's signature and date.

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

- 1.5.1 Site of treatment (including laterality, as appropriate).
- 1.5.2 Treatment modality/technique.
- 1.5.3 Dose per fraction or number of fractions.
- 1.5.4 Cumulative total dose to target(s).
- 1.5.5 Treatment date range.
- 1.5.6 Treatment tolerance and, if appropriate, disease response to treatment.
- 1.5.7 Concurrent systemic therapy.
- 1.5.8 Pain management plan for patients with unresolved pain.
- 1.5.9 Follow-up plan.
- 1.5.10 Radiation oncologist's signature and date within one month of the patient's completion of care.

**1.6 The ROP supports care coordination by transmitting necessary documents to other providers, as appropriate, including:**

- 1.6.1 The comprehensive patient evaluation within one month of the initial consultation.
- 1.6.2 The post-treatment summary within one month of treatment completion.

**1.7 Post-treatment care coordination.**

- 1.7.1 Patient follow-up occurs within four months of treatment completion.

## Standard 2: Treatment Planning

Pre-treatment processes are performed and documented during simulation and treatment planning. The ROP uses written notes and directives resulting in patient-specific treatment plans and calculations.

**2.1 The simulation (or pre-treatment) process:**

- 2.1.1 Is conducted according to a written directive/ order from a radiation oncologist.
- 2.1.2 Includes documentation of patient positioning and immobilization device(s) information.
- 2.1.3 Includes documentation of localization information.
- 2.1.4 Includes documentation that the planning staff verified 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(s) goals and normal tissue constraints.

**2.3 A formal treatment prescription includes the following elements:**

- 2.3.1 Anatomic treatment site; including laterality where applicable.
- 2.3.2 Treatment modality/technique.
- 2.3.3 Energy or radioisotope used.
- 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 Normalization/calculation method.
- 2.3.9 Imaging guidance.
- 2.3.10 Radiation oncologist's (or authorized user's) signature and date before initiation of treatment.

**2.4 A patient-specific treatment plan or calculation includes the following elements to align with the prescription:**

- 2.4.1 Anatomic treatment site; including laterality where applicable.
- 2.4.2 Treatment modality and technique.
- 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) (e.g., DVH, isodose distribution).
- 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 at each point in which patient-specific information is electronically transferred from one information system to another or when manually entered.
- 3.1.2 Verifying the patient identity using two patient-specific identifiers.

### 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 correct treatment.

### 3.3 The ROP has comprehensive SOPs for all appropriate techniques and modalities, including:

- 3.3.1 Simulation.
- 3.3.2 External beam radiation therapy (EBRT), including 2-D, 3-D, and 4-D; photons, electrons, Intensity-modulated radiation therapy (IMRT), and volumetric modulated arc therapy (VMAT).
- 3.3.3 Stereotactic radiosurgery (SRS).
- 3.3.4 Stereotactic body radiation therapy/ Stereotactic ablative radiotherapy (SBRT/SAbR).
- 3.3.5 Particle beam therapy, including protons, neutrons and carbon ions.
- 3.3.6 Intra-operative radiation therapy/Electronic brachytherapy (IORT).
- 3.3.7 High dose rate brachytherapy (HDR).
- 3.3.8 Low dose rate brachytherapy (LDR).
- 3.3.9 Radiopharmaceutical therapy (RPT).
- 3.3.10 Microspheres.
- 3.3.11 Hyperthermia.
- 3.3.12 Superficial radiation, including orthovoltage.
- 3.3.13 IGRT/SGRT.
- 3.3.14 Motion management.
- 3.3.15 Emergent radiation therapy.
- 3.3.16 EBRT for patients with cardiac implanted electronic devices (CIED).

### 3.4 Patient-specific plan checks. For non-emergent cases, qualified ROP staff verify the following elements:

- 3.4.1 A physics check of the treatment plan/calculation completed before treatment commences.
- 3.4.2 A physics check of the treatment plan/calculation completed if a replan was required during the course of treatment.
- 3.4.3 Independent check of the dose/time/MU before treatment commences.
- 3.4.4 Independent check of the dose/time/MU completed if a replan was required during the course of treatment.
- 3.4.5 Patient-specific plan QA completed before treatment commences.
- 3.4.6 Patient-specific plan QA completed if a replan was required during the course of treatment.

### 3.5 On-treatment checks.

- 3.5.1 A medical physics staff member performs periodic checks of the medical record at least every five 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 treatment completion.

## 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, board 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.
- 4.1.7 Therapist and physicist assistants.
- 4.1.8 Practice Manager/Administrator.
- 4.1.9 Radiation Safety Officer.

### 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:

- 5.1.1 A process for individuals who are eligible, but were not board-certified when employment commenced, to achieve that certification.
- 5.1.2 A timeline for individuals who are eligible, but were not board-certified when employment commenced, to achieve that certification.

### 5.2 For each professional discipline, the ROP defines the requirement for:

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

### 5.3 Staff on-boarding.

- 5.3.1 The ROP defines and completes an initial training, orientation and job-specific competency assessment process for each new team member.
- 5.3.2 Staff awareness of, and access to, organization procedures, including SOPs.
- 5.3.3 Initial training and competency assessment of new equipment and/or procedures before either are put into clinical use.
- 5.3.4 Staff competency assessment before they are permitted to use the treatment machine(s) without direct supervision.
- 5.3.5 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.

### 5.4 Staff training requirements include:

- 5.4.1 Annual radiation safety training to all staff assigned radiation exposure monitors.
- 5.4.2 Annual training for the infection control program.
- 5.4.3 Annual training for staff in emergency procedures
- 5.4.4 Annual or ongoing staff training on the Health Insurance Portability and Accountability Act (HIPAA).

## 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 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/7days a week a week to address patient needs and/or emergency treatments.
- 6.1.4 The ROP has a process for providing coverage during planned and unplanned absences of professional staff.
- 6.1.5 The ROP requires at least two radiation therapists per patient when non-emergent external beam radiation therapy is being delivered.

### 6.2 Temporary staffing (e.g., locum tenens, per diem, etc.) process includes:

- 6.2.1 Credentialing.
- 6.2.2 Background checks.
- 6.2.3 Orientation and training on the practice's SOPs.
- 6.2.4 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 States that all patient safety events, including near misses, are to be reported and tracked within the ROP.
- 7.1.2 Includes a method for staff to report a safety event that encompasses reporting that is compliant with institutional, state, local and national requirements.
- 7.1.3 Includes an option for staff to report anonymously.
- 7.1.4 Has a timeline for reporting all patient safety events by all staff.
- 7.1.5 States that procedures are not started until all questions and/or concerns are resolved.
- 7.1.6 Provides assurance that there will be no reprisals based on reporting of patient safety events.
- 7.1.7 Identifies a method for patients to report safety events.
- 7.1.8 Includes a method for undertaking an immediate review of safety events, with the goal of understanding underlying factors and taking action to prevent future occurrences.

### 7.2 Designated Culture of Safety Leadership is responsible for:

- 7.2.1 Collecting and investigating reported events.
- 7.2.2 Convening interdisciplinary safety meetings to report back to staff on activities and findings.

### 7.3 Culture of Safety interdisciplinary meetings:

- 7.3.1 Promote an interdisciplinary team-based approach to safety.
- 7.3.2 Review all patient safety events and unsafe condition data from patient, staff and equipment events.
- 7.3.3 Proactively assess the ROP's structure and processes that promote safety.
- 7.3.4 Assess the progress of action plans to improve safety.

## 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 Comply with regulatory requirements for the use of linear accelerators.
- 8.1.2 Comply with regulatory requirements for the use of radioactive sources.

### 8.2 Personnel radiation monitoring.

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

### 8.3 The ROP has brachytherapy and radiopharmaceutical processes defining the safe storage, handling and waste for radioactive materials, including:

- 8.3.1 Safe receipt of radioactive materials, including specific area.
- 8.3.2 Appropriate labeling, inventory, theft reporting.
- 8.3.3 Appropriate area and signage for radioactive material storage.
- 8.3.4 Appropriate patient areas for treatment delivery.
- 8.3.5 Safe disposal following local, state and federal requirements.
- 8.3.6 Radioactive material release (e.g., lost sources, spills).

### 8.4 Radiation surveys.

- 8.4.1 Pre-treatment surveys are conducted on the patient and room.
- 8.4.2 Post-treatment surveys are conducted on the patient and room.
- 8.4.3 Surveys are conducted using properly calibrated survey meters.

## 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 Emergency response, in which the ROP identifies and plans for equipment and facility related emergencies, including:

- 9.1.1 Power failure.
- 9.1.2 Information system failure.
- 9.1.3 Radiation equipment failure while patient is undergoing treatment.
- 9.1.4 Natural disasters and other external threats.
- 9.1.5 Clinical continuity.

### 9.2 Emergency response, in which the ROP identifies and plans for patient-related emergencies, including:

- 9.2.1 Falls.
- 9.2.2 Threats of violence.
- 9.2.3 Allergic events (e.g., contrast media).
- 9.2.4 Cardiac event.
- 9.2.5 Referring patients to the emergency room during operating hours.
- 9.2.6 Referring patients for emergency care after 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 Based on shielding calculations performed by a QMP.
- 10.1.2 Verified annually against current workload.
- 10.1.3 Validated with radiation surveys performed by a QMP.

## **10.2 Audio Visual (AV) equipment.**

- 10.2.1 The ROP has functional AV patient monitoring systems in all treatment rooms.
- 10.2.2 The ROP has functional indicator lights for treatment rooms.

## **10.3 ROP equipment infection control procedures for disinfection and/or sterilization of radiation oncology specific items including:**

- 10.3.1 Simulation, treatment and clinic room equipment.
- 10.3.2 Non-custom positioning devices and accessories.
- 10.3.3 Immobilization devices.

## **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) management:**

- 11.1.1 Limits access to information based on the user's job function and need for that information.
- 11.1.2 Designates authorized users for each type of system that use individualized passwords or other methods to prevent unauthorized access.
- 11.1.3 Uses the ability to track changes made to the electronic patient records or system specifications.

### **11.2 Treatment planning system(s) QA includes:**

- 11.2.1 Commissioning on TPS prior to clinical use.
- 11.2.2 Verification of beam models and TPS parameters following service of upgrades, as necessary.
- 11.2.3 Ongoing QA of TPS.

## **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 Linac QA program(s) are consistent with AAPM, or equivalent body, guidance on dosimetry, mechanical, safety and motion management checks for:**

- 12.1.1 Daily QA.
- 12.1.2 Monthly QA.
- 12.1.3 Annual QA.

### **12.2 Non-linac-based treatment equipment QA program(s) are consistent with AAPM, or equivalent body, guidance on checks during:**

- 12.2.1 HDR day of treatment.
- 12.2.2 HDR source exchange.
- 12.2.3 HDR annual.
- 12.2.4 LDR day of treatment.
- 12.2.5 IORT day of treatment.
- 12.2.6 IORT monthly.
- 12.2.7 IORT annual.
- 12.2.8 Radiopharmaceutical day of treatment.
- 12.2.9 Microspheres.
- 12.2.10 Hyperthermia.
- 12.2.11 Superficial daily.
- 12.2.12 Superficial monthly.
- 12.2.13 Superficial annual.



**12.3 Simulation equipment QA program(s) are consistent with AAPM, or equivalent body, guidance on image quality, mechanical, safety and motion management checks for:**

- 12.3.1 Daily QA.
- 12.3.2 Monthly QA.
- 12.3.3 Annual QA.

**12.4 External validation of machine output is performed:**

- 12.4.1 Prior to clinical use of new external beam equipment.
- 12.4.2 Annually for photons.
- 12.4.3 Biennially for electrons.
- 12.4.4 Annually for protons.

**12.5 Equipment QA checks:**

- 12.5.1 Acceptance testing.
- 12.5.2 Clinical commissioning and release of new equipment.
- 12.5.3 Annual QA of measurement equipment.
- 12.5.4 Annual end-to-end dosimetric system testing.
- 12.5.5 Routine preventative maintenance inspections.
- 12.5.6 Routine QA of secondary check programs.

**12.6 The ROP has a process for:**

- 12.6.1 Reinstating equipment for clinical use following repair, upgrade or maintenance.

## 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, either remotely or on site.

## Standard 14: Patient Education and Health Management

The ROP implements written procedures regarding patient management, including informed patient consent, patient education and acting upon patient experience feedback.

**14.1 The ROP secures informed consent by:**

- 14.1.1 Providing information regarding risks and benefits of the procedure.
- 14.1.2 Obtaining consent before the simulation phase of treatment begins.
- 14.1.3 Verifying consent is current.
- 14.1.4 Requiring a date and signature from the patient and the radiation oncologist or designee.

**14.2 Translation services.**

- 14.2.1 The ROP has a process for communicating with patients who have language barriers.
- 14.2.2 The ROP has a process for communicating with patients who have communication barriers other than language.

**14.3 Patient education.**

- 14.3.1 The ROP staff reviews treatment related side effects with the patient before treatment begins and at least one time during the course of treatment.
- 14.3.2 Patient education includes options for treatment and the rationale for each option (e.g., surgical, chemotherapy, or choices of radiation modality/techniques).
- 14.3.3 Patient education includes intent of treatment (curative/palliative).
- 14.3.4 Patient education includes what to expect during the treatment process.
- 14.3.5 Patient education includes management of treatment related side effects, as applicable.

**14.4 Education materials.**

- 14.4.1 The ROP provides written or online materials in addition to verbal communication to educate patients.

**14.5 Financial Cost of treatment.**

- 14.5.1 The ROP offers information on the cost of treatment to patients, including an assessment of the financial toxicity related to costs.

**14.6 The ROP offers patient referrals to:**

- 14.6.1 Supportive care to assist the patient.
- 14.6.2 Specialized radiation therapy and/or techniques not provided by the ROP.

**14.7 The patient experience is:**

- 14.7.1 Collected, at least annually, using a survey and/or other tools.
- 14.7.2 Evaluated and acted upon to improve patient experience.