



# Safety is No Accident

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A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY CARE

DEVELOPED AND SPONSORED BY

ASTRO



Safety  
is

# No Accident

A FRAMEWORK FOR QUALITY  
RADIATION ONCOLOGY CARE

**DEVELOPED AND SPONSORED BY:**

American Society for Radiation Oncology (ASTRO)

**ENDORSED BY:**

American Association of Medical Dosimetrists (AAMD)

American Association of Physicists in Medicine (AAPM)

American Board of Radiology (ABR)

American Brachytherapy Society (ABS)

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American Radium Society (ARS)

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Society for Radiation Oncology Administrators (SROA)



The content in this publication is current as of the publication date. The information and opinions provided in the book are based on current and accessible evidence and consensus in the radiation oncology community. However, no such guide can be all-inclusive, and, especially given the evolving environment in which we practice, the recommendations and information provided in the book are subject to change and are intended to be updated over time.

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# Acknowledgements

Safety is No Accident was first issued in 2012. The [first edition of this book](#) was based on an intersociety meeting where various representatives of sister radiation oncology societies came together to draft these safety recommendations. At the time, it was noted that technologic advances and systemic changes in health care delivery meant that the field of radiation oncology and its processes of care are in continuous evolution. These changes must be reflected in this framework so timely review and revision was envisioned.

In 2017, an effort to update the recommendations began by ASTRO's Multidisciplinary Quality Assurance Committee (MDQA) that includes physicians, physicists, and other members of the radiation oncology team.

## **A special thank you to the following MDQA members:**

**Phillip Beron, MD, University of California, Los Angeles**  
**Joseph Bovi, MD, Medical College of Wisconsin**  
**Bonnie Bresnahan, RT, Anne Arundel Medical Center**  
**Derek Brown, PhD, University of California, San Diego**  
**Bhisham Chera, MD, University of North Carolina**  
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**Gary Gustafson, MD, William Beaumont Hospital**  
**Mark Hurwitz, MD, Thomas Jefferson University**  
**Ajay Kapur, PhD, Northwell Health System**  
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**Lakshmi Santanam, PhD, Washington University**  
**Jing, Zeng, MD, University of Washington**

Members of the MDQA suggested revisions and then the revised draft was posted for comment to the sister societies, giving them the opportunity to provide additional updates. The suggested revisions from the sister societies were reviewed by MDQA leaders and ASTRO's Clinical Affairs and Quality Council leaders, Jim Hayman, MD, University of Michigan; Todd Pawlicki, PhD, University of California, San Diego; Benjamin Smith, MD, University of Texas MD Anderson Cancer Center; and Eric Ford, PhD, University of Washington. The revised draft was approved by the ASTRO Board in January 2019 and endorsed by sister societies by March 2019.



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## 2019 Forward

**I**n 2012, as part of its Target Safely initiative, ASTRO spearheaded the effort among our specialty societies to update the “Blue Book.” During the 20 years prior to its previous update, major advances had been made in treatment planning and delivery resulting in increased technical complexity. At the same time, cancer care was becoming much more multidisciplinary both within and outside our departments, resulting in the need for improved communication. These issues, along with several others, led us to refocus our efforts to improve the quality and safety of the care we deliver. The recommendations in Safety Is No Accident provided an updated framework for achieving that goal.

Since 2012, many additional efforts have been undertaken by our specialty societies to improve quality and safety. In the last five years, with the support of several other societies, ASTRO has initiated the RO-ILS: Radiation Oncology Incident Learning System<sup>®</sup>, one of the few specialty-specific national safety event reporting and shared learning systems. ASTRO has also launched its Accreditation Program for Excellence (APEX<sup>®</sup>), a comprehensive program based on a series of standards with a focus on continuous quality improvement. AAPM has also released reports and guidelines focused on quality and safety. For example, Task Group 263 focused on standardizing nomenclatures with a key goal to enhance future safety and quality efforts; Medical Physics Practice Guideline 4.a. focused on development, implementation, use and maintenance of safety checklists, and Task Group 100 focused on quality management and risk assessment. At the same time, there have been major advances in our specialty including increased use of MRI and PET-based simulation, knowledge-based planning, re-treatment, hypofractionation, surface imaging and MRI-guided treatments, particle therapy and immunotherapy.

In light of what we have learned from these new initiatives and advances, it is a logical time to update Safety is No Accident to incorporate this new knowledge. Given the extent of the revisions undertaken six years ago, it is not surprising that some updates have been made to clarify the standardization of routine processes and procedures. One major point of emphasis in this update is to make clear that quality and safety are not just the responsibility of departmental leadership but the entire treatment team. Other areas where the bar has been raised involve certification of dosimetrists and radiation therapists, radiation safety, and supervision of stereotactic treatments.

Over the next five years, it is likely that emerging technologies will continue to become part of routine practice and result in new unexpected challenges to quality and safety. In addition, we are entering an era where efficiency will be increasingly important, requiring us to reassess the usual way of doing things and focus only on those activities that add value. Going forward, we need to take what we have learned about quality and safety, combine it with the most effective technologies and activities such as automation, simplification and standardization, and incorporate them into a continuous quality improvement cycle to give our patients what they deserve, the best care possible.

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## 2012 Forward

**D**uring the latter part of the twentieth century, the “Blue Book” had a unique importance in defining the shape of a modern radiation oncology department. It set standards regarding personnel, equipment and quality assurance and has been an invaluable guide for department chairs and practice leaders. Twenty years have elapsed since the last edition was published and during that time the world of radiation oncology has changed beyond measure. These two decades have seen an unprecedented expansion in the technological tools at our disposal with clear benefits to our patients. At the same time, however, the “Great Expansion” has added the challenge of deep complexity to our planning and treatment delivery. These decades have also been associated with a vigorous awareness of safety in medicine generally and radiation oncology in particular. This movement is pushing the practice of medicine toward integrated teamwork and effective, simple, quality assurance procedures.

The safe delivery of radiation therapy was never a simple matter and is now exceedingly complex. This new document is designed to address the specific requirements of a contemporary radiation oncology facility in terms of structure, personnel and technical process in order to ensure a safe environment for the delivery of radiation therapy. It was developed through collaboration between all of the major societies in the field representing physicians, medical physicists, radiation therapists, medical dosimetrists, nurses and administrators. It explicitly sets a high bar below which no radiation oncology facility should operate, and it foresees that the bar will be raised further in the years ahead. This book is unapologetic in its strong stance because, as the title states, safety is no accident. It comes from well-run facilities with good processes operating harmoniously within their capabilities. We recognize that some with smaller facilities may find the standards set here hard to achieve but we do not believe that they are impossible. We recognize that, in a declining economy, these high bars may prove a challenge but we believe this interdisciplinary document will help facility leaders advocate on behalf of patients from a position of strength. The authors wish this book to be a living manifesto of the specialty’s dedication to patient safety and, after initial publication, will place it on the web with regular updating to follow.

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## CHAPTER

# 1

# The Process of Care in Radiation Oncology

**T**he “process of care” in radiation oncology refers to a framework for facilitating the appropriateness, quality and safety of all treatments received by patients undergoing radiation therapy (RT).<sup>1</sup>

The process of care can be separated into the following five operational categories:

- Patient Evaluation
- Radiation Treatment Preparation
  - Clinical Treatment Planning
  - Therapeutic Simulation (simulation)
  - Dosimetric Treatment Planning
  - Pretreatment Quality Assurance (QA) and Plan Verification
- Radiation Treatment Delivery
- Radiation Treatment Management
- Follow-up Evaluation and Care

A course of RT is a function of the individual patient situation, composed of a series of distinct activities of varying complexity. All components of care involve intense cognitive medical evaluation, interpretation, management and decision-making by the radiation oncologist and other members of the clinical team. Each time a component of care is performed, it should be appropriately documented in the electronic health record (EHR).

The clinical team, led by the radiation oncologist, provides the medical services associated with the process of care.

Other team members involved in the patient’s planning and treatment regimen include the medical physicist (physicist), medical dosimetrist (dosimetrist), radiation therapist, nursing staff and ancillary services. The radiation oncologist is responsible for coordinating care with other specialists.

Many of the procedures within each phase of care in radiation oncology should be completed before moving to the next phase in the patient’s care. Other processes will occur and recur during the course of treatment for various reasons (e.g., patient tolerance to treatment, changes in treatment) as dictated by the clinical scenario. Specific processes of patient care may vary between practices. While the process of care involves close collaboration between a team of qualified individuals, the attending radiation oncologist is ultimately accountable for all aspects of patient care. Most RT practices use standard operating procedures (SOPs) to describe the treatment approach and provide consistent protocols for staff. These SOPs are an essential component of any practice. There will be certain clinical scenarios which may require modification of the SOPs to optimally treat the patient, and they should be documented. Collaboration between clinical staff helps determine how treatment options outside of an SOP might be tailored to a particular patient’s situation.

## 1.1. PATIENT EVALUATION

At the request of another physician or patient, a radiation oncologist may be asked to evaluate the patient and

recommend treatment or care for a specific condition/problem, including further work-up. As part of this process, the radiation oncologist obtains and reviews a clear, accurate and detailed description of the patient's pertinent history, current and recent symptoms, physical findings, imaging studies, pathology and laboratory results, as appropriate. If treatment is recommended, the goals of treatment, including curative or palliative intent, should be clearly established and discussed with the patient. The radiation oncologist and the patient (and family, as appropriate) should engage in shared decision-making about the appropriate course of action, including a detailed discussion of the treatment risks and benefits. Following the radiation oncologist's evaluation, discussions with other members of the multidisciplinary care team may ensue, as indicated. Potential combination and optimal sequencing of treatment modalities, including surgery and systemic therapy (e.g., chemotherapy, hormonal therapy, immunotherapy, or molecular targeted therapy) should be considered. All factors pertinent to treatment decision-making (e.g., prior radiation and/or systemic therapy, implanted devices and pregnancy status) must be documented as part of RT preparation and made available to the clinical team. Full details of the patient evaluation and consent process are beyond the scope of this safety document.<sup>2</sup>

## 1.2. RADIATION TREATMENT PREPARATION

### 1.2.1. Clinical Treatment Planning

Clinical treatment planning is a comprehensive, cognitive effort performed by the radiation oncologist and clinical team for each patient undergoing RT. The radiation oncologist is responsible for understanding the natural history of the patient's disease process, conceptualizing the extent of disease relative to the adjacent normal anatomical structures, and integrating the patient's overall medical condition and associated comorbidities. Knowledge of the integration of systemic and surgical treatment modalities with RT is essential for appropriate care coordination in a safe and high-quality multidisciplinary approach.

Clinical treatment planning for all modalities (e.g., external beam radiation therapy [EBRT], brachytherapy or unsealed sources) is an important step in preparing for treatment. The timing of certain preparation components may vary depending on patient requirements and a practice's preference and workflow. These components include: determining the disease-bearing areas based on the imaging studies and pathology information; identifying the type and method

of RT delivery (e.g., intensity-modulated radiation therapy [IMRT], proton beam therapy, intensity-modulated proton therapy, three-dimensional [3-D] conformal radiation therapy [CRT], two-dimensional [2-D] CRT, low-dose-rate or high-dose-rate [HDR] brachytherapy, stereotactic radiosurgery [SRS], stereotactic body radiation therapy [SBRT]); specifying areas to be treated, dose, dose fractionation and treatment schedule. In developing the clinical treatment plan, the radiation oncologist may use information obtained from the patient's initial clinical evaluation, as well as additional tests, studies and procedures that are necessary to complete treatment planning. Studies ordered as part of clinical treatment planning may or may not be associated with studies necessary for staging cancer. Imaging studies and laboratory tests are often reviewed to determine the treatment volume and relevant critical structures, commonly referred to as organs at risk (OARs), in close proximity to the treatment area or more distant but receive radiation that needs to be monitored. Toxicities and tolerances associated with the intent of treatment, including the time intervals between any retreatment, should be evaluated.

Clinical treatment planning results in a complete, formally documented and approved directive/order for simulation or any pretreatment preparation.

### 1.2.2. Therapeutic Simulation, Fabrication of Treatment Devices and Preplanning Imaging

Simulation is the process by which the patient's anatomy is defined in relation to the geometry of the treatment device to develop an accurate and reproducible treatment delivery plan. For this purpose, radiographic and photographic images of the patient in the preferred treatment position are typically necessary. In general, the simulation procedure shows the relationship between the position of the target(s) and the surrounding critical structures. For treatment techniques not requiring dosimetric planning, volumetric simulation is not necessary as the pretreatment preparation may be completed via clinical setup and/or manual calculation.

#### 1.2.2.1. Therapeutic Simulation for EBRT

The simulation directive/order guides the procedure performed by the radiation therapist(s). It is helpful to think of the simulation step as the patient position and imaging needed to inform the dosimetric treatment planning process. Modern simulators, like the computed tomography (CT) simulator (less commonly magnetic resonance or position emission tomography (PET) simulator), have the ability to produce volumetric data in addition to 2-D images. Intravenous, intracavitary or

oral contrast may be used during simulation to improve visibility of both target and normal tissues/structures. Markers, such as wires, ball bearings or fiducials may be used to facilitate planning.

Selecting a reproducible and appropriate patient treatment position is an important part of the simulation process. The selected patient position should consider the location of the target and anticipated orientation of the treatment beams as well as the comfort of the patient. This may involve the construction or selection of certain immobilization devices used to facilitate treatment but should not restrict the treatment technique. A personalized approach is required, taking into consideration each patient's unique anatomy and other case-specific concerns to promote accurate treatment, provide support and enhance reproducibility. Some devices (e.g., vaginal dilators/obturators, mouth opening/tongue position devices and prostate-rectal spacers) may assist with reducing doses to adjacent normal tissue.

Preparing for EBRT treatment can also depend on other imaging modalities that are directly or indirectly introduced in the simulation process. In some cases, extra time and effort are required to directly incorporate the information available from other imaging modalities. Treatment planning systems (TPS) that include image registration capabilities allow the fusion of multiple imaging modalities, such as magnetic resonance imaging (MRI) and/or PET, with the standard CT dataset obtained during simulation in appropriate situations. In addition, it is possible to produce image datasets that quantify the motion of structures and targets due to respiration, cardiac motion and physiologic changes in the body. These four-dimensional (4-D) datasets include time as the fourth dimension and are used for motion management techniques like respiratory tracking or gating. Other motion management techniques (e.g., assisted or voluntary breath hold) may be used to help promote accurate treatment delivery and these are considered and included during simulation as needed.

In some cases, patients require imaging from outside of the radiation oncology practice. On such occasions, the exact patient positioning may not be duplicated for these images and therefore clinical considerations should be made to compensate for variations. Most image registration is still performed manually with rigid datasets. However, more practices are utilizing tools including deformable image registration for co-registering imaging

studies taken with different patient positioning. TPS and some CT-simulator devices can provide the software for this capability. Use of TPS software shifts this part of the process to the dosimetric treatment planning phase within the overall care process. The radiation oncologist reviews and verifies the accuracy of the fusion on the clinically relevant region prior to proceeding to target delineation and normal tissue definition.

#### **1.2.2.2. Therapeutic Simulation for Brachytherapy**

For certain brachytherapy procedures, treatment preparation is similar to the procedure described for EBRT. The simulation portion for this treatment modality is also typically imaging based and can involve planar X-rays, CT scans, or ultrasound images, sometimes in combination with MRI scans. Other imaging modalities may be important for some brachytherapy procedures; obtaining these studies is part of the preplanning imaging process.

#### **1.2.3. Dosimetric Treatment Planning**

The computer-aided integration of the patient's unique anatomy, the desired radiation dose distribution to the target(s), dose constraints to normal tissues and the technical specifications of the treatment delivery device yield a work product referred to as the dosimetric treatment plan. The plan is a programmed set of instructions for the linear accelerator or brachytherapy device whereby a combination of external beams or internal source positioning administers the intended dose of radiation to the target volume while limiting the exposure of normal tissues.

Accordingly, before the dosimetrist begins the dosimetric planning process, the radiation oncologist communicates and documents relevant clinical information and any additional instructions regarding treatment planning and treatment delivery in the planning directive/order. Additionally, the radiation oncologist has the following responsibilities:

- Confirm registration, when applicable;
- Define the target volumes on the images obtained during simulation;
- Specify the normal tissues requiring segmentation;
- Specify dosimetric objectives and priorities for the target(s) and OARs;
- Identify patients with prior radiation history and other patient-specific considerations documented during the initial consultation; and
- Detail the total desired dose, fractionation, treatment technique, energy, time constraints, on-treatment

imaging and all other aspects of the radiation prescription. In some cases, the prescription may be modified based on the results of the treatment planning process.

The dosimetrist and physicist must be appropriately trained in the efficient and effective use of the complex TPS hardware and software. They must also understand the clinical aspects of radiation oncology in order to interact with the radiation oncologist during the planning process. Treatment planning tools are evolving, and various systems may be used to optimize the treatment plan.

The radiation oncologist reviews treatment plan(s) generated during the dosimetric planning process using a combination of graphic visual representations of the radiation dose distribution inside the patient and quantitative metrics describing the dose to the target(s) and OARs (e.g., dose-volume histograms). The plan evaluation should include a review of OARs delineated by planning staff for accuracy. Additionally, these plans may be compared against a documented standard, such as output from a knowledge-based planning system or practice's protocol. The radiation oncologist then decides whether to accept or reject a given plan. This process may be iterative and require multiple revisions and adjustments to the initial plan to achieve a dose distribution that is both clinically acceptable and technically feasible. The radiation oncologist is responsible for selecting and formally approving the plan ultimately chosen for treatment, verifying that it satisfies the clinical requirements and prescription(s) and that it can be carried out accurately.

#### **1.2.4. Preparation for Radiation Therapy Using Unsealed Sources**

For clinical situations where therapy using unencapsulated radionuclides is indicated, a distinct treatment planning process is necessary due to its multidisciplinary execution. The process involves calculating the anticipated dose distribution to the target organ or tumor(s), and normal tissues, based on the patient's vascular anatomy or biological imaging (e.g., nuclear medicine scans). This process should include multidisciplinary evaluation of the patient and consideration of clinical indications and radiation safety precautions. The American College of Radiology (ACR)/American Society for Radiation Oncology (ASTRO) practice guideline on unsealed radiopharmaceutical sources and Nuclear Regulatory Commission regulations discuss the special and unique radiation safety risks and procedures associated with unsealed sources in greater detail.<sup>3,4</sup>

#### **1.2.5. Pretreatment QA and Plan Verification**

For safe and high-quality RT, a pretreatment QA program is required. The QA steps taken after treatment planning is completed and before starting treatment is critical to maximize patient safety. An important initial step is an independent check of the dose calculation (monitor units) for EBRT or dose (source strength and temporal pattern) and implant geometry for brachytherapy. Monitor units or dwell times can be manually verified by a point dose calculation in a high-dose region. Alternatively, verification may be performed with computer-assisted software, using the patient's planning image data set in a separate software program along with the plan parameters. In either case, confirmation of linear accelerator output settings or brachytherapy source strengths/dwell times by an independent method is required to reduce the risk of an input mistake in the primary treatment planning software. If an independent calculation method is not available, then an appropriate measurement technique should be used. Under the supervision of the physicist and/or radiation oncologist, appropriately trained clinical staff may approve such QA documents.

Secondary checks and a collaborative team environment are important for a comprehensive QA program. The physicist reviews the physician-approved plan, which includes analysis of the dose distribution, coverage of targets, protection of critical OARs and appropriate fusion of additional treatment planning imaging (i.e., MRI, PET) to the planning CT, and many other checks. Additional checks are required for brachytherapy plans, such as appropriate dwell time distribution and correct source activity. These are covered in more detail in Chapter 4.

Plan verification is accomplished in several different ways depending on the technique and complexity of treatment. One component of verification is to ensure that the intended target is being irradiated. Historically, this consisted of field aperture imaging using radiographic film, referred to as portal images or port films. These images are now frequently obtained using electronic portal imaging devices. With the introduction of IMRT, imaging of individual apertures is not always practical. However, the traditional method of verifying the plan isocenter position using orthogonal imaging is often used for both 3-D CRT and IMRT. For either portal imaging or isocenter verification imaging (using volumetric or planar images), a reference image for comparison is necessary. This information is generated from the imaging performed during the simulation step in the process.

For IMRT, this important QA technique is not completely sufficient to address safety concerns. Additionally, fluence verification should be performed for IMRT and other complex delivery techniques that use inverse treatment planning. This involves either patient-specific plan QA measurements or other independent calculation checks where appropriate. In the context of brachytherapy, pretreatment verification by independently verifying the dose calculation at several randomly chosen points is needed.

When organizing the steps in the process of care, integrating the verification step described in this subsection and the treatment delivery step described in Section 1.3 occurs prior to or on the first day of treatment and whenever the treatment plan is changed. While patient-specific plan QA measurements are obtained prior to the start of treatment, dosimeters are sometimes also placed on the patient as a verification of correct dose delivery. The information gathered on the first day of treatment, if within acceptable limits, allows the treatment to continue for all fractions using the same treatment plan. In certain situations, the radiation oncologist and/or physicist may need to assess the in-room setup, for example, to verify light fields for electron setups or bolus placement.

Image-guided radiation therapy (IGRT) equipment is available to check the patient setup on the treatment table immediately prior to treatment delivery and then to adjust the patient position as needed to localize the target volume precisely within the volume that receives the prescription dose. IGRT provides increased setup accuracy allowing for smaller target volumes that spares normal tissue surrounding the tumor. This equipment can be used to verify the patient setup daily and can supplement port film information. An advantage of IGRT is that it sometimes provides volumetric imaging capabilities. This process goes well beyond the simple plan verification process discussed earlier in this section.

The QA process must also include steps aimed at verifying data transfer integrity through the complete chain of systems (e.g., CT-simulator to TPS to treatment management system [TMS] to treatment delivery system [TDS]). A robust information technology infrastructure is a critical requirement for safe treatment delivery and timely review of imaging and other data.

## 1.3. RADIATION TREATMENT DELIVERY

### 1.3.1. External Beam Radiation Therapy

With treatment planning and pretreatment QA complete, the patient is ready for treatment. The initial step for radiation therapists in treatment delivery is verification of patient identity and treatment site. This is followed by patient setup on the treatment table using several different techniques, such as simple skin marks and a room laser system that localizes the treatment unit isocenter.

Prior to the initiation of treatment, the verification of the isocenter and/or treatment fields is performed by the imaging system, as appropriate. IGRT can be used to improve the accuracy of patient setup, especially in the context of an internal target that can move on a daily basis. The radiation oncologist must review all images and alignments during the prescribed course of treatment to confirm the therapy delivered conforms to the original clinical and dosimetric plans.

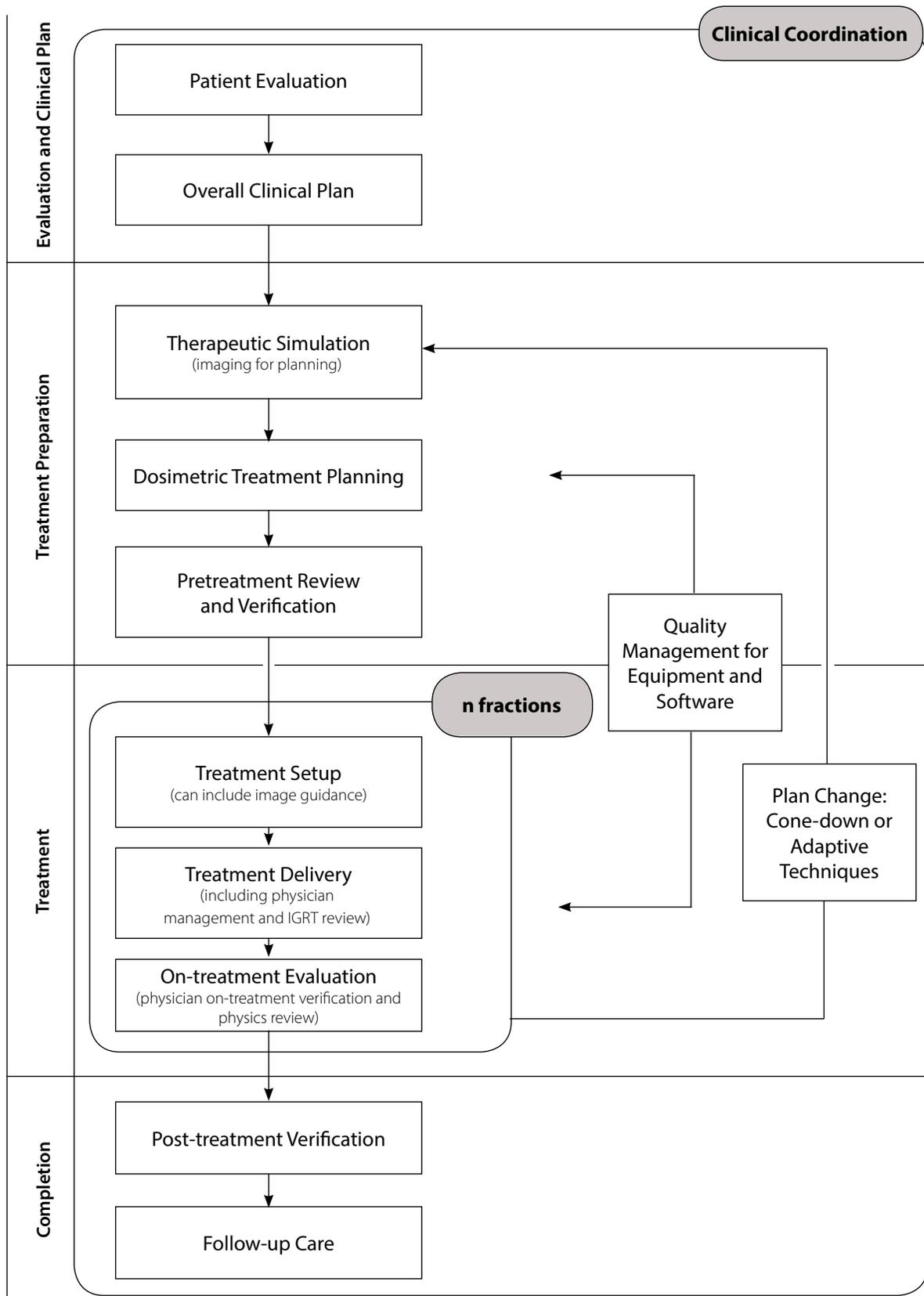
Similarly, management of organ motion during treatment delivery, when indicated, is the responsibility of the treating physician (**Figure 1.1**). A variety of motion management techniques (e.g., assisted or voluntary breath hold, surface imaging, and/or surrogate marker tracking) may be used to help promote accurate treatment delivery.

Adaptive techniques can involve a modification to the initial treatment plan to adjust for an observed change.

### 1.3.2. Brachytherapy

Brachytherapy involves the temporary or permanent placement of radiation source(s) (isotopic or electronic) inside or immediately adjacent to a tumor-bearing region (**Figure 1.1**). Additionally, brachytherapy may be used alone or in combination with EBRT. For example, permanent seed implants for prostate cancer can be used either as monotherapy for early stage or recurrent disease or as a boost before or after ERBT for intermediate- or high-risk disease. As in EBRT, treatment delivery includes various methods, modalities and complexities. The physicist and physician are responsible for verification and documentation of the accuracy of treatment delivery as related to the initial treatment planning and setup procedure. This includes the accurate identification and localization of catheters or needles immediately prior to treatment delivery. Depending on the treatment site and technique used, this may include ultrasound, CT, and/or MRI.

**Figure 1.1. Process of Care for EBRT and Brachytherapy**



IGRT, image-guided radiation therapy.

### 1.3.3. Calibration Procedures, Ongoing Equipment QA and Preventive Maintenance

The initial commissioning, ongoing performance evaluation and periodic calibration of RT delivery devices are important tasks that are vital to the safe administration of RT. The physicist is primarily responsible for the device evaluations necessary for compliance with applicable state and federal regulations concerning RT delivery technology and is accountable for calibrating the absolute dose output for any therapeutic radiation emitting device. The American Association of Physicists in Medicine (AAPM) has published extensive guidelines on the conduct of these duties and regularly updates its educational materials when new technologies enter into standard clinical practice. The radiation oncologist, physicist and other clinical staff should maintain a clear channel of communication on the issue of treatment device performance so that any sign of impending machine malfunction is quickly recognized and diagnosed, and corrective or reparative action taken prior to use of the machine to deliver a clinical treatment to a patient.

## 1.4. RADIATION TREATMENT MANAGEMENT

Treatment management encompasses the radiation oncologist's complete oversight of the course of treatment and care for the patient as well as checks and approvals provided by other clinical staff (e.g., physicist and therapist weekly chart check). This requires the radiation oncologist to provide a minimum of one patient medical evaluation and examination during their treatment. For treatments consisting of numerous fractions, examination and evaluation for each five-fraction treatment period is needed. Treatment management may include the following elements:

- Review of patient treatment setup;
- Review of treatment setup verification images (which may occur daily for IGRT or surface guided RT);
- Review of dosimetry, dose delivery and treatment parameters;
- Patient examination, including treatment tolerance and pain management assessment; and
- Response to treatment.

The radiation oncologist's evaluation may vary based on individual patient requirements, technique or treatment modifications. For example, use of port films may vary based on certain technical characteristics (e.g., electron beams) and modification of dose delivery can vary based on individual patient needs, the patient's tolerance of therapy, or variation in

tumor response. All evaluations should be documented in the patient's record.

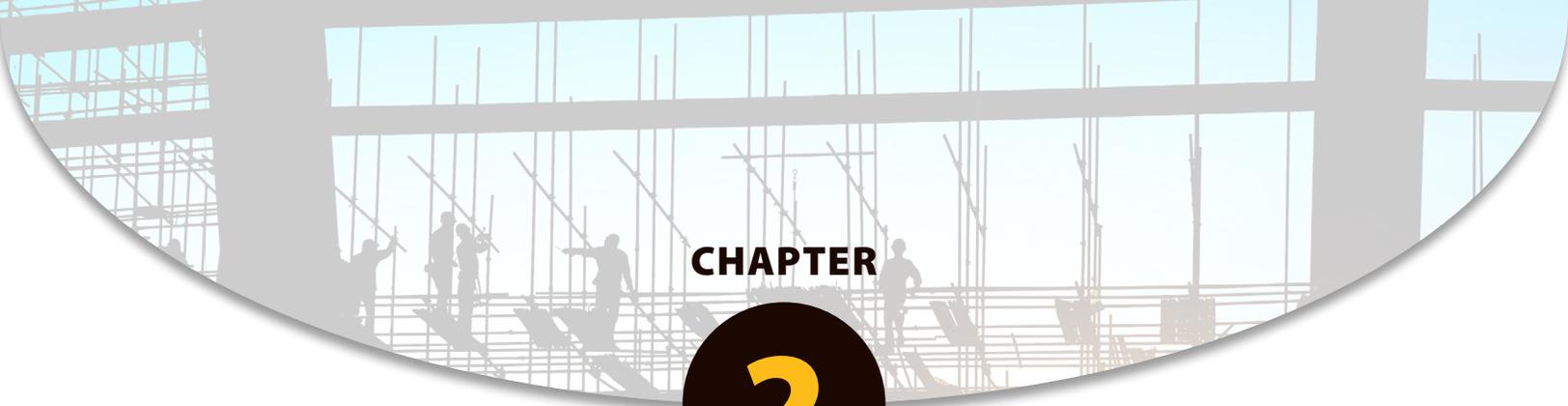
It should be emphasized that treatment management requires the integration of multiple medical and technical factors, which may be required on any day throughout the treatment course and is performed as often as necessary. While nurses and nonphysician providers effectively participate in managing patients receiving treatment, typically by helping manage side effects associated with the treatment, this is not a substitute for the personal evaluation by a radiation oncologist, who is ultimately responsible for comprehensive patient management.

## 1.5. FOLLOW-UP EVALUATION AND CARE

At the completion of treatment, the physicist reviews the patient's treatment documents (e.g., dosimetric treatment plan, calculation and chart check, record of delivered dose) for accuracy and completeness and prepares a technical summary. The radiation oncologist prepares the treatment summary documenting the start and end date of treatment (including any treatment breaks), treatment delivered, frequency of treatment, tolerance and toxicity of therapy, follow-up plan and any ongoing issues.<sup>5</sup> A copy of the treatment summary is shared with other providers of the patient's care team, which may include the primary care physician and the referring physician. When details of a patient's prior treatment are requested from an external provider, the treatment summary and any other necessary documents should be promptly shared.

Continued patient follow-up evaluation and care of those who received radiation is necessary to manage acute and chronic morbidity resulting from treatment, and to monitor disease status (i.e., free of disease; local, regional or distant relapse). Preferably, follow-up is performed by the treating radiation oncologist or a nonphysician provider to obtain the most accurate information regarding treatment tolerance, side effects and disease status. The radiation oncologist should consult with other clinical staff when unexpected morbidity is observed or reported to review the delivered plan for accuracy and identify potential measures to reduce the risk of toxicity for future patients. Survivorship clinics may play a role in the management of long-term cancer treatments.

The goal of radiation treatment is to achieve the best possible outcome for the patient. Creating a safe environment dedicated to continuous quality improvement is an essential part of any practice. This can be accomplished by having consistent processes that are formally documented and adhered to for each step in the process of care.



## CHAPTER

# 2

# The Radiation Oncology Team

## 2.1. ROLES AND RESPONSIBILITIES

The radiation oncology team works to provide every patient undergoing RT with the appropriate level of medical, nutritional, emotional and psychological care before, during and after treatment, through a collaborative multidisciplinary approach which may include other specialties (e.g., medical oncology, anesthesiology, urology).

The interdisciplinary radiation oncology clinical team (clinical team) typically consists of:

- Radiation oncologists;
- Medical physicists;
- Medical dosimetrists;
- Radiation therapists; and
- Oncology nurses.

The clinical team may include other individuals, such as nonphysician providers:

- Nurse practitioners;
- Clinical nurse specialists;
- Advanced practice nurses; or
- Physician assistants.

To meet the complex needs of patients, other staff may provide additional services on-site or by consultation including, but not limited to:

- Administrative staff (including IT);
- Dentists;
- Clinical social workers;
- Psychologists/psychiatrists;
- Nutritionists;
- Speech/swallowing therapists;
- Physical therapists;
- Occupational therapists;
- Genetic counselors;
- Physicist, therapist and nursing assistants;
- Patient navigators;
- Integrative medicine specialists; or
- Pastoral care providers.

Each aspect within the process of care requires knowledge and training in cancer biology, certain benign disease processes, radiobiology, medical physics and radiation safety that can only be demonstrated by board certification in radiation oncology to synthesize and integrate the necessary knowledge base to safely render complete care. In addition to knowledge and technical skills, clinical staff must function as a cohesive team by communicating and interacting effectively with colleagues and patients.<sup>6</sup>

Under the leadership of the radiation oncologist, the clinical team works together to deliver radiation safely and reproducibly.<sup>7</sup> Use of ionizing radiation in medical treatment requires direct physician management and input from the clinical team due to its irreversibility. Team interactions should be consistent with a culture of safety and should consider the

vital and unique role that each team member contributes. Each clinical team member is encouraged to ask clarifying questions as needed and to proceed to the next step in the process of care only when any concerns or issues have been addressed.

**Table 2.1** is an attempt to clarify the roles and relative responsibilities of the clinical team.

The scope of practice of each team member is based on criteria established by their professional organization and local jurisdiction. In addition, each practice must have policies and procedures to define the roles of clinical staff, their appropriate competency assessment, credentialing and periodic evaluations.

**Table 2.1. Roles and Responsibilities of the Clinical Team**

	Radiation Oncologist	Physicist	Dosimetrist	Radiation Therapist	Nonphysician Providers*	Oncology Nurse
Clinical evaluation	X				X	X
Ongoing psycho/social evaluation	X				X	X
Decision to deliver RT	X					
Patient +/- family education	X	X		X	X	X
Coordination of care	X			X	X	X
Patient positioning and image acquisition	X	X	X	X		
Fusion and registration	X	X	X			
Contouring/segmentation	X	X	X			
Dose-volume constraints	X	X	X			
Dose calculation	X	X	X	X		
Review of final treatment plan	X	X	X	X		
Patient-specific QA	X	X	X	X		
Treatment delivery	X	X	X	X		
Special procedures (SRS, SBRT, HDR, etc.)	X	X	X	X		
Monitor accuracy of delivery (ports, dose, etc.)	X	X	X	X		
Weekly evaluation	X	X	X	X	X	X
Follow-up	X				X	X
Survivorship	X				X	X
Equipment, software and system acceptance testing, maintenance and commissioning	X	X				

\*Nonphysician providers include nurse practitioners, clinical nurse specialists, advanced practice nurses and physician assistants.

HDR, high-dose-rate; QA, quality assurance; RT, radiation therapy; SBRT, stereotactic body radiation therapy; and SRS, stereotactic radiosurgery.

## 2.2. QUALIFICATIONS AND TRAINING

The primary consideration for establishing proper qualifications and training for clinical staff and nonphysician providers is board certification. The respective certifying bodies establish the eligibility requirements to sit for a board exam, including education, training and clinical requirements.

In addition, the clinical team and nonphysician providers must meet requirements for obtaining a state license, where applicable, as shown in **Table 2.2**.

**Table 2.2. Certification and Licensure Requirements\***

Profession	Relevant Certifying Body	State Licensure Required?	Information Resources
Radiation Oncologist	ABR AOBR RCPSC	Yes	<a href="http://www.theabr.org">www.theabr.org</a> <a href="https://certification.osteopathic.org/radiology/">https://certification.osteopathic.org/radiology/</a> <a href="http://www.royalcollege.ca/rcsite/home-e">www.royalcollege.ca/rcsite/home-e</a>
Physicist	ABR CCPM	Yes (In four states [FL, NY, TX, HI] as of 2018) <sup>8</sup>	<a href="http://www.theabr.org">www.theabr.org</a> <a href="http://www.ccpm.ca">www.ccpm.ca</a>
Dosimetrist	MDCB	No	<a href="http://www.mdcb.org">www.mdcb.org</a>
Radiation Therapist	ARRT	Yes (In most states) <sup>9</sup>	<a href="http://www.rrt.org">www.rrt.org</a>
Nurse Practitioner	AANP ANCC	Yes Yes	<a href="http://www.aanp.org">www.aanp.org</a> <a href="http://www.nursecredentialinganc.org">www.nursecredentialinganc.org</a>
Oncology Nurse	ANCC ONCC	Yes	<a href="http://www.nursecredentialing.org">www.nursecredentialing.org</a> <a href="http://www.oncc.org">www.oncc.org</a>
Clinical Nurse Specialists	ANCC	Yes	<a href="http://www.nursecredentialinganc.org">www.nursecredentialinganc.org</a>
Physician Assistant	NCCPA	Yes	<a href="http://www.nccpa.net">www.nccpa.net</a>

\*Information in this table is subject to change and is current as of the date of publication.

AANP, American Academy of Nurse Practitioners; ABR, American Board of Radiology; ANCC, American Nurses Credentialing Center; AOBR, American Osteopathic Board of Radiology; ARRT, American Registry of Radiologic Technologists; CCPM, Canadian College of Physicians in Medicine; FL, Florida, HI, Hawaii; MDCB, Medical Dosimetrist Certification Board; NCCPA, National Commission on Certification of Physician Assistants; NY, New York; ONCC, Oncology Nursing Certification Corporation; TX, Texas; RCPSC, Royal College of Physicians and Surgeons of Canada.

**2.2.1. Medical Director**

The Medical Director is a radiation oncologist who is responsible for oversight of the practice and for establishing clinical policies and procedures. They are also accountable for the quality of patient care.

**2.2.2. Radiation Oncologist**

The radiation oncologist has American Board of Radiology (ABR) certification in Radiation Oncology, Therapeutic Radiology or equivalent certification ([www.theabr.org/](http://www.theabr.org/)). Alternatively, the radiation oncologist can be certified by the Royal College of Physicians and Surgeons of Canada ([www.royalcollege.ca/rcsite/home-e](http://www.royalcollege.ca/rcsite/home-e)) or the American Osteopathic Board of Radiology (<https://certification.osteopathic.org/radiology/>).

**2.2.3. Nonphysician Providers**

The roles, qualifications, licensure requirements and maintenance of credentials for these individuals should be determined by their professional organizations, applicable scope of practice laws and regulations, rules of individual practices' and licensure regulations within individual jurisdictions (American Academy of Nurse Practitioners,

[www.aanp.org](http://www.aanp.org); American Nurses Credentialing Center, [www.nursecredentialing.org](http://www.nursecredentialing.org); National Commission on Certification of Physician Assistants, [www.nccpa.net](http://www.nccpa.net); American Academy of Physician Assistants, [www.aapa.org](http://www.aapa.org)).

**2.2.4. Physicist**

Physicists should be certified in accordance with the appropriate qualification for the designation of Qualified Medical Physicist (as published at [www.aapm.org](http://www.aapm.org)), Therapeutic Medical Physicist (as published at [www.theabr.org](http://www.theabr.org)) or equivalent certification.

**2.2.5. Dosimetrist**

Dosimetrists should be certified in accordance with the appropriate qualification for the designation of Certified Medical Dosimetrist through the Medical Dosimetrist Certification Board at [www.mdcb.org](http://www.mdcb.org).

**2.2.6. Radiation Therapist**

Radiation therapists should be certified and registered in accordance with the appropriate qualification for the designation of Radiation Therapist, published by the American Registry of Radiologic Technologists at [www.rrt.org](http://www.rrt.org).

### 2.2.7. Radiation Oncology Nurse

A qualified oncology or radiation oncology nurse has oncology certification, in addition to basic educational preparation to function as a registered professional nurse, as determined by the individual jurisdiction. Oncology certification can be obtained through the Oncology Nursing Certification Corporation ([www.oncc.org](http://www.oncc.org)), American Nurses Credentialing Center ([www.nursecredentialing.org](http://www.nursecredentialing.org)), or National Association of Clinical Nurse Specialists ([www.nacns.org](http://www.nacns.org)).

## 2.3. CONTINUING EDUCATION AND MAINTENANCE OF CERTIFICATION

The applications, technologies and methodologies of RT continue to expand and develop, therefore lifelong learning is vital to incorporating new knowledge into clinical practice. Each member of the clinical team should participate in available Continuing Medical Education and, where applicable, Maintenance of Certification (MOC) or Continuing Qualifications Requirements programs.

With guidance from the American Board of Medical Specialties (ABMS), medical specialties developed MOC programs to provide greater oversight of physicians and other health care providers. The ABMS defined four components of MOC: professional standing, lifelong learning and self-assessment, cognitive expertise and practice quality improvement. MOC is considered a critical component of good clinical practice, even if not mandatory in some situations.

Many specialty societies offer opportunities for clinical staff to satisfy the requirements of MOC. For example, ASTRO offers live and online courses with self-assessment continuing medical education to fulfill the lifelong learning requirements. To help radiation oncologists fulfill their practice quality improvement requirements, ASTRO provides several templates to be used with various ASTRO programs, including the Accreditation Program for Excellence (APEX<sup>®</sup>) and RO-ILS: Radiation Oncology Incident Learning System<sup>®</sup>. ACR has the R-O PEER program and the AAPM offers similar initiatives for physicists, such as an online library of self-assessment modules. Clinical staff should take advantage of these opportunities.

## 2.4. STAFFING REQUIREMENTS

The staffing needs of each practice are unique and can vary greatly based upon the patient mix and the complexity of the services offered. Patient load, number of machines, staff absences (planned and unplanned) and satellite/affiliated practices can impact the management and staffing of full-time equivalent (FTE) employees (**Table 2.3**). As such, it is impossible to prescribe definitive staffing levels.

The practice must have a qualified radiation oncologist on-call 24 hours a day, seven days a week, to address patient needs and/or emergency treatments. An adequate number of other clinical staff should be available to deliver urgent treatments regardless of operating hours, or the practice must arrange for referral of emergency patients for timely treatments.

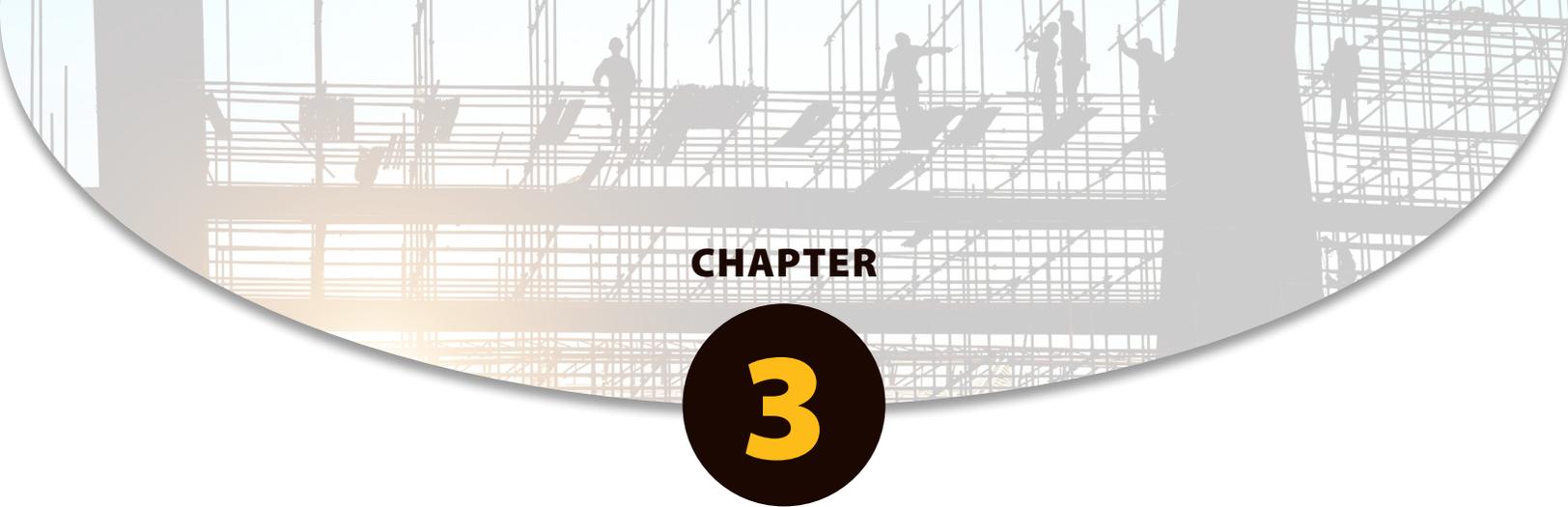
**Table 2.3. Minimum Personnel Requirements for Clinical Radiation Therapy**

Category	Staffing
Medical Director	One per practice
Radiation Oncologist	Minimum of one radiation oncologist present during treatment hours*
Physicist	Minimum of one physicist available during treatment hours*
Administrator	One per practice (in some practices this function may be filled by clinical staff)
Dosimetrist	As needed, ~ one per 250 patients treated annually†
Radiation Therapist	As needed, ~ one per 90 patients treated annually†‡
Mold Room Technologist	As needed to provide service
Other staff (e.g., nurse, social worker, dietician)	As needed to provide service

\* Refers to minimum requirements for treatment to take place. The number of clinical staff required to safely provide clinical care for patients is likely to be higher.

† This number may be higher or lower depending upon the complexity of patients and treatments.

‡ It is recommended that a minimum of at least two qualified individuals be present for any external beam treatment.



## CHAPTER

# 3

# Safety

### 3.1. THE NEED FOR A CULTURE OF SAFETY

Given the complex and rapidly evolving nature of RT, its safe delivery requires a concerted and coordinated effort by many individuals with varied responsibilities. Furthermore, efficiency also impacts safety. Inefficient systems lead to staff\* frustration, rushing and sometimes cutting corners, thus, all staff should work together to create a safe and efficient clinical environment and workflow.

The need for efficiency is heightened by the increasing demands being placed on all clinical staff. Changes (e.g., structural, financial) in health care systems and increasing levels of administrative burden (e.g., documentation requirements) require clinical staff to search for ways to improve efficiency. It is essential to provide time for clinical staff to perform critical safety-related activities.

As the field advances, traditional approaches, processes and workflows should be continually challenged and reassessed. Each member of the clinical team needs to accept that optimal approaches are not static but may be modified to accommodate the evolving practice.

Change is essential for continual improvement, but difficult for many individuals and organizations. Good clinical practices usually evolve over years if not decades, so change should be carefully implemented. It is important that the culture accepts and implements change, thereby facilitating safety and quality.

Furthermore, all clinical staff must be open to having any member of the team (whether in leadership positions or not) raise concerns about safety and suggest changes. Indeed, it is often the frontline staff that are more likely to understand the limitations of current procedures and propose improvements. In a safety-minded culture, all staff are encouraged to suggest and effect change to improve safety, quality and efficiency.

### 3.2. LEADERSHIP AND EMPOWERING OTHERS

The practice's leadership (headed by the Medical Director or Chair, working in conjunction with other radiation oncologists, physicists, other clinical and administrative staff) must create a culture of safety and empower all staff to actively participate in improving clinical processes without fear of reprimand or reprisal. This empowerment is a meaningful way to provide staff with a feeling of responsibility, thereby increasing job satisfaction, raising expectations and enhancing performance.

Although leadership has the ultimate responsibility to be champions of safety, all clinical staff should be empowered to operate as advocates for safety-related initiatives. Additionally, the patient should be empowered to play an active role in the culture of safety program.

\*For simplicity, the term 'staff' is used when referring to clinical staff, nonphysician providers and administrative staff.

**Table 3.1. Examples\* of Safety-related Roles and Challenges – Radiation Oncology Staff**

Team Member	Traditional Role	Evolving Role	Challenges
Physician	<ul style="list-style-type: none"> <li>• Patient care</li> <li>• Supervise RT (e.g., set dose/volume criteria, approve plan and treatment images, manage toxicity)</li> </ul>	<ul style="list-style-type: none"> <li>• Team leader for patient safety</li> <li>• Coordination with multidisciplinary team</li> <li>• Continuous education (e.g., image evaluation/segmentation, new software/technology)</li> </ul>	<ul style="list-style-type: none"> <li>• Relinquish some autonomy to other personnel</li> <li>• Engaging others in safety mission</li> <li>• Education in advanced process analysis tools for patient safety</li> <li>• Communication</li> </ul>
Physicist	<ul style="list-style-type: none"> <li>• Assure the safe and effective delivery of radiation as prescribed</li> </ul>	<ul style="list-style-type: none"> <li>• Incorporating technological innovations to improve patient/staff safety</li> <li>• Assess safety of treatment processes (e.g., failure mode analysis, fault trees)</li> </ul>	<ul style="list-style-type: none"> <li>• Education in advanced process analysis tools for patient safety</li> <li>• Broaden view of role beyond task-specific QA duties</li> <li>• Communication</li> </ul>
Dosimetrist	<ul style="list-style-type: none"> <li>• Perform treatment planning</li> </ul>	<ul style="list-style-type: none"> <li>• Changing modalities involved in image cataloging/manipulation (e.g., PET/MRI fusion/registration/segmentation)</li> <li>• Assist physicist in IMRT/IGRT equipment QA</li> <li>• Evolution in planning (e.g., knowledge-based planning, particle therapy planning, biological modeling)</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate instruction in anatomy</li> <li>• Proper utilization of emerging imaging/segmentation tools</li> <li>• Communication</li> </ul>
Radiation Therapist	<ul style="list-style-type: none"> <li>• Provide safe and effective delivery of radiation as prescribed</li> <li>• Perform daily equipment and new patient treatment QA</li> </ul>	<ul style="list-style-type: none"> <li>• Assessment of 2-D/3-D images to make decisions concerning patient alignment</li> <li>• Utilization of various motion management equipment</li> <li>• Adapting to changing modalities for IGRT and treatment (MRI linacs, surface imaging, particle therapy)</li> </ul>	<ul style="list-style-type: none"> <li>• Safe and proper use of imaging and TDS (DIBH, prone positioning, SGRT, etc.)</li> <li>• Communication</li> </ul>
Nurse	<ul style="list-style-type: none"> <li>• Assist with patient care/education</li> <li>• Manage toxicity</li> </ul>	<ul style="list-style-type: none"> <li>• Patient pain</li> <li>• Assist in multidisciplinary coordination</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate instruction in evolving technologies</li> <li>• Knowledge of evolving systemic agents</li> <li>• Communication</li> </ul>
Nonphysician Providers	<ul style="list-style-type: none"> <li>• Assist physician with patient care</li> </ul>	<ul style="list-style-type: none"> <li>• Coordination with multidisciplinary team</li> </ul>	<ul style="list-style-type: none"> <li>• Legal or regulatory restrictions</li> <li>• Adequate instruction in evolving technologies</li> <li>• Knowledge of evolving systemic agents</li> </ul>
Administrator	<ul style="list-style-type: none"> <li>• Oversight of regulatory compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Support patient safety program</li> <li>• Funding and supporting safety-critical operations</li> </ul>	<ul style="list-style-type: none"> <li>• Resource allocation</li> </ul>
IT Specialist	<ul style="list-style-type: none"> <li>• Provide desktop support</li> </ul>	<ul style="list-style-type: none"> <li>• Connectivity</li> <li>• Data archiving/recovery</li> </ul>	<ul style="list-style-type: none"> <li>• Resources</li> <li>• Space</li> <li>• Vendor interoperability</li> </ul>
All Clinical Staff	<ul style="list-style-type: none"> <li>• Proper patient identification</li> <li>• Peer review</li> </ul>	<ul style="list-style-type: none"> <li>• QA/QI</li> <li>• Increased documentation in EHR</li> <li>• Evolving peer review</li> <li>• Compliance with evolving regulatory requirements</li> </ul>	<ul style="list-style-type: none"> <li>• Identification/discussion of near-misses</li> <li>• Continuous education</li> <li>• Increased reliance on EHR</li> <li>• Adequate instruction with software/technological advances</li> <li>• Dedicating time for safety initiatives</li> <li>• Minimizing distractions</li> </ul>

\*This is not an exhaustive list.

DIBH, deep inspiration breath hold; EHR, electronic health record; IGRT, image-guided radiation therapy; IMRT, intensity-modulated radiation therapy; IT, information technology; MRI, magnetic resonance imaging; PET, positron emission tomography; RT, radiation therapy; SGRT, surface guided radiation therapy; TPS, treatment planning system; TDS, treatment delivery system; QA, quality assurance; and QI, quality improvement.

### 3.3. EVOLVING STAFF ROLES AND RESPONSIBILITIES

Clinical staff must keep pace with changes in practice. **Table 3.1** summarizes some safety-related changes and associated challenges to the rapidly changing clinical teams' roles and responsibilities.

### 3.4. EXAMPLES OF TOOLS AND INITIATIVES TO FACILITATE SAFETY AND SAFETY CULTURE

The rationale for assessing quality is to be able to improve it in a measurable way. Assessment of outcomes, however, is challenging as they may not be realized immediately, and co-factors (e.g., multidisciplinary care, sample sizes, evolving technologies and patient characteristics) complicate risk adjustment models.<sup>10,11</sup>

The following is not an exhaustive list of quality and safety tools and initiatives. Given varying degrees of supportive evidence, the tools needed, and how to effectively use and assess the tools may be at the discretion of the individual practice.

#### 3.4.1. Staffing and Schedules

Staffing levels need to be adjusted to reflect the workload, particularly in physics, dosimetry and treatment, where the demands have markedly changed (e.g., patient-specific QA for IMRT). An excessive workload can lead to errors so schedules should be realistic to avoid and minimize rushing through a given task. Conversely, light workloads can also be problematic since a certain workload level is needed to maintain "situational awareness."<sup>12,13</sup>

#### 3.4.2. Communication and Facilities

Systems, workflows policies and culture that facilitate clear, unambiguous and efficient communication between all clinical staff is critical. This is particularly true between the clinical team, given the large number of hand-offs and interdependent tasks that routinely occur during the planning and treatment delivery processes. Well-defined charting procedures, either paper or preferably electronic, are critical. EHRs have become a vital tool to facilitate interdisciplinary and multidisciplinary written communication and appropriate approval/attestation of documentation. The implementation of these systems is a

multifaceted and costly investment for a practice; however, there are clear benefits in terms of retrieving documentation and communication.<sup>14</sup>

For practice layout, centrally locating dosimetry and/or establishing dedicated time for radiation oncologists and dosimetrists to work together facilitates the iterative "directive-segment-computation-review-repeat" cycle. This is a challenge when physicians and planning staff rotate between facilities.

Enhanced tools are needed to enable efficient and accurate communication and the transfer of complex 3-D data between practices. A well-defined communication pathway between clinical staff will verify messages are sent/received and reduce the need for ad hoc and variable solutions.

#### 3.4.3. Standardization

Standardization is widely recognized as a means to reduce errors. Due to personal preference, clinical staff may utilize diverse approaches to processes to reach the same end goal. Having too many diverse approaches may lead to confusion, particularly given the numerous interactions between staff. Additionally, rotating between different physical locations and/or equipment may exacerbate misunderstandings. Adopting consistent practices agreed upon by staff establishes consistent expectation and processes.

Miscommunication of the treatment prescription can be a pervasive safety concern, as identified by RO-ILS® data. In response, ASTRO published a white paper standardizing the key elements of a prescription<sup>15</sup> and encourages adoption of these elements into standard practice. Critical prescription components should be presented in the following order: treatment site, method of delivery, dose per fraction (in cGy), total number of fractions and total dose (in cGy). Beyond the key prescription components, the radiation oncologist needs to provide additional details to guide treatment (e.g., prescription point or volume, treatment schedule, setup instructions and treatment imaging order).

Additionally, it is helpful for the clinical team to agree on standard approaches to common diseases within the practice (e.g., protocols, reference or guide sheets) to avoid confusion. To support this, the AAPM Task Group 263 has defined standard nomenclature for targets and OARs commonly used in treatment planning.<sup>16</sup> Widespread adoption of this standard nomenclature will likely decrease treatment planning confusion in practices, especially those with multiple facilities and clinical staff.

Standard treatment practices and QA mechanisms, as well as associated policies and procedures, should be vetted through a review committee and required for every technique or disease site, with regular updates, as needed. These SOPs should be posted with easy access for those referring to them.

#### 3.4.4. Lean Methods

Radiation treatments frequently require delivery of high doses of radiation in a compressed timeline, compounding the pressures of complex medical care.

Adapted from the Toyota Production System, some have utilized 'lean' approaches to streamline clinical workflow and alter the work environment.<sup>17</sup> The Kaizen methodology can be beneficial in the implementation of rapid improvement projects.<sup>18</sup> To begin, relevant staff create process maps for particular tasks. Value-added steps in the process map are identified, nonessential steps and unnecessary stressors are eliminated, resulting in a more streamlined, unambiguous standardized process which increases available time for critical tasks. Having stakeholders meet to discuss and define their work builds teamwork and mutual respect, while fostering an environment in which staff can positively impact their work.

#### 3.4.5. Risk Analysis

AAPM's Task Group 100 described another structured framework within which the clinical team can analyze and mitigate risk to enhance the safety and quality of a clinical process.<sup>19</sup> The Task Group 100 approach also starts with the clinical team developing a process map.

In failure modes and effects analysis (FMEA), individual steps of the process map are analyzed for ways in which the desired outcome of a step may not be achieved. These are known as potential failure modes. For each potential failure mode, three components are assessed and assigned a numerical value from zero to ten:

- Severity (possible outcome on a patient);
- Occurrence (how likely it is that the failure pathway occurs); and
- Detectability (how likely is it that the failure pathway, once initiated, will not be intercepted).

The numerical values of the three parameters are multiplied together to calculate the risk priority number. By ranking potential failure modes according to risk priority numbers, FMEAs enable the clinical team to understand where safety and quality issues could arise and their relative priority.

To gain further insight into how the potential failure modes might occur and propagate, the clinical team can utilize fault tree analysis (FTA). FTA is used to graphically describe how a possible cause or contributing factor could lead to a particular failure mode (i.e., a failure pathway). A series of FTAs can identify systemic issues within a clinical process and provide a basis for discussion on where in the pathway to place QA and quality control (QC) interventions.

Overall, the Task Group 100 approach combines process maps, FMEA and FTA to evaluate and change workflow safety and efficiency.

#### 3.4.6. Hierarchy of Effectiveness

Different methods used to affect behaviors have variable expectations for success.<sup>20</sup>

While a component of safe practice standards come from policies, procedures and training, they should not be solely relied upon as other strategies (e.g., computerization, standardization) are more effective. In a large database of errors from the State of New York, "failure to follow policies/procedures" was implicated as a contributing factor in 84 percent of events, versus "inadequate policies/procedures" in 16 percent of events. RO-ILS<sup>®</sup> reached the same conclusion within radiation oncology.<sup>21</sup> Whenever possible, it is best to "hardwire" the systems for success using simplification, standardization, automation and forcing functions to create workflows and systems that support human work.

Checklists and time-outs are effective especially if:

- They are focused on the task at hand;
- The user believes in their utility; and
- The user is forced to use them (e.g., "hard stop").<sup>22-24</sup>

Overall, "knowledge in the field" (automatic computer/machine functions and checklists) is more likely to improve human performance than is "knowledge in the head" (memory).

Regardless of the method, regular review mechanisms to evaluate workflows, policies and procedures should be used to ensure relevance to current practice. As mentioned in Section 3.4.5, an FMEA approach can be employed for such a review process.

### 3.4.7. Systems and Human Factors Engineering

Rather than focusing mainly on components, systems engineering is “an interdisciplinary approach and means to enable the realization of successful systems.”<sup>25</sup> “Systems engineering focuses on the system as a whole through all life cycles with particular emphasis on communication, uncertainty and complexity in the interaction of its components (including humans).”<sup>26</sup> With upfront discovery, learning, diagnosis and dialogue, a patient’s qualitative needs can be translated into quantitative product(s) and process specifications.

Human-machine interactions are ubiquitous. Human factors engineering aims to define processes, interfaces and machinery that facilitate correct usage.<sup>27</sup> For example, the forcing function of an automated teller machine can require withdrawal of the bankcard before money is dispensed. Similarly, placing console control buttons that perform particular functions in a consistent location enables users to more reliably operate equipment in a predictable and correct manner. Safety can also be improved with workspaces that are designed to reduce noise, interruptions and visual clutter. Improving lighting, temperature and desk height are additional factors proven to affect performance.

In the radiation oncology field, complicated computer screen layouts, keyboard functions and treatment consoles are a few examples of the countless human-machine interfaces that are navigated daily. These require increasing mental effort as they become more complicated or lack standardization. Many are designed with safety and operability in mind, but there is ample room for improvement. For example, within individual products, shortcut keyboard commands should be consistent whenever possible. Standardization of nomenclature, monitor layouts and shortcuts across different vendors are examples of enhancements that might also be helpful. A RO-ILS® aggregate report discusses human factors engineering in the events submitted to RO-ILS and provides case studies and suggestions for improvement.<sup>28</sup>

### 3.4.8. Automated QA Tools

Individual QC steps during simulation, treatment planning and pretreatment delivery via checklists or automation are important for safe delivery of treatments.<sup>29</sup> A logic-driven system for developing simulation and treatment planning directives/orders can help eliminate errors. For example, if a 4-D scan is selected for a lung SBRT case, the logic-driven system will also identify appropriate SBRT immobilization and other treatment-related devices. Simulation and treatment planning directives/orders are widely available, either in paper

form or incorporated in the existing oncology information system (OIS); however, automating and incorporating context-sensitive logic has been found to improve quality and safety.<sup>30</sup> To reduce planning variability, groups have worked to automate treatment planning using various methodologies, and these are being incorporated in commercial TPS.<sup>31</sup> In addition to routine pretreatment QA tests for IMRT delivery, integrity of data transfer from the TPS to the TMS needs to be verified, particularly when occurring between different vendor systems and this functionality is being implemented.<sup>32</sup> Finally, real-time checks of delivered treatments using the machine log files<sup>33</sup> have been commercialized and have the potential to detect differences between the planned and delivered treatment fields.

More development and adoption of automation is needed. The future direction of embedded automatic QA functions may include:

- For a new plan, the system searches its directory archive for patients with the same name to identify inadvertent retreatment.
- For common diagnoses, the TPS compares the proposed target volumes and associated dose parameters to a library of user-specified “expected” parameters and issues predefined alerts.
- Normal tissue dose-volume parameters are compared to user-specified constraints.
- Automatic highlighting of under-dosed target or normal tissue hot-spots.
- Beams and plans are named automatically to reflect the dosimetrist, date, etc.
- Common nomenclature is used for target volumes, OARs and plans to facilitate review of plans and identification of outliers.
- Flagging couch angle limitations.

### 3.4.9. Peer Review

Peer review is an essential part of the safe delivery of radiation and an important aspect of a lifelong learning program for the clinical team.<sup>34,35</sup> It is relevant in a number of different aspects of clinical practice (e.g., overall review of individual skills, methods and behavior) and is applicable throughout the RT process. Peer review can take many shapes and forms, including: intradisciplinary (e.g., physician to physician), interdisciplinary (e.g., amongst the radiation oncology clinical team) and multidisciplinary (e.g., with other specialties).

A distinction must be made between QA and peer review (**Table 3.2**). QA is often taken to relate to objective/

quantitative “right versus wrong” actions (e.g., Was the correct plan sent from the TPS to the treatment machine? Is the machine beam output correct?) that can readily lead to major clinical events that affect one or many patients. Peer review is often used to refer to somewhat more subjective items such as target definition or dose selection. Historically, QA was heavily physics-, planning- or therapy-based and peer review was a physician-focused activity. However, this distinction can be readily blurred. For example, an independent check of machine QA may be considered peer review. Similarly, a physician can make gross errors in target delineation (e.g., mislabeling the left atrium as a subcarinal lymph node) or misinterpreting published data, leading to systematic errors in treatment recommendation that could affect many patients.

All clinical staff benefit from receiving input and feedback from their fellow colleagues. For example, intradisciplinary physician review of target delineation and image segmentation prior to planning is beneficial. Other intradisciplinary peer review examples are presented in **Table 3.2**. Though not addressed in this document, intradisciplinary review processes for nursing and advanced practice providers are also important for the overall medical care of patients. There is additional utility to interdisciplinary peer review, often conducted as a part of the chart rounds process. A dosimetrist might note inconsistencies in the segmentations and directives, and

anticipate dosimetric challenges (e.g., “I cannot meet both the spinal cord and the planning target volume doses due to their proximity”) prior to initiating planning. Interdisciplinary interactions allow clinical staff an opportunity to communicate effectively with other members of the clinical team. The multimodality treatment of cancer patients often necessitates discussion of patient care with members of the multidisciplinary care team (e.g., tumor boards). See Chapter 4, Sections 4.1.5 and 4.1.6, for more details.

The timing of peer review can alter its impact. Prospective peer review is critical because once treatment has been initiated, the threshold for making a meaningful change is relatively high because of time-consuming replanning and QA requirements.<sup>36-38</sup> Establishing a preplanning/treatment meeting facilitates a healthy interdisciplinary dialogue that can make the subsequent planning and treatment processes smoother. It also supports safety culture but may require more time between simulation and treatment. There is also value in retrospective review processes as a learning tool. Steps for more effective peer review in brachytherapy should be considered, given the challenges of real-time peer review in an operating room environment involving implant placement, planning and delivery within a single session, particularly in practices with a limited number of radiation oncologists experienced in brachytherapy.

**Table 3.2. Examples of Intradisciplinary Peer Review and Quality Assurance Items\***

Team Member	Peer Review	Quality Assurance
Physician	<ul style="list-style-type: none"> <li>• Target definition</li> <li>• Dose selection</li> <li>• Technique selection</li> </ul>	<ul style="list-style-type: none"> <li>• Verify appropriate nomenclature and documentation</li> <li>• Verify dose constraints are within policy</li> <li>• Review portal films</li> </ul>
Physicist	<ul style="list-style-type: none"> <li>• Independent check of treatment machines’ output calibrations</li> <li>• Auditing plan reviews</li> </ul>	<ul style="list-style-type: none"> <li>• Verify the correct transfer of data from the TPS to the TMS</li> <li>• Plan review</li> </ul>
Dosimetrist	<ul style="list-style-type: none"> <li>• Assess selection of beam orientation and weighting</li> <li>• Plan optimization and evaluation</li> </ul>	<ul style="list-style-type: none"> <li>• Verify that prescription matches the treatment plan</li> </ul>
Radiation Therapist†	<ul style="list-style-type: none"> <li>• Double check patient setup accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure patient-specific procedure time-out</li> </ul>

\* Examples shown are items that might be divided into the peer review and quality assurance.

† In addition, two radiation therapists should always be available in the event of emergencies and as a “second set of eyes” to verify information during time-outs for procedures.<sup>39</sup>

### 3.4.10. Daily Morning Huddles

Having all clinical staff meet daily to review the upcoming clinical activities can be a useful exercise to preempt potential problems and promote team work and safety culture.<sup>40</sup> For example, the CT-simulation therapists can review the day's schedule, noting patients whose records lack clear directives. Patients presenting unique challenges or learning opportunities can also be identified and discussed. The availability or lack of openings for add-ons can be noted. Dosimetrists can alert the group regarding treatment plans that are proceeding more slowly than expected and seek direction. The chief radiation therapist can note to the group patients who will need pretreatment films/imaging reviewed that day, the daily patient treatment census and potential challenges (e.g., anesthesiology cases). All clinical staff are invited to raise concerns and make announcements. The morning huddle serves the practical function of trying to anticipate the upcoming challenges and avoid chaos in the clinic. It also serves a social and cultural function to bring the clinical team together daily, fostering an environment of easy communication among all team members.

### 3.4.11. Safety Rounds

Safety rounds may be characterized by brief, open discussions between key members of the leadership team and frontline staff at their worksite.<sup>41</sup> These periodic open forums may include asking staff about near-misses or unsafe conditions that could cause potential or real harm to patients or employees and gathering suggestions for improvements.

### 3.4.12. Routine Public Announcements and Updates

Issues relating to safety, quality or efficiency should be routinely included in all the practice's activities. For example, the morning huddle is a good opportunity for leadership to make announcements about ongoing safety-related initiatives.

Similarly, regular reports summarizing the outcomes of safety rounds can be provided to all staff members and posted in prominent locations throughout the practice. This demonstrates leadership's responsiveness and reinforces their commitment to process improvement. Achievements of staff working in these areas should be publicly acknowledged and celebrated. This helps to create an environment where people may be more willing to speak openly about safety concerns.

### 3.4.13. Incident Learning

Staff should be encouraged to report all safety events, including incidents (events that reached the patient, with or without harm), near-misses (events that did not reach the patient) and unsafe conditions (circumstances that increase the probability of a patient safety event occurring) and operational

improvements to a voluntary patient safety event reporting system.<sup>42</sup> The reporting of all safety events should be met positively, in a supportive environment, and without fear of punitive action. Increased event reporting and a strong safety culture are associated with fewer significant adverse events.<sup>43</sup> Therefore, emphasis should be placed on studying events and learning from them, in reducing the severity of events, the number of events progressing through one or more QA checks and the number of events reaching the patient. In a practice with a strong safety culture, a large number of events reported (especially with a high ratio of total reports to incidents) reflects the strength of this culture rather than the weakness of the practice. Incentive programs can facilitate such reporting. In the process of developing a safety culture that encourages open reporting, employees should have the option to submit information anonymously.

The study of near-misses is powerful in identifying work process problems that can lead to an incident. Near-misses should be addressed with a similar vigor and supportive environment as those applied to incidents and reported through the practice's QA committee. Launched in 2014, RO-ILS<sup>®</sup> provides practices access to a secure, web-based portal to enter, analyze and send patient safety data to a federally listed patient safety organization. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. Based on reported data from across the country, aggregate data reports are available to the public as a means of educating the entire radiation oncology field on error-prone processes and suggested corrective actions. RO-ILS is co-sponsored by ASTRO and AAPM, with support from the American Society of Radiologic Technologists and American Association of Medical Dosimetrists.

In addition to a voluntary incident learning system, safety events that reach a certain threshold may require external reporting and additional analysis. If a threshold has been met, reportable events must be reported to local, state and/or federal agencies in compliance with regulatory requirements.

### 3.4.14. Quality Assurance Committee

A dedicated formal QA committee should consist of an interdisciplinary clinical team (e.g., physicians, physicists, dosimetrists, nurses, radiation therapists) and other staff (administrative and IT support) that incorporates all disciplines involved in each treatment modality, meets regularly and serves as a liaison with leadership and health system-wide safety committees.

This committee should have the following responsibilities:

- Develops initiatives related to patient safety, which are feasible and work best for the individual practice.
- Ensures that a mechanism for reporting and monitoring safety events is in place, that leadership is aware of trends, and that a process exists for implementing change when needed.
- Monitors appropriate compliance with local, state and national safety, licensure and credentialing standards.
- Develops mechanisms to analyze all events reported through the incident learning system (Section 3.4.13).
- Develops mechanisms to investigate serious or potentially serious incidents in near real-time (e.g., <24 hours). Such mechanisms may include:
  - having a dedicated team on-call to meet with staff involved in an incident, to help in determining root causes of the error and to provide input on the potential impact of the error and on proposed solutions or recommended changes (if any).
  - reviewing publicly available reports from national and international reporting systems in radiation oncology to identify critical vulnerabilities found in other facilities.
  - frequent in-house auditing of compliance with policies and procedures. This allows the QA committee to identify barriers to adherence and proactively assess processes.
- Disseminates safety information to all staff through various communication methods and meetings (e.g., peer review meetings, the morning huddles and safety rounds, in addition to more formal safety, QA or possibly morbidity/mortality rounds).

Peer review meetings, QA committees, morning huddles and safety rounds are examples of initiatives that promote staff involvement in seeking positive change in their workspace. These activities help foster a sense of openness, mutual respect, group participation and responsibility. Staff should be encouraged to raise concerns and be reassured that reporting and raising safety concerns will not be punished.

### 3.4.15. Credentialing and Training of Staff

Radiation oncology is a technologically demanding field which is dependent on well-trained and highly-skilled members of the clinical team (Section 2.2). Clinical staff should have proper credentials and training in the simulation, treatment planning, treatment delivery and QA processes of each specialized treatment technique. It is crucial that team

members maintain the proper credentials, skills and training levels, satisfying clinical competencies annually.

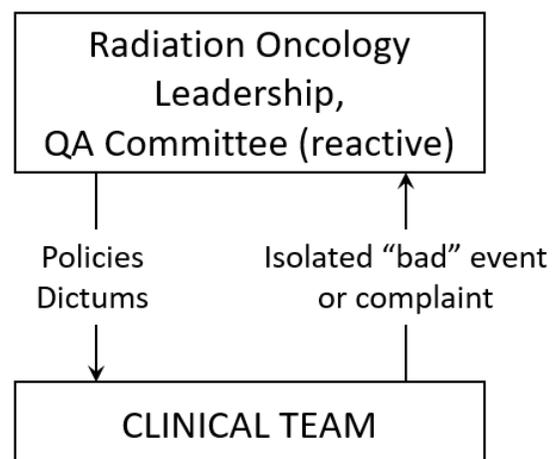
Staff should also be appropriately trained to use each specific device. In some cases (for example, radiation therapists moving between different kinds of treatment machines), additional training or review sessions on the use of specific devices may be necessary more often than annually. This may be challenging with new technologies where there are few training programs or the technology is rarely available. Nevertheless, practices must ensure that providers are qualified to deliver the appropriate care.

## 3.5. INGRAINING SAFETY INTO EVERYDAY PRACTICE

Safety and quality initiatives are often viewed as separate from routine practice. For example, QA meetings may be viewed as something that The Joint Commission requires or where the leadership reacts to events in the practice by generating rules/policies in a hierarchical manner that are often ignored. This is an unfortunate historical paradigm. A preferred approach is to ingrain safety considerations into the fabric of clinical operations, such that it is a natural component of evolving clinical practice (**Figures 3.1A and B**). This requires a persistent acknowledgement of safety concerns by the leadership to enable an increased mindfulness among the staff.

**Figure 3.1A. Hierarchical Model**

## HIERARCHICAL MODEL



**Figure 3.1B. Collaborative Model**

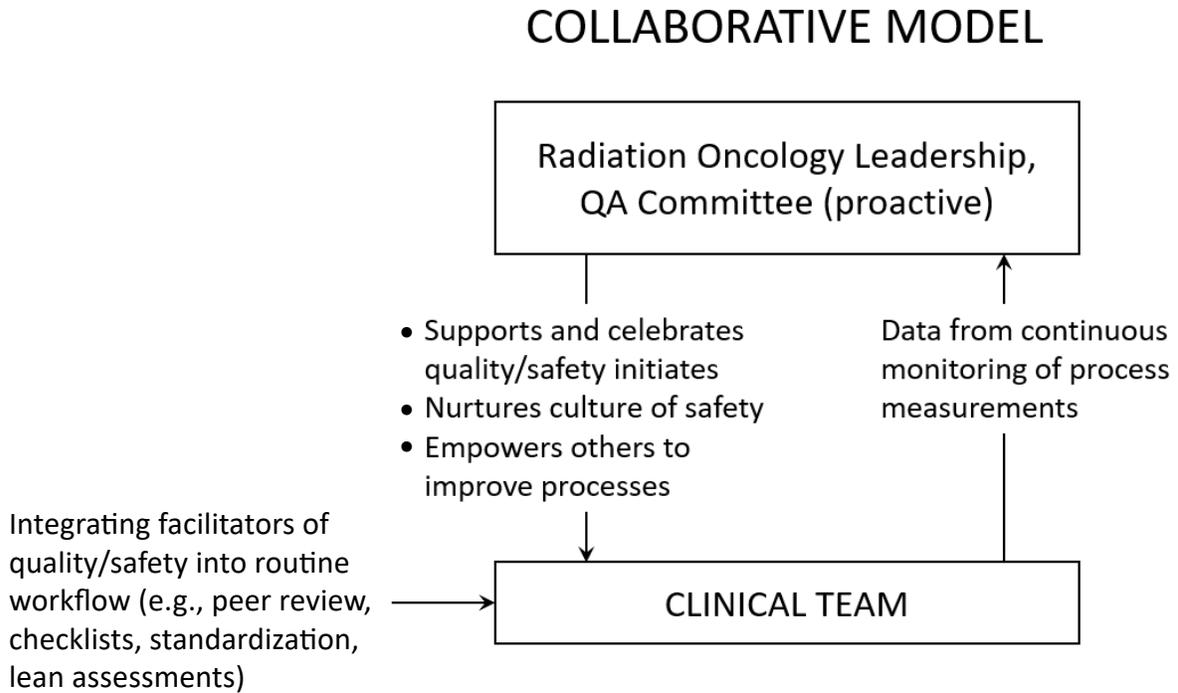


Figure 3.1. Panel A: Hierarchical model where practice leadership and QA committee operate in a largely reactive mode where policies and dictums are “handed down” to the staff, often in response to isolated events.

Panel B: Collaborative Model where practice leadership and QA committee proactively support and nurture a culture of safety. All staff are encouraged to become engaged in improving operations. Measures from the practice are continually monitored to assess for opportunities for improvement.

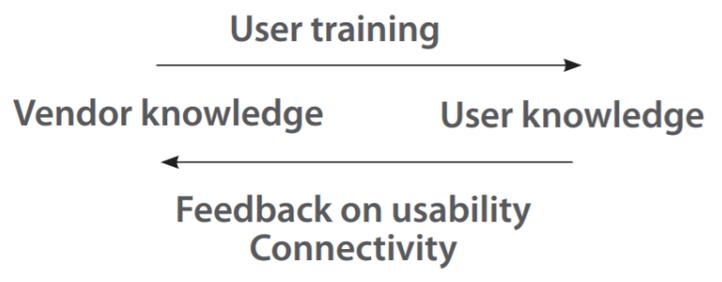
### 3.6. COLLABORATION BETWEEN USERS AND VENDORS

The practice of modern radiation oncology requires the use of multiple commercial products. To address safety concerns, a partnership with the vendors of these products must mature. An open exchange is needed where users and manufacturers work synergistically for the healthy evolution of safe and useful products to maximize the likelihood of optimal outcomes (Figure 3.2). Their responsibilities and opportunities are complementary. The vendor needs to educate the user as to the capabilities and limitations of their products. Users need to share their concerns with the vendors and work with them to improve products.

Vendors need to create user-friendly products to maximize the probability that they are used as intended (Section 3.4.7). Products should typically not be marketed until they are relatively free of known flaws, especially those with serious clinical implications. Vendors should be forthcoming with information about all known shortcomings of their products.

This should include challenges related to the integration of their products with other vendor’s products (i.e., even when the “problem” is not inherent to their product alone, but rather arises from the interaction with other products). Since these issues often only become known to the vendors as their products become more widely used, vendors need to share this information, as it evolves, rapidly with their wider user-base.

**Figure 3.2. User/Vendor Relationship**



Similarly, users need to operate products in the settings and modes in which they were intended, and use care when utilization is extended to uncharted territory. Problems, both real and potential, should be reported to the vendor (and regulatory agencies, as required) in a timely fashion, and with enough information and context to enable the vendor to make a full assessment. Users should take the time to familiarize themselves with the functionality of new or evolving products prior to their clinical implementation and communicate with the vendors so they can work together to seek needed improvements to products. There could be logistical challenges that limit the ability of vendors to rapidly alter products (e.g., U.S. Food and Drug Administration regulatory review, and user acceptance of “short cycle” upgrades).

The team tasked with managing the needs of the RT practice’s information technology must review and approve any and all software or hardware involved in treatment planning and delivery.<sup>44</sup> Vendor specifications and network connectivity requirements must be approved prior to the purchase of any new system (see Chapter 4, Section 4.1.6).

### 3.7. INVOLVING THOSE BEYOND RADIATION ONCOLOGY

Cancer care is multidisciplinary and often involves surgeons, medical oncologists, diagnostic radiologists, pathologists, internists (e.g., gastroenterology, pulmonary, neurology), social workers and others. Communication between disciplines is challenging but exceedingly important as treatment approaches involve multiple disciplines. Many of the initiatives and concepts described herein can, and should, be applied on a broader multidisciplinary scale (**Table 3.3**).

**Table 3.3. Interdisciplinary and Multidisciplinary Approaches to Quality in Cancer Care Delivery**

Radiation Oncology Initiative	Analogous Multidisciplinary Initiative
Pretreatment clinical team discussion	Tumor board
Daily morning huddle	Regular multidisciplinary meetings to review patients under treatment
Determining unambiguous methods of communication between clinical staff in the OIS	Determining unambiguous methods of communication between multidisciplinary care providers in an oncology-specific or health system-wide EHR
Safety rounds within radiation oncology	Safety rounds within the health system
Safety culture amongst radiation oncology staff	Safety culture within the health system
Discipline-specific training	Team training

EHR, electronic health record; and OIS, oncology information system.

## CHAPTER

# 4

# Quality Management and Assurance in Radiation Oncology

This chapter is focused on quality management (QM), which is the overall program that aims to organize all the efforts appropriately to promote quality, safety and consistency. QM systems provide a structure for doing things properly, efficiently and effectively. They aid both short- and long-term strategies to help a practice run smoothly, regardless of its size.

Discussed in detail later in this chapter, a practice's QM program will be comprised of many components, including:

- Radiation monitoring, including management of radioactive sources;
- Quality and safety, including incident learning;
- Staff education and peer review;
- Referral to other specialists;
- Patient management, including outcome measurement;
- Treatment process QA;
- Equipment and system QA; and
- Standardized processes documented in policies and procedures.

## 4.1. QUALITY REQUIREMENTS FOR RADIATION ONCOLOGY PRACTICES

### 4.1.1. Physical Requirements for Practices

A radiation oncology practice must satisfy numerous requirements, including but not limited to:

- General space requirements including providing adequate clinic space, exam rooms and equipment, patient waiting and private changing space, convenient patient parking, treatment rooms, office space for clinical staff (e.g., physicians, physicists, nursing) and physics laboratory/equipment storage space. The size of the practice should be appropriate for the total number of staff employed, volume of patients seen and treated, as well as the modalities and techniques offered.
- Treatment rooms for linear accelerators or other treatment machines (e.g., cobalt, robotic accelerator) must be carefully designed for radiation shielding, environmental conditions, adequate storage space for spare parts, testing and dosimetry/physics equipment, patient access and safety, while also allowing for installation, testing and repair of the treatment system. Treatment room design must include video and audio patient monitoring systems, dosimetry monitors (when required), and radiation-protected access conduits for electronic cables for dosimetry, computers and other systems.
- Each practice must have access to CT imaging for simulation and treatment planning. Radiation oncology CT-simulator room designs must protect staff from accidental radiation exposures, while allowing accurate patient positioning, immobilization device implementation or fabrication. If offered, the same requirements apply to other imaging modalities used for simulation (e.g., MRI, PET) with the

- additional requirement of an appropriate safety zone.
- If brachytherapy is offered, rooms used for procedures require special attention to the specific radiation protection requirements associated with the particular techniques. If the workload warrants it, a brachytherapy suite should be available, including patient waiting space, procedure rooms, recovery rooms (if necessary) and source preparation and storage area. The entire brachytherapy process should be performed within a well-designed and controlled space, to ensure radiation protection and source control that meets federal requirements.<sup>45</sup>

#### 4.1.2. Radiation Safety

Radiation safety, for patients, staff and service personnel, is an important responsibility for all members of the clinical team. This section summarizes the technical requirements for practices and safe use of equipment.

##### 4.1.2.1. Radioactive Source Procedures

All radioactive sources, and access to them, must be carefully controlled and monitored. Reports from AAPM Task Groups 56,<sup>46</sup> 59,<sup>47</sup> 138,<sup>48</sup> 144,<sup>49</sup> 160,<sup>50</sup> and 192,<sup>51</sup> outline safety and quality standards for the handling of radioactive sources consistent with state and federal regulations. The radiation oncologist, physicist and radiation safety officer should have radiation safety processes in accordance with societal and regulatory brachytherapy guidelines.

##### 4.1.2.2. Equipment Safety

Once the treatment room is correctly designed, staff procedures for accelerator use, patient treatment and other work performed in the accelerator room must be designed to limit patient and staff radiation exposure. Radiation shielding for each radiation area should be consistent with the workload and monitored for ongoing compliance when there are changes in utilization or equipment. These should be based on calculations and validated by radiation surveys performed by a qualified medical physicist.

Although clinical staff do not generally meet the requirements for mandatory radiation monitoring (anticipated exposure greater than 10 percent of the annual limit), it is recommended that they be monitored due to the magnitude of exposures when incidents occur. Staff assigned radiation monitoring must be trained annually on the current radiation safety procedures.

##### 4.1.2.3. Safety for Imaging Devices

There is a strong correlation between increased imaging and improved quality of delivery of the therapeutic dose. However, imaging during treatment adds dose to an already high level of radiation, therefore consideration of appropriate imaging is needed. The emphasis in RT should be to optimize imaging rather than to simply minimize dose. AAPM Task Group 75 provides guidance on optimal use of imaging and strategies for reducing imaging dose without sacrificing its clinical effectiveness.<sup>52</sup> Correspondingly, Task Group 180 provides recommendations on the inclusion of imaging doses in the TMS.<sup>53</sup>

#### 4.1.3. Program Accreditation

Each radiation oncology practice should become accredited by an established radiation oncology-specific accreditation program. This process verifies that crucial basic capabilities are in place, procedures necessary for quality RT are performed and general treatment quality is increased. Currently, multiple specialty-specific accreditation programs exist for radiation oncology. ASTRO's APEX<sup>®</sup> program is predicated on a self-assessment which provides applicants with the opportunity to confidentially self-study, assess their compliance with standards, and implement a process change if necessary. Through a review of documented policies and procedures and a site visit by a radiation oncologist and a physicist, APEX evaluates practices focusing on quality and safety of radiation oncology processes. Based on established practice parameters and technical standards, the ACR Radiation Oncology Practice Accreditation program assesses the practice's personnel, equipment, treatment planning and treatment records, as well as patient safety policies and QC/QA activities, through reviews of documented policies, procedures, performance measures and a site visit by a radiation oncologist and a physicist.

#### 4.1.4. Monitoring Safety, Quality and Professional Performance

One of the most crucial activities in a quality radiation oncology practice is the organized review and monitoring of all aspects of safety, errors and quality. Creating a culture of safety depends on guidance, direction and financial support from leadership, individual effort of every team member and organized support for quality and safety at every level in the practice. This section briefly describes a few of the health system- and practice-level activities that can help to create the necessary culture and awareness.

**4.1.4.1. Safety, Quality and Error Monitoring**

Each practice should have a review committee which monitors quality issues, near-misses and errors in treatment, diagnosis, patient care or other procedural problems that might lead to errors. This committee organizes the collection and analysis of safety events via an incident learning system in a non-punitive environment, works to identify potential problems in devices or processes, and then tries to mitigate these problems by modifying processes or adding new checks or actions to minimize the likelihood of further problems (Sections 3.4.13 – 3.4.14). The committee must regularly educate all staff about ongoing quality initiatives and continuously perform quality improvement. When applicable, these kinds of safety-related efforts, data and notes may be protected from legal discovery under state (e.g., peer review) and/or federal (e.g., Patient Safety and Quality Improvement Act of 2005) laws and regulations.

**4.1.4.2. Morbidity and Mortality Rounds**

Practices must at a minimum hold rounds quarterly, or more typically monthly, to review patient morbidity and

mortality, dose discrepancies and any incident reports involving an accident, injury or untoward effect to a patient. Morbidity and mortality reviews should include unusual or severe acute complications of treatment, unexpected deaths or unplanned treatment interruptions. Participants should represent all clinical staff and administrators. Minutes of the review should be recorded and may be protected based on state peer review statutes.

**4.1.4.3. Minimizing Time Pressures**

In order to avoid safety problems or quality lapses caused by rushing to meet unrealistic scheduling expectations, each practice should determine the appropriate time allocated for each step in the process of care. While the time needed to perform processes will vary between practices, **Table 4.1** provides a template, listing basic steps in the process. The goal of this effort is to avoid safety issues caused by time pressures, while satisfying the responsibility of the clinical team to set a course of action that will assure a timely, yet safe and accurate transition from patient clinical evaluation to treatment.

**Table 4.1. Scheduling and Minimum Process Time (Required for Safety)\***

Process Step	Minimum Process Time Required for Safety
After imaging: Completion of target volumes, definition of plan intent, normal structure volumes; anatomy approved	x days
After anatomy approval: Planning: 3-D CRT Planning: IMRT, VMAT Planning: SBRT Planning: SRS	x days x days x days x days/hours
Plan evaluation and radiation oncologist approval	x minutes (though x hours must be allocated to schedule this time)
Treatment preparation (transfer from TPS to TMS before treatment start)	Allow x hours
IMRT QA and/or other pretreatment QA measurements and analysis	To be completed x hours before treatment
Final checks before treatment (physics checks, dosimetry checks and therapy checks)	x minutes or hours
Treatment setup and delivery (based on complexity)	x minutes

\*Individual practices should create a table like this for their process(es) and circumstances, assigning appropriate values to the minimum process times (“x”). Cases identified as emergencies and other specialized techniques will require special consideration.

CRT, conformal radiation therapy; IMRT, intensity-modulated radiation therapy; TMS, treatment management system; TPS, treatment planning system; QA, quality assurance; SBRT, stereotactic body radiation therapy; SRS, stereotactic radiosurgery; and VMAT, volumetric-modulated arc therapy.

#### 4.1.4.4. **Monitoring Professional Performance**

Practice policies must exist for appropriate training and competency assessment of personnel (Section 3.4.15). Each practice must ensure that clinical staff are able to maintain continued competence in their job responsibilities. In addition to general roles, responsibilities and training requirements (Section 2.1), there may be specific needs depending on the treatment technique. For example, a list of roles, responsibilities and training requirements for each staff member related to IMRT is described in the Safety White Paper on IMRT.<sup>54</sup> Additionally, intradisciplinary peer review is an important tool to help individuals learn from colleagues and to monitor professional performance (Section 3.4.9).

#### 4.1.4.5. **Peer Review**

Each practice must have a well-developed strategy for peer review. This includes review processes for the entire practice and its procedures, for individual clinical care, and qualitative decisions made throughout the process of care (e.g., treatment plan quality, patient setup and technique acceptability). There may be variations between practices on their interdisciplinary and intradisciplinary peer-review processes, including:

- In most practices, details of each patient's evaluation and intent for treatment is briefly presented to the other radiation oncologists and clinical team and is used as early peer review for the basic treatment decisions and plan. This may be incorporated as a part of patient chart rounds or interdisciplinary prospective disease-site treatment planning conferences.
- After the radiation oncologist defines target volumes and normal tissues, when possible, another physician should review and confirm the contours before treatment planning begins.
- Chart rounds are an important interdisciplinary peer review procedure in RT. Treatment details such as pathology, informed consent, treatment site, prescription and dosimetry are reviewed. The ongoing review of patients under treatment is crucial, and many practices are attempting to develop improved methods for both peer review and technical QA techniques.
- Electronic peer review or other collaborative methods from other locations may be necessary, especially for small or remote practices.

Modern oncology patient care often involves multiple modalities and can benefit from the review and discussion of experts in various oncology-related disciplines. This is especially true for complex cases. Therefore, regular presentation of cases at multidisciplinary physician conferences (tumor boards) is encouraged to determine the appropriate combination (and coordination) of therapies for each individual case. An alternate approach is to have patients seen in traditional or virtual multidisciplinary practices by various specialists (e.g., surgeon, radiation oncologist, medical oncologist) in concurrent or sequential fashion. In smaller practices, the effort to obtain multidisciplinary input when needed is recommended and may include virtual conferences with a larger practice or external peers.

## 4.2. PATIENT-CENTERED QUALITY MANAGEMENT

Patient-specific issues, needs and outcomes must be carefully managed and analyzed.

### 4.2.1. **General Medical Issues**

Each radiation oncology practice, regardless of its location, size or complexity, must appropriately adhere to high-quality standards of practice by managing and documenting general medical issues, such as:

- Allergies to drugs and other agents (e.g., imaging contrast);
- Do-not-resuscitate orders;
- Cleanliness and efforts to reduce infection, including management of treatment-related devices and patients on contact precautions; and
- Monitoring of electronic implanted devices (e.g., pacemakers, defibrillators, insulin pumps, deep brain stimulators, cochlear implants).

### 4.2.2. **Patient Access to Multidisciplinary Care and Technique Specialists**

Each practice must have access to medical oncology, surgical oncology and other physicians involved in the multidisciplinary care of the patient. Additionally, access to dentistry, nutrition, laboratory testing and other supportive services is necessary for patient care or handling of patient toxicity that may arise during (or after) therapy.

A patient referral process for specialized treatment and/or other techniques not provided by the practice should be

supported and encouraged. Some practices may specialize in treating complex circumstances (e.g., pediatric cases) or advanced treatment delivery techniques (e.g., SRS, brachytherapy, proton therapy). These types of practices can provide focused expertise that may require special staffing and training.

#### 4.2.3. Outcome Assessment

Changes in patient response to treatment may identify large or even subtle changes in technique, equipment performance or clinical decision strategies, and are a valuable independent check on the success of the practice's overall QM system. Routine and consistent assessment of patient outcomes and toxicity during and after treatment should be performed in a systematic manner, preferably in the RT practice. Outcomes data is most accurate if obtained by the radiation oncologists or nonphysician providers in the practice where the patient was treated.

In many clinical circumstances, to determine a baseline status, performance status and organ function should be assessed prior to treatment. Following treatment, patient follow-up visits are crucial to clinical patient management and to gather information about treatment outcomes. The frequency and method of follow-up are specific to each type of cancer, stage and clinical status of the patient. When applicable, practices should always employ standard toxicity scoring schemes (e.g., NRG [formerly RTOG], European Organisation for Research and Treatment Center or similar). Additionally, practices should consider collecting patient-reported outcomes through validated instruments.

#### 4.2.4. Outcomes Registry

In addition to the assessment of outcomes by each individual practice for their local QA program, reporting clinical patient outcomes (e.g., treatment-related toxicity and control rates) to a shared registry serves an important role in the development of the "Rapid Learning Health System".<sup>55</sup> Registries also serve to

identify variations in technique, physician methods, process of care, patient selection and various other confounding variables that allow for improvement in treatment. When possible, outcomes information may be linked with government quality reporting programs.

#### 4.2.5. QA for the Standard Treatment Process

Nearly all treatment processes involve most or all of the following steps, each of which must be carefully confirmed as part of the patient-specific QA process:

- Determination of patient setup position and immobilization;
- Cross-sectional imaging (CT, MRI-simulation);
- Creation of the anatomical model (contouring);
- Specification of the treatment intent;
- Creation of the planning directive and treatment prescription by the radiation oncologist;
- Computerized treatment planning and/or dose calculation;
- Monitor unit or time calculation;
- IMRT leaf sequencing;
- Plan and electronic chart preparation;
- Plan evaluation;
- Transfer of data to TMS and from TMS to TDS;
- Patient-specific plan QA, typically performed for IMRT, SRS and SBRT;
- Patient setup and delivery;
- Plan verification checks;
- Plan adaptation and modifications; and
- Physicist and therapist weekly chart checks.

**Table 4.2** describes a standard set of QA process steps commonly used to help prevent errors or loss of quality in most standard treatment processes. The sequence and appropriateness of these steps may vary depending on clinical presentation and circumstance.

**Table 4.2. General Clinical QA Guidelines\***

Subject	Checks Performed By	Tasks	Most Efficient Timing
Overall treatment strategy	Radiation Oncologist Peer Review, Multidisciplinary Physician Conference/ Clinic	Review of patient case, clinical issues, possible treatment strategies, overall patient treatment strategy to be pursued; peer review of general treatment strategy.	Before planning process
Planning directive	Radiation Oncologist, Dosimetrist, Physicist	Describe plan intent, target volumes, dose expectations, normal tissue limits, other treatment constraints or goals; peer review of goals and limits is important. <sup>56,57</sup>	Before planning process
Approval of volumes	Radiation Oncologist, Dosimetrist, Physicist	Verify accuracy and appropriateness of target volumes (including GTVs, CTVs, PTVs, ITVs (per ICRU-50, <sup>58</sup> ICRU-62, <sup>59</sup> and ICRU-70 <sup>60</sup> ) and critical normal tissues; peer review of target volumes and decisions is important.	Initial step of planning process
Treatment prescription	Radiation Oncologist, Dosimetrist, Physicist	Define dose fractionation techniques and dosimetric constraints.	Before final plan checks
Treatment plan quality	Dosimetrist, Physicist	Verify beam designs, dose calculation parameters and reasonability of dosimetric results; check evaluation metrics for correctness and compare to plan directive; peer review of plan adequacy, quality and complexity is important.	Before final physics and physician review, before plan preparation for treatment
Treatment plan approval	Radiation Oncologist	Approval of treatment plan.	Before final checks and clinical use
MU calculation	Physicist	Verify accuracy and appropriateness of MU calculation.	After plan approval; before plan download to TMS
Preparation and export of electronic plan	Physicist	Verify plan information has been prepared correctly and exported accurately from TPS into TMS.	Recommended at least one hour before treatment, as last-minute difficulties are a potentially serious problem
Patient-specific QA checks	Physicist	Dosimetric (e.g., IMRT) or geometric patient-specific checks of plan data, delivery accuracy, etc.	Typically, day before treatment starts
Day one treatment verification	Radiation Oncologist, Physicist, Radiation Therapist	Specific Day 1 verification methods, including portal imaging, patient SSD measurements, etc.	Day one: For each changed plan
Daily treatment verification	Radiation Therapist	Standard daily treatment protocol (includes patient identification, setup, prescription check, etc.)	Daily as part of each fraction
“Weekly” chart checks	Physicist	Formal procedure for chart check, including dose tracking, prescription, plan parameters, etc.	At least every five fractions (standard fractionation), as often as daily for fewer fractions
Final check	Radiation Oncologist, Physicist, Dosimetrist	Verify accuracy and completeness of the record of the patient’s treatment course, including the physician’s summary.	Following completion of treatment

\*This table describes optimal QA process checks which are commonly used during routine RT. There are a wide variety of times when these checks are performed. This table describes the timing that is likely the most efficient.

CTV, clinical target volume; GTV, gross target volume; ICRU, International Commission on Radiation Units and Measurements; IMRT, intensity-modulated radiation therapy; ITV, internal target volume; MU, monitor unit; PTV, planning target volume; QA, quality assurance; SBRT, stereotactic body radiation therapy; SSD, source to surface distance; TMS, treatment management system; and TPS, treatment planning system.

## 4.3. EQUIPMENT AND DEVICE QUALITY MANAGEMENT

Radiation oncology is a highly technical field which relies on computer-controlled treatment machines, interconnected imaging, delivery and planning systems and important ancillary equipment. This section describes general requirements for radiation oncology equipment and systems, including guidance on system-specific QA. For any device, system or process to be integrated into the process of care, many of the same general methods and issues must be addressed, as described here.

### 4.3.1. Equipment, Devices and Systems

#### 4.3.1.1. System Specification, Acceptance Testing, Clinical Commissioning and Clinical Release

Any new RT system should go through the following process as it is prepared for clinical use:

- **System Specification:** To prevent future safety or effectiveness problems, the following specifications should be carefully considered before acquisition, purchase or development: design, expectations, capabilities, tolerances, hazards, necessary training, usability and technical specifications.
- **System Connectivity:** To prevent data communication errors and clinical efficiency issues, each system should be interoperable and interconnectable with other systems in the practice (Section 4.3.1.4).
- **Acceptance Testing:** Acceptance testing must be overseen by a qualified medical physicist as defined by AAPM<sup>61</sup> and documented. Often, the documented acceptance criteria and/or testing methods are part of the specification for the system.
- **Clinical Commissioning:** A qualified medical physicist also oversees clinical commissioning, which includes all activities that must be performed to understand, document, characterize and prove that a given system is ready for clinical use. Determining the limitations under which the system can be safely used is one of the important parts of the commissioning process. Since commissioning is dependent on the clinical use(s) of the system which usually changes with time and clinical need, it is typically not a static activity that can be done only once. SOPs, training and hazard analysis is also part of the commissioning process.

Adequate time and resources must be allocated to the commissioning process, as errors during commissioning will likely result in systematic mistakes that may affect multiple patients. End-to-end testing is strongly encouraged to fully test a system prior to clinical implementation.

- **Clinical Release:** Each new system, device, capability and process is formally released for clinical use after clinical commissioning has been completed.

#### 4.3.1.2. Process QA

A QM program must be established for each new system or process and should include hazard analysis, QC, QA, training and documentation, and ongoing quality improvement efforts. This kind of program has many aspects:

- **Hazard Analysis:** Hazard analysis, the active evaluation of the potential for failures that will cause incorrect results or harm to the patient, may be performed for any new system, to help delineate issues which can benefit from QC, QA, training or other mitigation strategies. The methodologies, such as FMEA, that are prevalent in the industrial world are being adapted for process and quality improvement in health care.<sup>19</sup> See Section 3.4.3 for a brief outline of the Task Group 100 approach. The Joint Commission requires hospitals to select one high-risk process and conduct a proactive risk assessment at least every 18 months.
- **Quality Control:** QC includes activities that impose specific quality on a process. It entails the evaluation of actual operating performance characteristics of a device or a system, comparing it to desired goals and acting on the difference.
- **Quality Assurance:** QA includes all activities that demonstrate the level of quality achieved by the output of a process. QA checks, along with QC, are essential parts of the QM for most devices and systems, as they can check the output of potentially complicated decisions or actions performed by the system. The choice of which method depends on how to prevent errors most efficiently.
- **Training and Documentation:** Proper use of any system requires training staff in goals, methods, results, operation and evaluation of the quality of output. Documentation of SOPs is also critical to train new staff. Both training and documentation

should be updated often. In particular, it is often necessary to retrain staff after time away from a system, or to refresh current knowledge.

The QM program for each system, device or process should be individualized to attain the most effective safety and quality as efficiently as possible. Adequate time and resources should be allocated for the QM program, including regular peer review to monitor adherence.

#### 4.3.1.3. Maintenance

All devices, systems and processes (including QA tools) require adequate time, materials and resources for routine maintenance:

- **Mechanical Systems:** Routine mechanical and preventative maintenance programs are crucial to prevent major component failures, which can potentially lead to major safety problems. This includes auxiliary systems such as air compressors and water supply systems.
- **Electronic Systems:** Preventative maintenance in electronic systems can involve monitoring parameter values and behavior to look for components of the device that are beginning to fail or show undesirable performance.
- **Software Systems:** Since software is rarely bug-free, and the use of the system can evolve as experience is gained, software maintenance often involves the installation of new versions. This new version can be a simple “bug-fix” version with no planned new functionality, or it can be a major version upgrade with major new functionality and/or internal structure. Any new version (minor or major) may contain significant new problems that are unrecognized before commercial release of the software. Therefore, these upgrades may involve new testing, commissioning, QA and training as part of the release of that software. It is crucial to investigate the scope of any new software upgrade, and to design appropriate commissioning, QA and training to assure the safety of the clinical use of that new system.
- **Processes:** Similar to medical devices, electronics and software, processes also need routine maintenance. All processes evolve as they are used clinically. This evolution changes the potential failures that the process may be sensitive to, so the QM program associated with that progress must be modified as needed.

#### 4.3.1.4. Interconnectivity and Interoperability of Devices and Systems

Nearly all major pieces of radiation oncology equipment are computer-controlled or software-based devices, and they are mostly all interconnected. The safety and quality of treatment is dependent on the accuracy and completeness with which the various devices communicate data, commands and the overall process which is being performed. Any flaws in the communication protocols, interfaces or underlying system designs can allow errors, most of which will be systematic errors that regularly occur given a specific set of circumstances. These errors can be difficult to find without specific, formal hazard analysis and directed testing.

Practices must have a QA program in place to rigorously test and document the accuracy of all computer system interconnections, interfaces and interoperability. The Integrating the Healthcare Enterprise-Radiation Oncology (IHE-RO) program is one effort to improve interoperability and practices should evaluate the IHE-RO compliance of their software systems.

#### 4.3.1.5. External Review

Single points of failure or extremely unlikely combinations of errors can happen to anyone or any practice. Independent review of crucial aspects of any QM program by an external person or entity (e.g., Imaging and Radiation Oncology Core (IROC) Houston) is an extremely effective way to avoid those highly unlikely or single point failures and should be used wherever practical.

The creation of mechanisms to support the following independent, external reviews is recommended:

- Basic treatment machine calibration should be confirmed before clinical use and annually thereafter.
- Delivered dose should be validated through an externally provided end-to-end test.<sup>54,62</sup>
- Advanced treatment programs (e.g., IMRT, SBRT, SRS, IGRT, intraoperative radiation therapy [IORT]) should seek external peer review initially and at regular intervals thereafter.
- TPS implementation should be reviewed initially and at regular intervals. Comparisons can be detailed or more limited, as performed with the appropriately designed plan comparison strategies, including use of similar machine data and calculation methods.

- Treatment protocols and SOPs should be peer reviewed by an external accrediting body at least every four years.
- Additional aspects of a radiation oncology program will benefit from similar review, including the device calibration and QA program, clinical protocols and nursing support.

#### **4.3.1.6. Equipment Replacement, Upgrades and Additions**

Equipment requires replacement or upgrade(s) when they become technologically obsolete or reach the end of their life cycle. For example, the average life of a linear accelerator is typically 8-10 years if: the equipment is properly maintained; replacement parts are readily and economically available; and the operational characteristics and mechanical integrity meet performance and safety standards. A TPS requires replacement or upgrade when the hardware becomes obsolete or the software functionality limits its ability to satisfy the current standard of care. Continued use of outdated equipment creates challenges in maintenance as vendors may stop providing support for older models.

A TPS and/or TDS needs to be withdrawn from clinical service if it cannot be upgraded to warranty status, even if it is not technologically obsolete. This periodic replacement and renovation of equipment is necessary not only for quality care, but for patient and personnel safety and efficient economical operation. Equipment replacement must be justified based on clinical practice, not geographical or political needs.

Furthermore, the need for additional equipment in a specific practice should be based upon an increasing number of patients requiring treatment, changing complexity of treatment or addition of a new specialized service. An increased commitment to clinical research and teaching is another reasonable justification for equipment addition.

### **4.3.2. External Beam Radiation Therapy**

#### **4.3.2.1. Qualification of EBRT Personnel**

Clinical staff requirements include:

- Clinical experience with use of CT scanner equipped with CT-simulation software and laser alignment devices;
- Appropriate use of patient positioning and immobilization devices (mask, alpha cradle, etc.) to allow reproducible patient positioning;

- If MRI, PET or other imaging is used for planning, software and clinical knowledge, combined with experience in image dataset registration and information fusion;
- Anatomical knowledge and the ability to correctly contour target(s) and adjacent critical structures;
- Knowledge and experience with treatment planning software, including the ability to perform volumetric dosimetric analysis with dose-volume histograms and other plan evaluation metrics; experience creating optimized treatment plans, when indicated;
- Experience with design and use of beam shaping devices (including cerrobend blocks, multileaf collimators, compensators); and
- Experience with multiple photon energy linear accelerators with electron beams, on-board kilovoltage and megavoltage imaging devices and auxiliary localization imaging devices when available.

#### **4.3.2.2. Minimum Device Requirements**

Standard features required to deliver EBRT (e.g., 2-D, 3-D CRT and IMRT) include one or more photon energies, multiple electron energies, multileaf collimator, electronic portal imager and a computerized TDS and TMS. The equipment capabilities should be sufficient to provide a continuum of care for patients.

#### **4.3.2.3. Minimum QA Requirements**

A complete QM program with appropriate documentation is essential for each device and should include routine QA and QC procedures and daily, monthly and annual testing. See **Table 4.3** for basic QA/QC and clinical practice guidelines for these procedures. QA processes require direct oversight by the physics staff.

**Table 4.3. Basic External Beam QA Requirements**

Topic	Guidance Document(s)
Linear Accelerator Use and MLC	TG 40, <sup>63</sup> TG 142, <sup>64</sup> TG 148, <sup>65</sup> TG 135, <sup>66</sup> MPPG 8.a. <sup>67</sup>
3-D CRT and Treatment Planning	ACR 3-D Practice Parameter, <sup>68</sup> TG 53, <sup>69</sup> TG 180 <sup>53</sup>
IMRT	ASTRO IMRT Safety White Paper <sup>54</sup>
IGRT	ASTRO IGRT Safety White Paper <sup>70</sup>

ACR, American College of Radiology; CRT, conformal radiation therapy; IGRT, image-guided radiation therapy; IMRT, intensity-modulated radiation therapy; MPPG, medical physics practice guideline, MLC, multileaf collimator; QA, quality assurance; and TG, task group.

**4.3.2.4. Intensity-modulated Radiation Therapy and Volumetric-modulated Arc Therapy**

IMRT and VMAT are methods of delivering highly conformal therapy. In addition to the requirements for 3-D CRT, IMRT/VMAT also requires the following:

- The machine must be equipped with IMRT delivery capability, such as segmental or dynamic multileaf collimator delivery or physical compensators for modulation of the beam intensity and use computer-controlled delivery and verification of the IMRT plan for each treatment fraction.
- The IMRT planning and delivery system must be carefully commissioned, and techniques for routine patient-specific IMRT plan QA must be implemented, tested and characterized so that accuracy of individual patient IMRT plans are confirmed.
- It is the responsibility of physicists (along with other clinical staff) to modify existing QA programs to make them as effective as possible for the new treatments (e.g., flattening filter-free delivery) and to deal with evolution of the technology and capabilities of the equipment.

**4.3.2.5. Particle Therapy**

Particle therapy is a form of EBRT using particulate beams of energetic protons, neutrons or ions. Currently the most common type of particle therapy is proton therapy and trends are emerging in the use of light ion therapy (carbon ion).

**4.3.2.5.1. Minimum Device Requirements**

To ensure safe and accurate treatment planning and delivery of particle therapy, minimum device requirements include online image guidance, a robotic couch capable of six degrees of motion (three translations plus pitch, roll and rotation), a robust immobilization system, a computerized TMS to manage treatment preparation and delivery and adequate QA equipment.

**4.3.2.5.2. Minimum QA Requirements**

The precision and accuracy of both the treatment planning and delivery of proton therapy are greatly influenced by uncertainties associated with the delineation of volumes of interest in 3-D imaging, imaging artifacts, tissue heterogeneities, patient immobilization and setup, inter- and intra-fractional patient and organ motion, physiological changes and treatment delivery. Development of robust planning techniques are encouraged to minimize effects of intrafractional motion.

The physics of the dose deposition in media (i.e., Bragg peak), and its dependence on stopping power dictates the need for a stricter approach to all QA aspects of the process. For example, validation of Hounsfield unit conversion curves on the simulation-CT and exhaustive validation of the artifact reduction software (if used) is an additional burden on the program and requires additional staffing.<sup>71</sup>

Patient-specific QA is similar to that of IMRT/SRS with the use of detectors appropriately selected and calibrated for use with the specific treatment modality, with methods allowing 3-D dose deposition analysis preferred. For QA purposes, 2-D – 2-D matching may be suboptimal relative to 3-D IGRT. Additional time, compared to IMRT QA, is needed to conduct the appropriate analysis.

If exit dosimetry equipment is available, conducting daily gamma analysis to assure that the dose is delivered as planned is beneficial.

Some guidance documents are available on particle therapy (i.e., the ACR-ASTRO practice parameter<sup>72</sup> and ACR-AAPM technical standard for proton therapy<sup>73</sup>). It is the responsibility of physicists (and other clinical staff) to modify existing QA programs to meet the needs of particle therapy systems.

#### 4.3.2.6. Specialized Techniques and Devices

Advances in imaging, computer science and information technologies, coupled with the development of sophisticated radiation delivery systems, have resulted in a plethora of specialized RT techniques and devices. Robotic radiation delivery systems, stereotactic, IORT, superficial radiation therapy, MRI-guided RT, motion and setup management devices and unsealed radiopharmaceutical sources are some examples of such specialized techniques and devices. The delivery of these specialized techniques, including superficial RT, should be supervised, delivered and managed by radiation

oncologists working with appropriately trained physicists. **Table 4.4** provides a list of societal guidelines for various specialized techniques.

Each of these techniques and devices have unique performance and QA requirements that should be critically evaluated before introducing them in the practice. Issues for consideration include: reason(s) for device/technique introduction and use; minimum requirements to use the device safely; description of how to introduce the device; necessary training; and need to compare the clinical objectives for use and outcomes with the current clinical standard.

The development of guidelines on new technologies usually lag behind their clinical implementation. It is incumbent upon the early adopters of emerging technologies and techniques, particularly radiation oncologists and physicists, to develop clinical procedures and QA programs that can ensure safe and efficient use of specialized techniques and devices in the absence of published guidance documents.

**Table 4.4 General Procedure Guidelines**

Specialized Technique/Modality	Guidance Document(s)
3-D External Beam and Conformal RT (EBRT, CRT)	ACR Practice Parameter <sup>68</sup>
Image Guided Radiation Therapy (IGRT)	ACR-ASTRO Practice Parameter, <sup>74</sup> ASTRO White Paper <sup>70</sup>
Intensity-modulated Radiation Therapy (IMRT)	ACR Practice Parameter, <sup>75</sup> ASTRO White Paper <sup>54</sup>
Stereotactic Radiosurgery (SRS)	ACR Practice Parameter, <sup>76</sup> ASTRO White Paper <sup>77</sup>
Stereotactic Body Radiation Therapy (SBRT)	ACR-ASTRO Practice Parameter, <sup>78</sup> ASTRO White Paper, <sup>77</sup> AAPM TG 101, <sup>79</sup> AAPM-RSS MPPG 9.a. <sup>80</sup>
Total Body Irradiation (TBI)	ACR-ASTRO Practice Parameter, <sup>81</sup> AAPM TG 29 <sup>82</sup>

AAPM, American Association of Physicists in Medicine; ACR, American College of Radiology; ASTRO, American Society for Radiation Oncology; CRT, conformal radiation therapy; EBRT, external beam radiation therapy; IGRT, image-guided radiation therapy; IMRT, intensity-modulated radiation therapy; MPPG, medical physics practice guideline; PBI, partial breast irradiation; RSS, Radiosurgery Society; SBRT, stereotactic body radiation therapy; SRS, stereotactic radiosurgery; TBI, total body irradiation.

#### **4.3.2.6.1. Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy**

SRS and SBRT either use multiple beams or conformal/modulated arcs carefully shaped to the target to deliver RT in five or fewer fractions with high precision (e.g., IGRT guidance). While SRS is typically confined to the brain and spine, clinical data on the use of SBRT to sites in the body has been growing.

For patients treated with SRS or SBRT, a qualified radiation oncologist must be present at the start of the treatment fraction.<sup>77</sup> A qualified medical physicist must be present for the entirety of the first treatment and must be present in the practice and immediately available for assistance for any subsequent fractions.<sup>80</sup> Use of radioactive materials for either SRS or SBRT is regulated by the Nuclear Regulatory Commission, requiring appropriate personnel to supervise the treatment.<sup>83</sup>

#### **4.3.2.6.2. Intraoperative Radiation Therapy**

IORT is most commonly given as a single boost dose with electrons, low kV x-ray, or HDR brachytherapy, and may be combined with standard fractionated EBRT for patients treated with curative intent. Occasionally, IORT is given as the only component of irradiation (e.g., primarily early breast cancer). In view of the large single fraction size, a qualified radiation oncologist and physicist should be present for the treatment. IORT performed with radioactive materials is regulated by the Nuclear Regulatory Commission, requiring appropriate personnel supervise the treatment.<sup>83</sup>

### **4.3.3. Brachytherapy**

#### **4.3.3.1. Qualification of Brachytherapy Personnel**

Brachytherapy personnel require enhanced, technique-specific expertise. Board certification or eligibility is required for the radiation oncologist and the physicist must meet the requirements as an Authorized Medical Physicist.<sup>84</sup> The clinical team should undergo at least annual training per Nuclear Regulatory Commission regulations and meet any additional state requirements.<sup>85</sup> Trained personnel must be appropriately informed and work together to ensure accurate and safe treatment of a variety of well-defined procedures. Performing cross-team double checks prior to each treatment is essential for minimizing delivery errors. To administer HDR brachytherapy, the authorized user and an Authorized Medical Physicist must be physically present for the initiation of treatment. During the HDR treatment, an Authorized Medical Physicist and either an authorized user or a physician under the supervision of an authorized user, must be physically present.<sup>83</sup>

#### **4.3.3.2. Minimum Device Requirements**

The field of brachytherapy has grown into a subspecialty with devices developed specifically for each disease site; it is not feasible to outline the minimum standards for each device. However, the expected minimum standard is to provide at least the same current level of safety and capability as existing devices. Several organizations have generated guidelines that review details of the processes required for proper patient care for specific disease sites (**Table 4.5**).

**Table 4.5. General Brachytherapy Guidance for Specific Clinical Sites**

Site	Issue	Guidance Document(s)
General Principles	HDR	ACR-ASTRO Practice Guideline, <sup>86</sup> ACR-AAPM Technical Standard, <sup>87</sup> ASTRO White Paper <sup>88</sup>
	LDR	ACR-ABS Practice Parameter <sup>89</sup>
Gynecology	General principles	ABS Consensus Guidelines, Part I <sup>90</sup>
	HDR	ABS Consensus Guidelines Part II, <sup>91</sup> ABS Recommendations <sup>92</sup>
	LDR/PDR	ABS Consensus Guidelines Part III, <sup>93</sup> ABS Recommendations <sup>94</sup>
	Contouring	GEC-ESTRO Working Group I <sup>95</sup>
	Dose-volume parameter reporting	GEC-ESTRO Working Group II <sup>96</sup>
	Postoperative cylinder	ABS Recommendations, <sup>97</sup> ABS Consensus Guidelines <sup>98</sup>
	Vaginal cancer interstitial	ABS Consensus Guidelines <sup>99</sup>
Prostate	LDR	ACR-ASTRO Practice Guideline, <sup>100</sup> ACR Appropriateness Criteria, <sup>101</sup> ACR-ABS Practice Parameter, <sup>102</sup> ABS Recommendations, <sup>103-105</sup> ABS Consensus Guidelines <sup>106</sup>
	HDR	ABS Consensus Guidelines <sup>107</sup>
Breast		ASTRO Consensus Statement, <sup>108,109</sup> GEC-ESTRO Recommendations, <sup>110</sup> ABS Report, <sup>111,112</sup> ABS Consensus Statement <sup>113</sup>
Esophageal	Endoluminal	ABS Consensus Guidelines <sup>114</sup>
Liver		ACR-SIR Practice Parameter, <sup>115</sup> AAPM TG 144 <sup>49</sup>
Vascular		ABS Perspective, <sup>116</sup> GEC-ESTRO Recommendations <sup>117</sup>
Sarcoma		ABS Recommendations <sup>118</sup>
Head and Neck		ABS Recommendations <sup>119</sup>
Uveal Melanoma		ABS Recommendations <sup>120</sup>

AAPM, American Association of Physicists in Medicine; ABS, American Board of Surgeons; ACR, American College of Radiology; ASTRO, American Society for Radiation Oncology; ESTRO, European Society for Radiotherapy and Oncology; GEC, Groupe Européen de Curiethérapie; HDR, high-dose-rate; LDR, low-dose-rate; MR, magnetic resonance; and PDR, pulsed-dose-rate.

#### 4.3.3.3. Minimum QA Requirements

The QA process for brachytherapy is similar to that of EBRT and involves many of the general components listed in Section 4.2.5. Additionally, patient-specific QA management includes: applicator commissioning; applicator periodic checks; imaging (e.g., CT-simulation, ultrasound or plain film) checks. Some aspects of QA directed at preventing errors in treatment planning and delivery specific to brachytherapy are summarized in **Table 4.6**.

#### 4.3.4. Imaging Devices

The utilization of IGRT is growing as use of hypofractionation increases and treatment margins decrease (planning target volume margins) and is an increasingly important component of treatment delivery.

Numerous imaging modalities are an integral part of the RT planning process (e.g., CT, MRI, PET) and are used during treatment for patient setup, positioning, alignment, motion assessment and IGRT (e.g., megavoltage portal imaging, kilovoltage imaging, ultrasound imaging, cone beam CT, radiofrequency beacons). Diagnostic systems used in RT (e.g. CT, MRI, PET) must satisfy the usual diagnostic QA requirement,<sup>132-134</sup> plus the more stringent requirements necessary for the use of the images for patient and beam geometry. QA for the kV and MV imaging systems which are used for patient localization, setup and motion assessment is described in AAPM reports,<sup>64-66,135-139</sup> ASTRO's IGRT Safety White Paper<sup>70</sup> and the ACR/ASTRO IGRT Standard of Practice.<sup>74</sup> These guidance documents should be followed to appropriately handle the specific requirements of the IGRT

or other positioning techniques (e.g., surface guided RT) but modified when necessary. Staff should pay close attention to the tolerances as the process allows.

Finally, the advent of adaptive and individualized approaches to the treatment course, based on advanced imaging, has led to new QA requirements for the use of these systems. The use of functional and metabolic imaging as part of the adaptive treatment process is a developing technique. For each specific metric, biomarker and/or decision process used for adaptive treatment strategy changes, the sensitivity, repeatability and tolerances of the metrics with respect to their clinical use must be considered as specific QA methods are developed.

#### 4.3.5. Commissioning and QA of the Treatment Planning and Delivery Process

Commissioning and QA of the processes used for treatment planning and delivery is just as important as the commissioning and QA for the equipment and systems.<sup>62</sup> After testing each component of the clinical system, it is essential that the full process be considered, tested and finally released after commissioning has been completed. This process typically includes the following:

- Commissioning and testing of each individual component of the process;
- End-to-end testing for representative treatments, performing the entire process, with dosimetric or other quantitative tests that can be evaluated at the end of the test to confirm accurate delivery of the planned treatment;

**Table 4.6. Brachytherapy Devices**

Brachytherapy Sources or Devices	Guidance Document(s)
General	TG 32, <sup>121</sup> TG 40, <sup>63</sup> TG 43 <sup>122</sup>
HDR and PDR afterloaders	TG 56, <sup>46</sup> TG 121, <sup>123</sup> TG 138, <sup>48</sup> TG 41 <sup>124</sup>
LDR sources	TG 59, <sup>47</sup> TG 137 <sup>125</sup>
Electronic brachytherapy devices	TG 72 <sup>126</sup>
Unsealed radioactive sources	TG 167, <sup>127</sup> TG 144 <sup>49</sup>
IVBT sources	TG 60, <sup>128</sup> TG 149 <sup>129</sup>
Applicators	TG 56, <sup>46</sup> TG 167 <sup>127</sup>
Hardware	TG 56 <sup>46</sup>
Imaging devices	TG 56 <sup>46</sup>
TPSs and dose calculation processes	TG 32, <sup>121</sup> TG 40, <sup>63</sup> TG 43 <sup>122</sup> , TG 180, <sup>53</sup> TG 53, <sup>69</sup> TG 56 <sup>46</sup>
Survey instruments, badges, radiation safety	TG 32, <sup>121</sup> TG 40, <sup>63</sup> TG 56 <sup>46</sup>
QA	ACR-AAPM Technical Standard, <sup>87</sup> ESTRO, <sup>130</sup> IAEA <sup>131</sup>

HDR, high-dose-rate; IAEA, International Atomic Energy Agency; IVBT, intravascular brachytherapy; LDR, low-dose-rate; PDR, pulsed-dose-rate; TG, task group; and TPS, treatment planning system.

- Identification of quality metrics which can be monitored to ensure that the process is performing as designed and which can help identify problems in the process;
- Directed testing of the interfaces between systems (i.e., testing the download connection from TPS to the TMS and TDS);
- Periodic beam data constancy checks; and
- Risk assessment of the process using a hazard analysis or similar technique to look for potential weak points in the process (Section 3.4.5).

### 4.3.6. Treatment Planning Systems

#### 4.3.6.1. Minimum Device Requirements

High-quality and comprehensive treatment planning using 3-D computerized treatment planning for dose calculations, image generation and other aspects of the planning process, is essential. At a minimum, this should be performed on a CT image data set generated during simulation. Safe and effective use of planning requires direct input of CT, MRI and other imaging information; the ability to define (by contouring and

other segmentation) 3-D anatomical objects (targets and normal tissues); beams and/or radioactive sources defined in 3-D; well-characterized and accurate dose calculations; reproducible beam characteristics; heterogeneity corrections; dose-volume histograms and other plan evaluation metrics; and electronic downloading of treatment plan information to the TMS. Many special treatment techniques require use of additional planning capabilities (**Table 4.7**).

#### 4.3.6.2. Minimum QA Requirements

QA of the hardware, software and process used for planning is the responsibility of physicists. AAPM's Medical Physics Practice Guideline 5.a.<sup>62</sup> and Task Group 53<sup>69</sup> provides guidance on using modern treatment planning in a safe and appropriate way, including discussion of acceptance testing, clinical commissioning, routine QA, training, dosimetric and nondosimetric testing, and more, while more specialized technique issues are described in **Table 4.7**. Specific dose calculation algorithm issues are described by a number of reports, including the Task Group 105 on Monte Carlo treatment planning issues.<sup>143</sup>

**Table 4.7. Additional Treatment Planning Requirements**

Technique	Requirement	Guidance Document(s)
IMRT/VMAT	Automated optimization, cost function creation, MLC sequencing (or equivalent delivery script creation)	TG 119, <sup>140</sup> ASTRO White Paper, <sup>54</sup> ACR Practice Parameter <sup>75</sup>
SBRT	Preparation of IGRT reference data (annotated DRRs or reference data for CBCT comparisons)	ASTRO White Paper, <sup>77</sup> TG 101, <sup>79</sup> ACR-ASTRO Practice Parameter <sup>78</sup>
SRS	Integrated use of stereotactic frame coordinate systems, integrated use of specialized SRS applicators and arc delivery	ACR Practice Parameter <sup>76</sup>
Use of MRI, PET, etc.	Requires image dataset registration and fusion of imaging information	TG 180, <sup>53</sup> TG 53, <sup>69</sup> TG 132 <sup>141</sup>
NTCP and Biological Modeling Features	Clinical use of NTCP or other biological modeling information requires appropriate algorithms and especially the relevant clinical data. Specifically note the QUANTEC project publications. <sup>56</sup>	QUANTEC, <sup>56</sup> TG 166 <sup>142</sup>

CBCT, cone beam computed tomography; DRRs, digitally restored radio-graphics; IGRT, image-guided radiation therapy; IMRT, intensity-modulated radiation therapy; MLC, multileaf collimator; MRI, magnetic resonance imaging; NTCP, normal tissue complication probability; PET, positron emission tomography; QUANTEC, Quantitative Analysis of Normal Tissue Effects in Clinic; SBRT, stereotactic body radiation therapy; SRS, stereotactic radiosurgery; and VMAT, volumetric-modulated arc therapy.

### 4.3.7. Treatment Management Systems

#### 4.3.7.1. Minimum Device Requirements

Contemporary RT involves the use of a computerized TMS which manages treatment delivery and/or the treatment preparation and planning steps involved before treatment. These systems evolved from record and verification systems which were used to check manually set treatment parameters on “analog” treatment machines. TMS now involve 1) an information system piece (i.e., RT-electronic medical record) which includes database(s) storing patient demographics, planning and treatment delivery data, applications used to create/modify/edit and manage the data, as well as some procedural and workflow tools, and 2) a TDS that directly manages the flow of

activities during treatment delivery. This includes patient setup, imaging, treatment verification and other activities that happen during each fraction of a patient’s treatment. The TMS may communicate with other information systems (e.g., practice network, health system EHR, other ancillary treatment setup, verification, dosimetry and scheduling systems).

#### 4.3.7.2. Minimum QA Requirements

The TMS is less well-described and understood than almost any other system. New efforts to develop improved guidance in this area are needed. With limited published guidance, QM of the TMS should address features listed in **Table 4.8**.

**Table 4.8. QM of Treatment Management and Delivery System**

Safety/Quality Issue	Recommendations	Guidance Document
Computer-controlled delivery	Acceptance test procedures for new software and/or control features should be designed to test software and control aspects of the system.  Safety interlocks and new functionality should be tested in accordance with vendor documentation and testing information.	TG 35 <sup>144</sup>
Software upgrade testing	Routine updates of software for a computer-controlled machine should be treated as if it includes the possibility of major changes in system operation. All vendor information supplied with the update should be studied carefully and a detailed software/control system test plan created.  All safety interlocks and dosimetry features should be carefully tested, regardless of the scope of the changes implied by the update documentation.	TG 35 <sup>144</sup>
System interconnectivity	IHE-RO protocols <sup>145</sup>	TG 201 <sup>146</sup>

IHE-RO, Integrating the Healthcare Enterprise-Radiation Oncology.

## 4.4. DOCUMENTATION AND STANDARDIZATION

### 4.4.1. Medical Record Documentation

In a highly technical field like radiation oncology, rigorous documentation of relevant details of the overall plan for patient care is essential. This includes documentation of the patient's comprehensive evaluation, technical details of all procedures and the clinical trade-off decisions and compromises that led to decisions about the treatment course. Documentation processes must be periodically reviewed and enhanced and, when possible, conducted in a standard format within the EHR.

The majority of practices have transitioned from paper charts to EHRs, so many of the old standards of care are being revised or completely changed to handle the new EHR environment. With this move toward an entirely paperless environment, practices and vendors must continue to improve the design, implementation and effectiveness of electronic documentation, including the development of a universal ontology for the field. These modifications to processes and QM strategies are needed to address fundamental changes and the kinds of errors or misunderstandings that may commonly occur with electronic systems.

Currently, there is significant emphasis from governmental bodies, including through regulations, to push the health enterprise toward improved use of EHR technology. These government programs utilize reimbursement adjustments to incentivize physicians and nonphysician providers to improve the quality of care, including the meaningful use of electronic technology, while reducing costs. The clinical team should make use of EHR technology to enhance patient care coordination, as required by the HITECH ACT.<sup>147</sup> Additionally, emphasis on utilizing discrete data elements within EHRs to enable interoperability and measurement of quality performance is strongly encouraged. The 21st Century Cures Act enables the federal government to play a stronger role in the regulation and development of health information technology standards to promote interoperability.<sup>148</sup>

By consistently documenting in the EHR, important patient information should be available to other staff who interact with the patient, so they can make informed and appropriate decisions. Maintenance and improvement of the quality and accessibility of the documentation of patient's care is a high priority.

Patient confidentiality and the security of protected health information must be a top priority for practices. Each practice must have a HIPAA-compliant practice and/or health system EHR. Since computer systems provide access and/or hold sensitive patient data, special attention should be devoted to protection against computer viruses and malicious attacks. This should include compliance with the HIPAA Security Rules, use of U.S. Food and Drug Administration-approved solutions and periodic staff training on proper use of practice's electronic resources.

### 4.4.2. Policies and Procedures

Each practice must develop and carefully implement well-described policies and procedures for the process of care, its QA steps, staff conduct and issues impacting patient/staff safety. Each specific treatment (e.g., IMRT, SBRT) should have detailed documentation of its treatment planning and delivery process, roles and responsibilities of each team member, QA checklists and test procedures, with a plan for continuous quality improvement and safety. Policies and procedures relevant to a team member's responsibilities should be reviewed during new staff orientation as a prerequisite before beginning patient care and then periodically by all staff. It is recommended that reviews are documented via staff-dated signatures. Policies and procedures should be reviewed on a regular basis, updated as necessary and easily accessible to all staff, ideally in electronic format. Following standard policies and procedures and clearly documenting communication promotes safety within the practice.

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## APPENDIX I.

# Abbreviations

**2-D** = two-dimensional

**3-D** = three-dimensional

**4-D** = four-dimensional

**AAPM** = American Association of Physicists in Medicine

**ABR** = American Board of Radiology

**ACR** = American College of Radiology

**APEx** = Accreditation Program for Excellence

**ASTRO** = American Society for Radiation Oncology

**CRT** = conformal radiation therapy

**CT** = computed tomography

**EBRT** = external beam radiation therapy

**EHR** = electronic health record

**EORTC** = European Organisation for Research and Treatment Center

**FMEA** = failure mode and effect analysis

**FTA** = fault tree analysis

**FTE** = full-time equivalent

**GEC-ESTRO** = Groupe Européen de Curiethérapie-European Society for Therapeutic Radiology and Oncology

**HIPAA** = Health Insurance Portability and Accountability Act of 1996

**HDR** = high-dose-rate

**IGRT** = image-guided radiation therapy

**IHE-RO** = Integrating the Healthcare Enterprise-Radiation Oncology

**IMRT** = intensity-modulated radiation therapy

**IORT** = intraoperative radiation therapy

**LDR** = low-dose-rate

**MOC** = Maintenance of Certification

**MRI** = magnetic resonance imaging

**NRG** = NSABP, RTOG, GOG

**OAR** = organs at risk

**PDR** = pulsed-dose-rate

**PET** = positron emission tomography

**QA** = quality assurance

**QC** = quality control

**QM** = quality management

**RO-ILS** = Radiation Oncology Incident Learning System

**RT** = radiation therapy

**SBRT** = stereotactic body radiation therapy

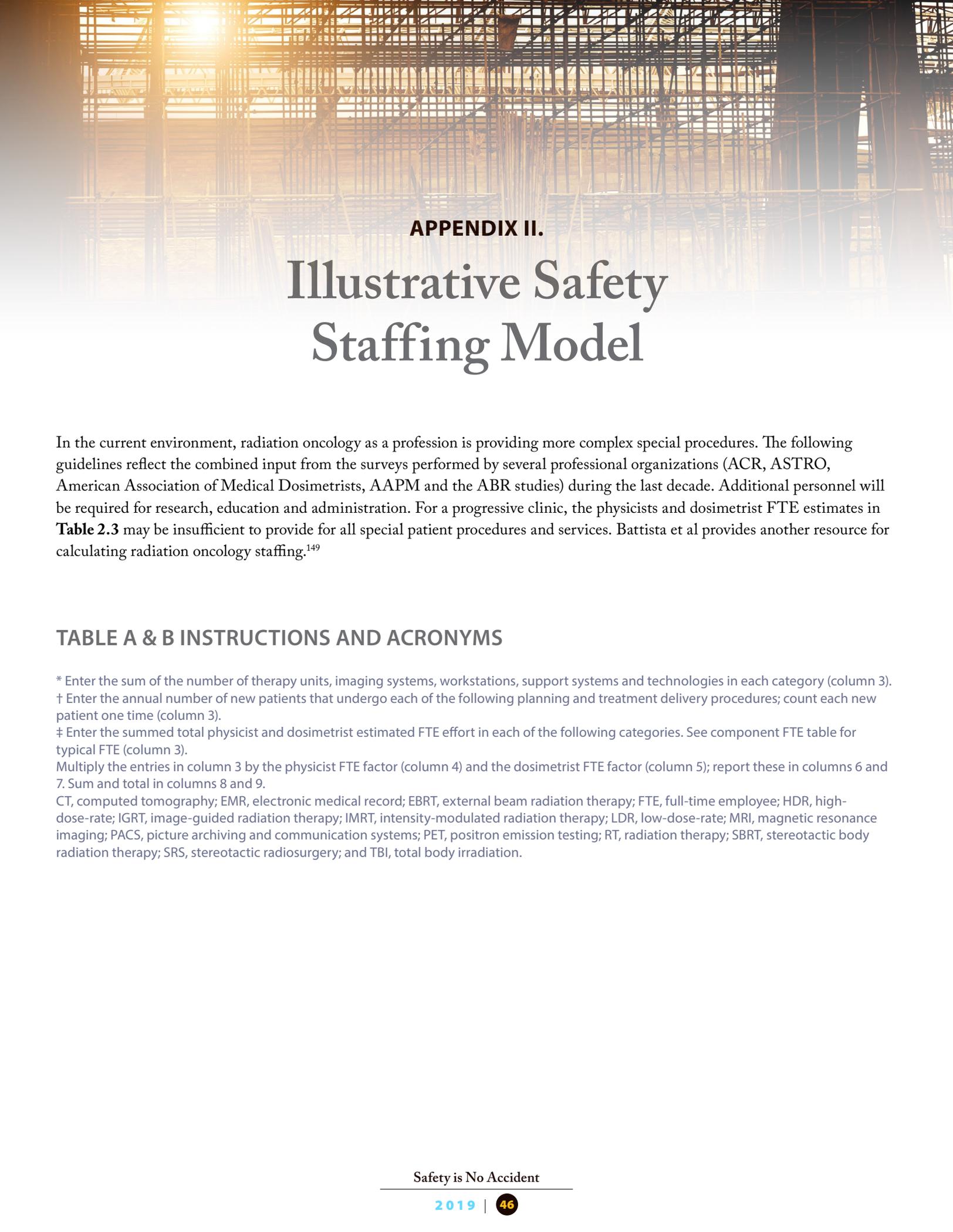
**SOP** = standard operating procedure

**SRS** = stereotactic radiosurgery

**TDS** = treatment delivery system

**TMS** = treatment management system

**TPS** = treatment planning system



## APPENDIX II.

# Illustrative Safety Staffing Model

In the current environment, radiation oncology as a profession is providing more complex special procedures. The following guidelines reflect the combined input from the surveys performed by several professional organizations (ACR, ASTRO, American Association of Medical Dosimetrists, AAPM and the ABR studies) during the last decade. Additional personnel will be required for research, education and administration. For a progressive clinic, the physicists and dosimetrist FTE estimates in **Table 2.3** may be insufficient to provide for all special patient procedures and services. Battista et al provides another resource for calculating radiation oncology staffing.<sup>149</sup>

## TABLE A & B INSTRUCTIONS AND ACRONYMS

\* Enter the sum of the number of therapy units, imaging systems, workstations, support systems and technologies in each category (column 3).

† Enter the annual number of new patients that undergo each of the following planning and treatment delivery procedures; count each new patient one time (column 3).

‡ Enter the summed total physicist and dosimetrist estimated FTE effort in each of the following categories. See component FTE table for typical FTE (column 3).

Multiply the entries in column 3 by the physicist FTE factor (column 4) and the dosimetrist FTE factor (column 5); report these in columns 6 and 7. Sum and total in columns 8 and 9.

CT, computed tomography; EMR, electronic medical record; EBRT, external beam radiation therapy; FTE, full-time employee; HDR, high-dose-rate; IGRT, image-guided radiation therapy; IMRT, intensity-modulated radiation therapy; LDR, low-dose-rate; MRI, magnetic resonance imaging; PACS, picture archiving and communication systems; PET, positron emission testing; RT, radiation therapy; SBRT, stereotactic body radiation therapy; SRS, stereotactic radiosurgery; and TBI, total body irradiation.

**Table A. Sample worksheet for calculating physics and dosimetry staffing in radiation oncology**

Column 1	2	3	Relative FTE Factor		Required FTE		Required Total FTE	
			4	5	6	7	8	9
<b>Equipment, Sources and Systems</b>	<b>Services -- # of Units or Licenses*</b>	<b>No. of systems*</b>	<b>Physicist</b>	<b>Dosimetrist</b>	<b>Physicist</b>	<b>Dosimetrist</b>	<b>Physicist</b>	<b>Dosimetrist</b>
	Multienergy Accelerators		0.25	0.05				
	Single Energy Accelerators		0.08	0.01				
	Tomotherapy, CyberKnife, GammaKnife		0.3	0.03				
	Cobalt Units, IMRT, PACS, EMR and Contouring		0.08	0.03				
	Orthovoltage and Superficial Units		0.02	0.01				
	Manual Brachytherapy; LDR Seed Implants		0.2	0.03				
	HDR Brachytherapy		0.2	0.02				
	Simulator, CT-Simulator, PET, MRI Fusion		0.05	0.02				
	Computer Planning System (per 10 workstations)		0.05	0.02				
	HDR Planning System		0.2	0.01				
<b>Subtotal</b>								
<b>No. Patient Procedures</b>	<b>Annual # of Patients undergoing Procedures†</b>	<b>No. of patients†</b>						
	EBRT with 3-D Planning		0.0003	0.003				
	EBRT with Conventional Planning		0.0002	0.002				
	Sealed Source Brachytherapy (LDR and HDR)		0.008	0.003				
	Unsealed Source Therapy		0.008	0.005				
	IMRT, IGRT, SRS, TBI, SBRT		0.008	0.005				
<b>Subtotal</b>								
<b>Nonclinical - Estimated Total FTE Effort</b>	<b>Estimated Total (Phys &amp; Dosim) FTE Effort‡</b>	<b>FTE Effort‡</b>						
	Education and Training (FTE)		0.667	0.333				
	Generation of Internal Reports (FTE)		0.667	0.333				
	Committees and Meetings; Inc. Rad. Safety (FTE)		0.667	0.333				
	Administration and Management (FTE)		0.667	0.333				
<b>Subtotal</b>								
<b>Total</b>								

**Table B. Completed example worksheet for calculating physics and dosimetry staffing in radiation oncology**

Column 1	2	3	Relative FTE Factor		Required FTE		Required Total FTE	
			4	5	6	7	8	9
<b>Equipment, Sources and Systems</b>	Services -- # of Units or Licenses*	No. of systems*	Physicist	Dosimetrist	Physicist	Dosimetrist	Physicist	Dosimetrist
	Multienergy Accelerators	4	0.25	0.05	1	0.2		
	Single Energy Accelerators	0	0.08	0.01	0	0		
	Tomotherapy, CyberKnife, GammaKnife	1	0.3	0.03	0.3	0.03		
	Cobalt Units, IMRT, PACS, EMR and Contouring	0	0.08	0.03	0	0		
	Orthovoltage and Superficial Units	0	0.02	0.01	0	0		
	Manual Brachytherapy; LDR Seed Implants	1	0.2	0.03	0.2	0.03		
	HDR Brachytherapy	1	0.2	0.02	0.2	0.02		
	Simulator, CT-Simulator, PET, MRI Fusion	1	0.05	0.02	0.05	0.02		
	Computer Planning System (per 10 workstations)	1	0.05	0.02	0.05	0.02		
HDR Planning System	1	0.2	0.01	0.2	0.01			
					<b>Subtotal</b>		2.00	.033
<b>No. Patient Procedures</b>	Annual # of Patients undergoing Procedures †	No. of patients †						
	EBRT with 3-D Planning	500	0.0003	0.003	0.15	1.5		
	EBRT with Conventional Planning	200	0.0002	0.002	0.04	0.4		
	Sealed Source Brachytherapy (LDR and HDR)	100	0.008	0.003	0.8	0.3		
	Unsealed Source Therapy	25	0.008	0.005	0.2	0.125		
IMRT, IGRT, SRS, TBI, SBRT	400	0.008	0.005	3.2	2			
					<b>Subtotal</b>		4.39	4.33
<b>Nonclinical - Estimated Total FTE Effort ‡</b>	Estimated Total (Phys & Dosim) FTE Effort ‡	FTE Effort ‡						
	Education and Training (FTE)	0.1	0.667	0.333	0.0667	0.00333		
	Generation of Internal Reports (FTE)	0.1	0.667	0.333	0.0667	0.00333		
	Committees and Meetings; Inc. Rad. Safety (FTE)	0.1	0.667	0.333	0.0667	0.00333		
Administration and Management (FTE)	0.5	0.667	0.333	0.0667	0.00333			
					<b>Subtotal</b>		0.53	0.27
					<b>Total</b>		6.92	4.92