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TARGETING CANCER CARE

SAFETY IS NO ACCIDENT

A FRAMEWORK FOR
QUALITY RADIATION
ONCOLOGY AND CARE

DEVELOPED AND ENDORSED BY:

American Association of Medical Dosimetrists (AAMD)
American Association of Physicists in Medicine (AAPM)
American Board of Radiology (ABR)
American Brachytherapy Society (ABS)
American College of Radiology (ACR)
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Association of Freestanding Radiation Oncology Centers (AFROC)
Society of Chairmen of Academic Radiation Oncology Programs
(SCAROP)
Society for Radiation Oncology Administrators (SROA)



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SAFETY IS NO ACCIDENT: A Framework for Quality Radiation Oncology and Care

Technologic advances and systemic changes in health care delivery mean that the field of radiation oncology and its processes of care are in continuous evolution. These changes must be reflected in this book and so a mechanism for timely review and revision is necessary. The radiation oncology intersociety meeting is held biennially, bringing together the participating societies to discuss issues of importance to the field. As planning begins for each intersociety meeting, this safety document will be reviewed to assess whether a significant update is needed. If so, the update will become the subject of the next intersociety meeting.

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The content in this publication is current as of the publication date. The information and opinions provided in the book are based on current 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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Table of Contents

Introduction	1
Chapter 1: The Process of Care in Radiation Oncology	3
1.1 Patient Evaluation	3
1.2 Preparing for Treatment	4
1.3 Radiation Treatment Delivery	8
1.4 Radiation Treatment Management	9
1.5 Follow-up Evaluation and Care	9
Chapter 2: The Radiation Oncology Team	11
2.1 Roles and Responsibilities	11
2.2 Qualifications and Training	11
2.3 Continuing Education and Maintenance of Certification	13
2.4 Staffing Requirements	14
Chapter 3: Safety	19
3.1 The Need for a Culture of Safety	19
3.2 Leadership and Empowering Others	19
3.3 Evolving Roles and Responsibilities of Each Team Member	20
3.4 Examples of Tools/Initiatives to Facilitate Safety and the Safety Culture	20
3.5 Ingraining Safety into Everyday Practice	24
3.6 Collaborations Between Users and Vendors	25
3.7 Involving Those Beyond Radiation Oncology	26
Chapter 4: Management and Assurance of Quality in Radiation Oncology	29
4.1 Quality Requirements of Radiation Oncology Programs	29
4.2 Patient-Related Quality Management	38
Appendix I: Acronym Glossary	51

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Introduction

During the later 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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The Process of Care In Radiation Oncology

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The “process of care” in radiation oncology refers to a conceptual framework for guaranteeing the appropriateness, quality and safety of all patients treated with radiation for therapy. Each of the aspects of the process of care in radiation oncology requires knowledge and training in the natural history of cancer, certain benign disease processes, radiobiology, medical physics and radiation safety that can only be achieved by Board certification in radiation oncology (or equivalent training), to synthesize and integrate the necessary knowledge base to safely and completely render care. This high level of training and Board certification applies as a recommendation for all of the specialists on the radiation oncology team. The medical therapeutic application of ionizing radiation is irreversible, may cause significant morbidity and is potentially lethal. Use of ionizing radiation in medical treatment, therefore, requires direct or personal physician management, as the leader of the radiation oncology team, as well as input from various other essential coworkers.

The radiation oncology process of care can be separated into the following five operational categories.

- Patient Evaluation
- Preparing for Treatment
 - Clinical Treatment Planning
 - Therapeutic Simulation
 - Dosimetric Treatment Planning
 - Pretreatment Quality Assurance and Plan Verification
- Radiation Treatment Delivery
- Radiation Treatment Management
- Follow-up Evaluation and Care

A course of radiation therapy 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 completed and reported, it should be appropriately documented in the patient record.

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, medical dosimetrist, radiation therapist and nursing staff. Many of the procedures within each phase of care will be carried to completion before the patient’s care is taken to the next phase. Others will occur and recur during the course of treatment, and they are by necessity repeated during treatment due to patient tolerance, changes in tumor size, need for boost fields or port size changes, protection of normal tissue or as required by other clinical circumstances (that is, certain procedures may need to occur multiple times during the treatment course).

1.1.0 PATIENT EVALUATION

Patient evaluation is a service provided by a physician at the request of another physician, the patient, or an appropriate source, and is intended to recommend care for a specific condition or problem, including further work-up, or to recommend treatment. The radiation oncologist, as part of this process, will review the pertinent history, patient complaints, physical findings, imaging studies, pathology and lab findings. If treatment is recommended and accepted, this patient visit, or a return visit, should

also be used for patient counseling, informed consent, coordinating care and making recommendations about other aspects of oncologic management or staging.

The evaluation with the radiation oncologist will often be followed by discussions with other members of the multidisciplinary care team, as indicated. This will include a review of details regarding pathology, disease extent based on radiographic imaging and other procedures, and potential sequencing of treatment modalities either used or planned, including surgery, chemotherapy, hormonal therapy or molecular targeted therapy. Full details of the patient evaluation are beyond the scope of this safety document.

1.2.0 PREPARING FOR TREATMENT

1.2.1 Clinical Treatment Planning

Clinical treatment planning is a comprehensive, cognitive effort performed by the radiation oncologist for each patient undergoing radiation treatment. The radiation oncologist is responsible for understanding the natural history of the patient's disease process, conceptualization of the extent of the disease relative to the adjacent normal anatomical structure, integration of the patient's overall medical condition and associated comorbidities. Knowledge of the integration of chemotherapeutic and surgical treatment modalities with radiation therapy is essential. An understanding of the integration of the various radiation treatment modalities is an essential part of this phase in the process of care.

Clinical treatment planning for either external beam radiation therapy (EBRT) or brachytherapy is an important step in preparing for radiation oncology treatment. This planning includes several components: determining the disease-bearing areas based on the imaging studies described above and pathology information; identifying the type (brachytherapy, photon beam, particle beam, etc.) and method of radiation treatment delivery (intensity modulated radiation therapy [IMRT], intensity modulated proton therapy [IMPT], three-dimensional conformal radiation therapy [3-D CRT], two-dimensional conformal radiation therapy [2-D CRT], low-dose-rate [LDR] or high-dose-rate [HDR] brachytherapy, etc.); specifying areas to be treated; and specifying dose and dose fractionation. In developing the clinical treatment plan, the radiation oncologist may use information obtained from the patient's initial clinical evaluation, as well as the additional tests, studies and procedures described above 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 the cancer, and may be

needed to obtain specific information to accomplish the clinical treatment plan. In this regard, the radiation oncologist must consider toxicities and tolerances associated with definitive radiation therapy or combined-modality therapy. Review is needed of imaging studies and lab tests to determine treatment volume and critical structures, commonly referred to as organs at risk (OARs), in close proximity to the treatment area or more distant and receiving a dose of radiation that needs monitoring.

For either EBRT or brachytherapy, clinical treatment planning results in a complete, formally documented and approved directive. Details including total desired dose to all targets and OARs, fractionation, treatment modality, energy, time constraints and all other aspects of the radiation prescription are recorded in a written or electronic format and must be provided by the radiation oncologist prior to the start of treatment planning. In some cases, this prescription can require modification based on the results of the treatment planning process.

1.2.2 Therapeutic Simulation, Fabrication of Treatment Devices and Preplanning Imaging

Simulation is the process by which the geometry of the treatment device in juxtaposition to the patient is simulated for the purpose of developing an accurate and reproducible treatment delivery plan. For this purpose, it is necessary initially to acquire radiographic images of the patient in the preferred treatment position. Selecting a comfortable and appropriate patient position for treatment is an important part of the simulation process. The selected position should consider the location of the target and anticipated orientation of the treatment beams. Appropriate immobilization devices provide comfort, support and reproducibility.

In some cases the exact treatment position cannot be duplicated for some imaging procedures that are not under direct control of the radiation oncology team; clinical considerations should be made to compensate for such differences.

Some computed tomography (CT)-Simulator devices include the ability to register imaging datasets. However, most image registration is still performed manually with rigid datasets. Treatment planning systems can also provide the software for this capability. Using the software included with the treatment planning system shifts this part of the process to the treatment planning phase of the overall care process.

1.2.2.1 Team Interaction

The radiation oncology team, under the leadership of the radiation oncologist, works to deliver irradiation safely and reproducibly. Most radiation treatments use standard

operating procedures (SOPs) describing the treatment approach. These SOPs are considered to be an essential component of any radiation oncology department. In those situations where the patient presents with target and critical sensitive structure geometric relationships that are not easily handled using available SOPs, the involvement of the radiation therapy team is necessary. Team interactions that include the radiation therapists, medical dosimetrists, medical physicists and representation from the departmental nursing staff can prove helpful in specific situations. The purpose of these meetings is to carefully consider how treatments might be tailored to a particular patient's situation.

1.2.2.2 Fabrication of Immobilization Treatment Devices

Immobilization of the patient in a comfortable position for treatment might involve the construction or selection of certain treatment devices, facilitating accurate treatment delivery. This step must take into account the potential treatment planning considerations so that the immobilization aids do not restrict the treatment techniques. A personalized approach is required here, taking into consideration each patient's unique anatomy, at times requiring special accommodations appropriate for the individual case-specific concerns.

1.2.2.3 Therapeutic Simulation for EBRT

Simulation is the process of determining critical information about the patient's geometry, to permit safe and reproducible treatments on a megavoltage machine. Simulation for external beam radiation treatment is imaging based. Most simulation procedures have now shifted away from the direct use of the treatment beam to using X-rays in the diagnostic range of energies. In general, this part of the overall process of care reveals the relationship between the position of the target, or targets, and the surrounding critical structures. It is helpful here to think of the simulation step as the imaging needed for input to the treatment planning process. These images can be obtained in a large number of ways. Modern conventional simulators, like the CT-Simulator, can include the ability to produce volumetric data in addition to 2-D images. Intravenous contrast should be used during simulation, as indicated, to improve enhancement within both target and normal tissues/structures.

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. For example, magnetic resonance (MR) and/or positron

emission tomography (PET) are now available, and treatment planning systems that include image registration capabilities allow combining of information from other imaging modalities with the standard CT dataset obtained during simulation in appropriate situations. It is now 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. Ultrasound imaging has a role in both EBRT and brachytherapy. Ultrasound comes into play as a preplanning imaging technique and can also be used as an image guided radiation therapy (IGRT) technique during the treatment delivery and verification steps of the care process.

1.2.2.4 Therapeutic Simulation for Brachytherapy

For certain brachytherapy procedures, preparing for treatment is similar to the procedure described above for EBRT. The simulation portion for this treatment modality is also imaging based, and can involve either planar X-rays or CT scans. Other imaging modalities may be important for some brachytherapy procedures and these studies can be obtained as part of the preplanning imaging process.

1.2.2.5 Treatment Planning 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 can involve calculations of the anticipated dose distribution to the target organ or tumor(s) based on knowledge of the patient's vascular anatomy or biological imaging, such as 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 Guidelines regarding the Performance of Therapy with Unsealed Radiopharmaceutical Sources and NRC Guidelines discuss these issues in greater detail^[1].

1.2.3 Dosimetric Treatment Planning

The computer-aided integration of the patient's unique anatomy, the desired radiation dose distribution to the tumor and normal tissues inside the patient, 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 position-

ing will administer the intended dose of radiation to the target volume while minimizing the exposure of normal tissues. Accordingly, before the medical dosimetrist begins the treatment planning process, the radiation oncologist needs to define the target volumes and dose limiting organs and structures on the diagnostic images obtained during simulation.

The skills of the appropriately trained and credentialed medical dosimetrist and medical physicist relate to the efficient and effective use of the complex treatment planning system hardware and software. These individuals must also understand the clinical aspects of radiation oncology in order to interact with the radiation oncologist during the planning process. The role of the medical physicist is to guarantee proper functioning of the hardware and software used for the planning process, consult with the radiation oncologist and medical dosimetrist, check the accuracy of the selected treatment plan and perform measurements and other checks aimed at assuring accurate information exchange between radiation therapy devices and delivery of the treatment plan.

At various steps in the treatment planning process, the radiation oncologist is presented with one or more treatment plans for evaluation. The plans are evaluable by a combination of graphic visual representations of the radiation dose distribution inside the patient and quantitative statistics describing the dose to the tumor and normal tissue of interest. The radiation oncologist must then decide whether to accept or reject a given plan. Typically, this process is iterative and requires multiple revisions and adjustments to the initial plan in order 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 selected for treatment.

1.2.4 Pretreatment Quality Assurance (QA) and Plan Verification

The QA steps taken after treatment planning is completed and before the start of treatment are critical for guaranteeing patient safety. An important initial step is an independent calculation of the machine output setting (monitor units) for external beam radiation therapy or radioactive source dwell times for brachytherapy. This recalculation may be accomplished as a manual point dose verification in the center of the treatment volume based on printed tables relating the effective field size to the administered dose at given depths from the surface. Alternatively, this can be performed in a computer-assisted manner, whereby data from the patient's planning images are entered into a separate software program along with parameters describing the prescription dose to the tumor and beam or source

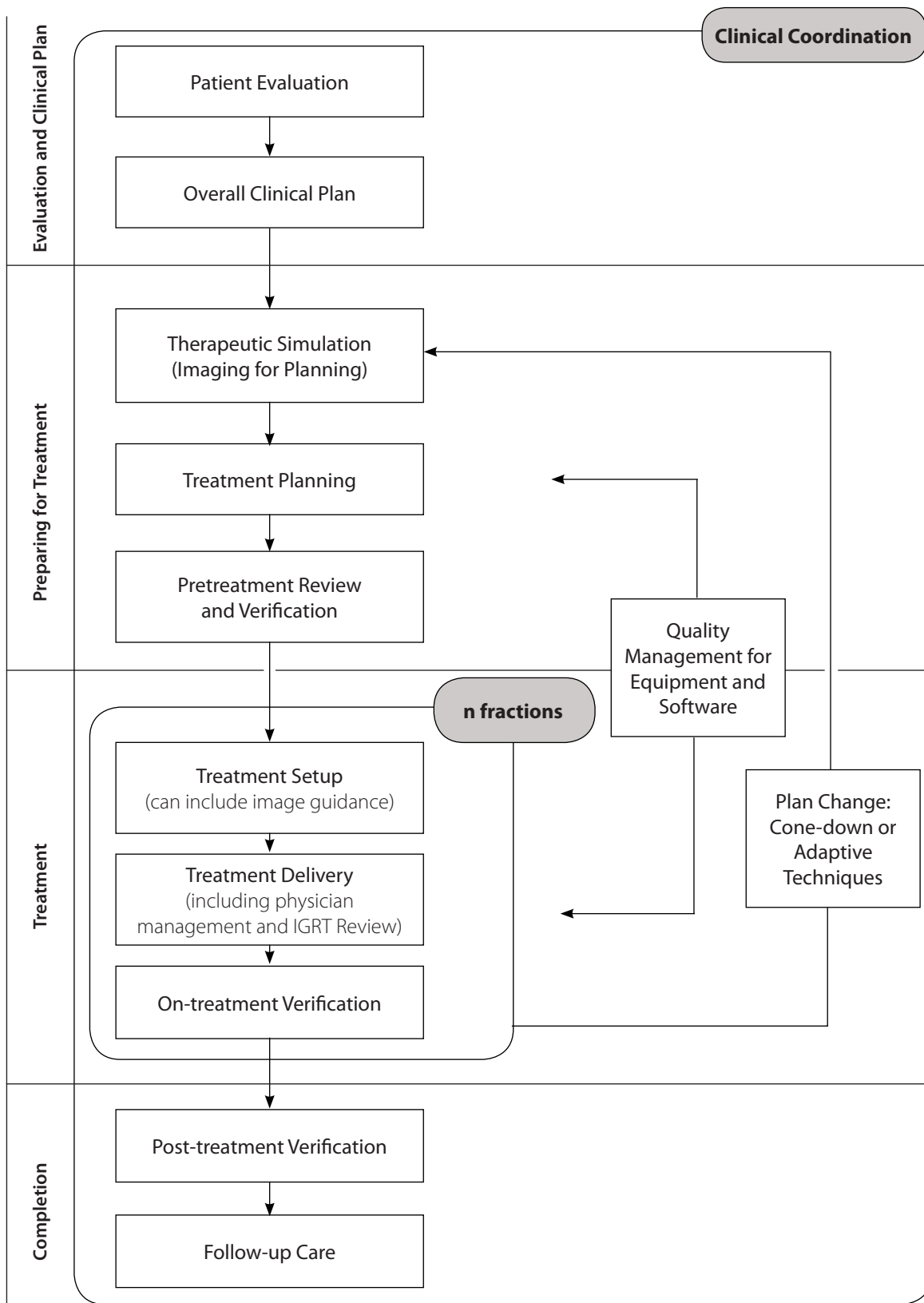
arrangements. In either case, the key result is confirmation of linear accelerator output settings or brachytherapy dwell times that reduce the risk of error related to an input mistake in the initial treatment planning software operation. If an independent calculation method is not available, then an appropriate measurement technique should be used. The radiation oncologist ensures that a pretreatment quality assurance program is in place and followed for every patient.

In the past, treatment verification consisted of field aperture imaging using radiographic film. These images are referred to as portal images or port films. These images are now frequently obtained using electronic portal imaging devices (EPIDs). With the introduction of IMRT, imaging of individual apertures is no longer 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 IMRT, this important QA technique is not considered to be completely sufficient to guarantee patient safety. In addition to this isocenter check procedure, patient-specific QA measurements are also required for IMRT and other complex delivery techniques that use inverse treatment planning. In terms of clearly organizing the different steps in the process of care for radiation oncology, a blurring of the separation between the verification step described in this subsection and the treatment delivery step described in section 1.3.0 occurs on the first day of treatment and whenever the treatment plan is changed. While patient-specific 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.

IGRT equipment is now available for checking the patient setup on the treatment table immediately prior to treatment delivery and then adjusting the patient position as needed to localize the target volume precisely within the volume that receives the prescription dose. This equipment can be used to verify the patient setup daily and can supplement port film information. IGRT has the advantage that it sometimes provides volumetric imaging capabilities. The extra setup accuracy provided by IGRT can allow for the use of treatment plans that reduce the volume of normal tissue around the tumor receiving a high dose of radiation, since there is less uncertainty in the target volume location. This process goes well beyond the simple plan verification process discussed further in the treatment delivery section.

For either portal imaging or isocenter verification imaging (using volumetric or planar images), it is necessary to have a reference image for comparison. This information

Figure 1.1. Process of Care for External Beam Radiation Therapy



is obtained from the imaging that is performed during the therapeutic simulation step in the process.

The QA process must include other steps that are aimed at checking the accuracy of both the dose calculations and the data used for treatment through the complete chain of systems (e.g., CT-Simulator to treatment planning to record and verify to accelerator control computer).

Another important step in the QA part of the process is the performance of secondary monitor unit calculations to check the primary calculation used to treat the patient.

1.3.0 RADIATION TREATMENT DELIVERY

1.3.1 External Beam Radiation Therapy

With treatment plan and treatment portal verification complete, the patient is ready for treatment. The initial step in this part of the process is patient setup on the treatment table using several different techniques, such as simple skin marks or a room laser system that localizes the treatment unit isocenter in space. Alternatively, the IGRT system may be used on each day of treatment.

Radiation treatment delivery includes various methods, modalities and complexities of radiation therapy. The physician is responsible for verification and documentation of the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

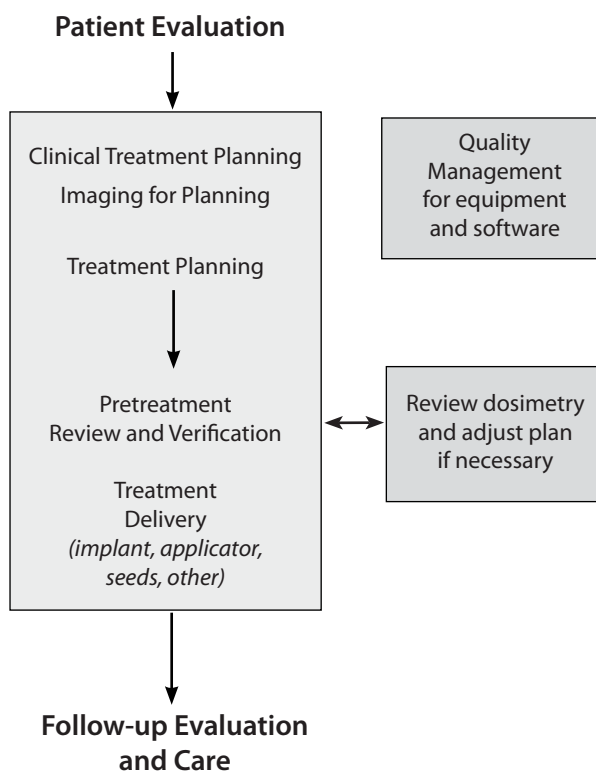
IGRT may be performed to ensure accurate targeting of precise radiation beams where certain needs of dose and organs at risk (OARs) tolerance exist. IGRT corrects for the positioning errors encountered when an internal target can move from day to day and can be reliably identified. The physician is responsible for the supervision and review of these images and shifts in order to ensure 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, see page 7*).

The overall clinical plan can involve selection of chemotherapy, surgery, EBRT, brachytherapy or a combination of modalities. 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 radioactive material inside or immediately adjacent to a tumor-bearing region. One example is permanent seed implants for prostate cancer, either as definitive therapy for early stage disease or as a boost treatment following external beam treatment for intermediate- or high-risk disease (*Figure 1.2*).

Figure 1.2.
Process of Care for Brachytherapy



1.3.3 Calibration Procedures, Ongoing Equipment QA and Preventive Maintenance

The initial commissioning, ongoing performance evaluation and periodic calibration of radiation treatment delivery devices are important tasks that are vital to the safe administration of radiation therapy. In general, it is the medical physicist who is primarily responsible for the device evaluations necessary for compliance with applicable state and federal regulations concerning radiation treatment delivery technology. 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, medical physicist and other members of the radiation therapy team should maintain a clear channel of communication on this issue of treatment device performance so that any possible sign of impending machine malfunction is quickly recognized and diagnosed, and any necessary corrective or reparative action is taken prior to use of the machine to deliver a clinical treatment to a patient.

1.4.0 RADIATION TREATMENT MANAGEMENT

Radiation treatment management encompasses the radiation oncologist's overall management of the course of treatment and care for the patient as well as checks and approvals provided by other members of the radiation therapy team that are necessary at various points in the process. For the radiation oncologist, radiation treatment management requires and includes a minimum of one examination of the patient by the physician for medical evaluation and management. The professional services furnished during treatment management may include:

- Review of portal images
- Review of dosimetry, dose delivery and treatment parameters
- Review of patient treatment setup
- Patient evaluation visit (described in section 1.1.0)

Not all of these parameters of treatment management are required for all patients for each week of management (except for the patient evaluation visit) because the clinical course of care may differ due to variation in treatment modality and individual patient requirements. For example, use of port films may vary based on certain technical characteristics (i.e., electron beams) and modification of dose delivery can vary based on individual patient needs, depending on the patient's tolerance of therapy or variation in tumor response. Examinations and evaluations may be required more often than weekly.

It should be emphasized that weekly treatment management requires the integration of multiple medical and technical factors, which may be required on any day through the treatment course. While nurses and nonphysician providers can effectively participate in the management of patients receiving radiation therapy, typically by helping to manage side effects associated with the treatment (*Table 2.1, see page 12*), their efforts do not

represent the comprehensive effort of management for which the radiation oncologist is solely responsible.

Additionally, regardless of whether a nurse or nonphysician provider evaluates the patient, the proper quality care for a patient receiving radiation therapy involves a personal evaluation by the radiation oncologist at least once for every five treatments given, and this evaluation should be documented in the patient's record.

1.5.0 FOLLOW-UP EVALUATION AND CARE

Continued follow-up evaluation and care of patients who have completed irradiation is necessary to manage acute and chronic morbidity resulting from treatment, as well as to monitor the patient for tumor relapse. Such follow-up is preferably provided through in-person examinations by the radiation oncologist and/or nonphysician provider, or when this is not feasible, by electronic communications and/or patient reports. The radiation oncologist should consult with the other members of the radiation therapy team when unexpected morbidity is observed or reported for the purpose of trying to identify measures that might reduce the risk of toxicity for future patients.

The ultimate goal for radiation treatment is to achieve the best possible outcome for the patient. This result depends on a number of factors. The training of the various members on the radiation therapy team is a major consideration. Board certification is one useful measure of competency of the team members. After receiving this important credential, the members of the team should actively pursue continuing education as required by the certifying Board.

Creating an error-free environment is an essential part of any radiation oncology department. This can be accomplished by understanding and properly implementing all steps in the process of care as described here.

CHAPTER REFERENCES

^[1] Henkin RE, Del Rowe JD, Grigsby PW, et al. ACR-ASTRO practice guideline for the performance of therapy with unsealed radiopharmaceutical sources. *Clin Nucl Med* 2011;36(8):e72-80.



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2.1.0 ROLES AND RESPONSIBILITIES

The radiation oncology team ensures every patient undergoing radiation treatment receives the appropriate level of medical, emotional and psychological care before, during and after treatment, through a collaborative multidisciplinary approach.

The primary radiation oncology team consists of, but is not limited to, radiation oncologists, medical physicists, medical dosimetrists, oncology nurses and radiation therapists. On-site or by consultation, services provided by nonphysician providers can include, but are not limited to, nurse practitioners, clinical nurse specialists, advanced practice nurses and physician assistants, dentists, clinical social workers, psychologists/psychiatrists, nutritionists, speech/swallowing therapists, physical therapists, occupational therapists, genetic counselors, integrative medicine specialists and pastoral care providers. These services are available to the interdisciplinary team to meet the complex needs of patients.

The process of care in radiation oncology involves close collaboration between a team of qualified individuals. The attending radiation oncologist has ultimate and final responsibility, as well as accountability for all aspects of patient care.

While **Table 2.1** (*see page 12*) does not specifically define individual roles within the radiation oncology team, it is an attempt to clarify those roles and relative responsibilities. The scope of practice of each team member should be based on the criteria established by their professional organization and local jurisdiction. Each facility must have policies and procedures defining the roles of these team members.

2.2.0 QUALIFICATIONS AND TRAINING

Board certification is the primary consideration for establishing proper qualifications and training for a professional working in radiation oncology. The relevant professional societies establish the eligibility requirements to sit for a board exam, including education, training and clinical residency requirements. In addition, where applicable, professionals must meet requirements for obtaining a state license, as shown in **Table 2.2** (*see page 13*).

Each facility should have a policy regarding orientation, competency, credentialing and periodic evaluations of all team members.

2.2.1 Medical Director

The medical director is a radiation oncologist who is responsible for oversight of the facility, in addition to establishing policies and procedures.

2.2.2 Radiation Oncologist

The radiation oncologist has American Board of Radiology (ABR) certification in Radiation Oncology, Therapeutic Radiology or equivalent certification. Additional processes of certification as defined by ABR are published at: www.theabr.org.

2.2.3 Nonphysician Providers (Physician Extenders)

Nonphysician providers include, but are not limited to, nurse practitioners, clinical nurse specialists, advanced practice nurses and physician assistants. The roles, qualifications, licensure requirements and maintenance of credentials for these individuals should be determined by their professional organizations, scope of practice, rules and

Table 2.1. Roles and Responsibilities of the Radiation Oncology Team

	RADIATION ONCOLOGIST	MEDICAL PHYSICIST	MEDICAL DOSIMETRIST	RADIATION THERAPIST	NONPHYSICIAN PROVIDERS (NP/PA)	ONCOLOGY NURSE
Clinical evaluation	X				X	X
Ongoing psycho/social evaluation	X				X	X
Decision to deliver external radiation therapy (XRT)	X					
Patient +/- family education	X			X	X	X
Interdisciplinary 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			
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 systems acceptance testing, maintenance and commissioning	X	X	X	X		

regulations of individual institutions and licensure regulations within individual jurisdictions (American Academy of Nurse Practitioners [AANP], www.aanp.org; American Nurses Credentialing Center [ANCC], www.nursecredentialing.org; National Commission on Certification of Physician Assistants [NCCPA], www.nccpa.net; American Academy of Physician Assistants [AAPA], www.aapa.org).

2.2.4 Medical Physicist

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

Table 2.2. Certification and Licensure Requirements

Profession	Relevant Certifying Body	State Licensure Required?	Information Resources
Radiation Oncologist	ABR	Yes	www.theabr.org
Medical Physicist	ABR ABMP CCPM	In 3 states as of 2011 (FL, NY, TX)	www.theabr.org www.abmpexam.com www.ccpm.ca
Medical Dosimetrist	MDCB	No	www.mdcb.org
Radiation Therapist	ARRT ASRT	Yes (Currently in 35 states)	www.rrt.org www.asrt.org
Nurse Practitioner	AANP ANCC	Yes Yes	www.aanp.org www.ancc.org
Oncology Nurse	ANCC ONCC	Yes	www.nursecredentialing.org www.oncc.org
Clinical Nurse Specialists	ANCC	Yes	www.ancc.org
Physician Assistant	NCCPA	Yes	www.nccpa.net

2.2.5 Medical Dosimetrist

A medical dosimetrist is competent to practice under the supervision of a qualified physician and qualified medical physicist. An individual is considered competent to practice in medical dosimetry if that individual is eligible or certified in accordance with the appropriate qualification for the designation of Qualified Medical Dosimetrist through the Medical Dosimetrist Certification Board (MDCB) at www.mdcb.org.

2.2.6 Radiation Therapist

A qualified radiation therapist is considered competent to practice in radiation therapy if he or she is eligible or certified in accordance with the appropriate qualification for the designation of Radiation Therapist, published by the American Registry of Radiologic Technologists (ARRT) at www.rrt.org and the American Society of Radiologic Technologists (ASRT) at www.asrt.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 (ONCC, www.oncc.org), American Nurses Credentialing Center (ANCC, www.nursecredentialing.org), or National Association of Clinical Nurse Specialists (NACNS, www.nacns.org).

2.3.0 CONTINUING EDUCATION AND MAINTENANCE OF CERTIFICATION

The applications, technologies and methodologies of radiation oncology continue to expand and develop. Lifelong learning is vital to ensure incorporation of new knowledge into clinical practice, therefore, each member of the interdisciplinary team should participate in available Continuing Medical Education (CME) and, where applicable, Maintenance of Certification (MOC) programs.

2.4.0 STAFFING REQUIREMENTS

The staffing needs of each facility are unique and vary based greatly upon the patient mix, as well as on the type and complexity of the services offered. Patient load, number of machines and satellites/affiliated centers also influence the need to allocate management manpower and full-time employees (FTEs) (*Table 2.3*), as well as teaching responsibilities and vacation time. As such, it is impossible, in the current era, to prescribe hard staffing levels.

The radiation oncology facility should 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 members of the radiation oncology team should be available to deliver urgent treatments in off-hours. Otherwise, the facility must have arrangements for referral of emergency patients for timely treatments.

CHAPTER APPENDIX: ILLUSTRATIVE SAFETY STAFFING MODEL

In the current environment, radiation oncology as a profession is providing more complex special procedures. The above guidelines reflect the combined input from the surveys performed by several professional organizations (ACR, ASTRO, AAMD, AAPM and the ABR studies) during the last decade. Additional personnel will be required for research, education and administration. For a progressive clinic, the above recommendations may be insufficient to accurately estimate the medical physics and dosimetry FTE effort required to provide all special patient procedures and services.

Table 2.3 Minimum Personnel Requirements for Clinical Radiation Therapy

CATEGORY	STAFFING
Chief Radiation Oncologist	One per facility
Chief Medical Physicist	One per facility
Department Manager	One per facility (in some departments this function may be filled by a member of the team)
Medical Dosimetrist	As needed, approximately one per 250 patients treated annually
Radiation Therapist	As needed, approximately one per 90 patients treated annually
Brachytherapy Technologist	As needed, approximately one per 100 brachytherapy patients treated annually
Mold Room Technologist	As needed to provide service
Social Worker/Dietician	As needed to provide service

A sample worksheet for calculating medical physics and dosimetry staffing in radiation oncology:

	Services -- # of Units or Licenses*	No. of systems*	Relative FTE Factor		Required FTE		Required Total FTE	
			Physicist	Dosimetrist	Physicist	Dosimetrist	Physicist	Dosimetrist
Equipment, Sources and Systems	Multi energy accelerators		0.25	0.05				
	Single energy accelerators		0.08	0.01				
	Tomotherapy, CyberKnife, GammaKnife		0.3	0.03				
	Cobalt Units, IMRT, PACS, EMR & 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				
			Subtotal					
No. Patient Procedures	Annual # of Patients undergoing Procedures**	No. of patients**						
	External Beam RT with 3D planning		0.0003	0.003				
	External Beam RT with conventional planning		0.0002	0.002				
	Sealed source Brachytherapy (LDR & HDR)		0.008	0.003				
	Unsealed source therapy		0.008	0.005				
	IMRT, IGRT, SRS, TBI, SBRT		0.008	0.005				
				Subtotal				
Nonclinical - FTE Effort	Estimated Total (Phys & Dosim) FTE Effort***	FTE Effort***						
	Education & Training (FTE)		0.667	0.333				
	Generation of Internal Reports (FTE)		0.667	0.333				
	Committees & Meetings; Inc. Rad. Safety (FTE)		0.667	0.333				
	Administration and Management (FTE)		0.667	0.333				
			Subtotal					
			Total					

* 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 deliver procedures; count each new patient one time (column 3).

***Enter the summed total medical physicist and medical 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. Example below:

Equipment, Sources and Systems	Services -- # of Units or Licenses*	No. of systems*	Relative FTE Factor		Required FTE		Required Total FTE	
			Physicist	Dosimetrist	Physicist	Dosimetrist	Physicist	Dosimetrist
	Multi energy 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 & 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		
							Subtotal	2.00
No. Patient Procedures	Annual # of Patients undergoing Procedures**	No. of patients**						
	External Beam RT with 3D planning	500	0.0003	0.003	0.15	1.5		
	External Beam RT with conventional planning	200	0.0002	0.002	0.04	0.4		
	Sealed source Brachytherapy (LDR & 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		
						Subtotal	4.39	4.33
Nonclinical - FTE Effort	Estimated Total (Phys & Dosim) FTE Effort***	FTE Effort***						
	Education & 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 & 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		
						Subtotal	0.53	0.27
						Total	6.92	4.92

Another resource for calculating radiation oncology staffing is: Battista JJ et al. Medical physics staffing for radiation oncology: a decade of experience in Ontario, Canada. *J Appl Clin Med Phys.* 2012;13(1):3704.





CHAPTER 3

Safety

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3.1.0 THE NEED FOR A CULTURE OF SAFETY

Modern radiation therapy is complex and rapidly evolving. The safe delivery of radiation therapy requires the concerted and coordinated efforts of many individuals with varied responsibilities. Further, safety and efficiency go hand in hand. Inefficient systems lead to staff frustration, rushing and sometimes cutting corners, thus, all team members need to 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 members of the radiation oncology team. Changes in the levels of reimbursement for some clinical activities, global changes in the national healthcare system (e.g., structural, financial) and increasing levels of administrative burden (e.g., documentation requirements) require physicians to search for improved levels of efficiency. This is essential in order to provide staff with necessary time to perform critical safety-related activities.

The rapidly-evolving nature of radiation oncology requires that processes and workflows be continually reassessed. Each member of the team needs to accept that optimal approaches are not static, but will necessarily change to accommodate the evolving practice. Long-held traditional approaches will need to be challenged and possibly modified.

People may be hesitant to change, often for good reasons. Good clinical practices usually evolve over years if not decades, so change should be carefully implemented. It is critical that a culture that appropriately manages change exists, ensuring change facilitates safety and quality.

Furthermore, all team members must be open to having any member of the team (whether in leadership positions or not) raise concerns about safety as well as suggesting and considering change. Indeed, it is often the frontline staff that are more likely to understand the limitations of current procedures and suggest improvements. Thus, an ideal open environment with a safety-minded culture only exists where staff are permitted and encouraged to suggest and lead change to improve safety, quality and efficiency.

3.2.0 LEADERSHIP AND EMPOWERING OTHERS

Physicians and medical physicists comprise the primary leadership roles within a radiation oncology clinical site. They must empower all members of their team to be active participants in improving clinical processes. This is true from a practical perspective, as one person cannot possibly understand all aspects of the complex field. Further, such empowerment is a meaningful way to provide team members with a feeling of responsibility, thereby increasing job satisfaction, raising expectations and enhancing performance. Staff should know that they have a meaningful and beneficial impact in the work environment.

In the radiation oncology clinic, these professionals are ultimately responsible for creating a culture of safety. Society has entrusted physicians and medical physicists as the guardians of both the individual and societal health care structure. With this trust, they are empowered to operate as advocates for safety-related initiatives. Leadership needs to make all staff feel comfortable to raise concerns about safety without fear of reprimand or reprisal.

3.3.0 EVOLVING ROLES AND RESPONSIBILITIES OF EACH TEAM MEMBER

The field of radiation oncology is ever-evolving, and as such, there are rapid changes in the roles and responsibilities of each team member. **Table 3.1** (see page 21) summarizes some of these changes and associated challenges. Entries are meant as examples, as this is not an exhaustive list.

3.4.0 EXAMPLES OF TOOLS/INITIATIVES TO FACILITATE SAFETY, AND THE SAFETY CULTURE

3.4.1 Staffing/Schedules

Staffing levels need to be adjusted to reflect the workload, particularly in physics, dosimetry and treatment, where the demands have markedly increased (e.g., patient-specific QA for IMRT). Schedules should be realistic to avoid/minimize hurrying through a given task and risking error. An excessive workload can lead to errors. Conversely, light workloads can also be a problem since a certain level is needed to maintain “situational awareness”^[1,2].

3.4.2 Communication/Facilities

Systems that facilitate clear, unambiguous and efficient communication between all team members are critical. This is particularly true between physicians, medical dosimetrists, medical physicists and radiation therapists, given the large number of hand-offs and interdependent tasks that routinely occur during the planning and treatment-implementation processes. Well-defined charting procedures, either paper or preferably electronic, are critical. In planning the layout of a department, one might centrally locate dosimetry, and/or establish dedicated time for physicians and medical dosimetrists to work together, thereby facilitating the iterative “directive-segment-computation-review-repeat” cycle. This is a particular challenge when physicians and planners rotate between facilities. Enhanced tools are needed to enable efficient and accurate communication/transfer of complex 3-D data between centers. A well-defined communication pathway between workers will reduce the need for ad hoc/variable solutions and provide for messages being sent, received and verified.

3.4.3 Workflow/Efficiency

Clinical practice is complex, often mired in administrative and historically-derived procedures. Efficiency impacts quality and safety. Harried workers are more prone to error, therefore eliminating nonessential tasks increases time available for critical tasks. Lean approaches (adapted from the Toyota Production System)^[3] have been adopted by many to streamline clinical workflow and alter the work environment. Some have implemented rapid improvement events (Kaizens^[4]) where participating representative members of involved groups create process maps for particular tasks. Value-added steps are identified, with wasteful steps and unnecessary stressors being eliminated, and a more streamlined, unambiguous, standardized process emerges. Having stakeholders meet to discuss and define their work builds teamwork and mutual respect, while fostering an environment in which staff know that they can positively impact their work.

3.4.4 Standardization

Standardization is widely recognized as a means to reduce errors and confusion. This might be particularly useful in group practices where radiation therapists, medical dosimetrists and medical physicists interact with numerous physicians, each having their own preferred methods. Having too many diverse approaches can lead to confusion. It is helpful if providers can agree on standard approaches to common diseases using reference or guide sheets to avoid confusion among planning 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 site, with regular updates, as needed. These should be posted with easy access for all who may need to refer to them.

3.4.5 Hierarchy of Effectiveness

Different methods used to affect behaviors have variable expectations for success^[5]. Reliance on policies and training is the usual but least effective approach. 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. Whenever possible, it is best to “hardwire” the systems for success using simplification, standardization, automation and forced functions to create workflows and systems that support human work. Checklists and time-outs are effective^[6,7] 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”).

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"> • Patient care • Supervises RT (e.g., sets dose/volume criteria, approves plan and treatment images, manages toxicity) 	<ul style="list-style-type: none"> • Team leader for patient safety • Coordination with multidisciplinary team • Continuous education (e.g., image evaluation/segmentation, new software/technology) 	<ul style="list-style-type: none"> • Relinquish some autonomy to other personnel • Engaging others in safety mission
Medical Physicist	<ul style="list-style-type: none"> • Assure the safe and effective delivery of radiation as prescribed 	<ul style="list-style-type: none"> • Incorporating technological innovations to improve patient/staff safety • Assess safety of treatment processes, (e.g., with statistic processes, failure mode analysis, fault trees, etc.) 	<ul style="list-style-type: none"> • Role shift to increase emphasis on safety-related work • Education in advanced process analysis tools for patient safety
Medical Dosimetrist	<ul style="list-style-type: none"> • Treatment planning • Plan and TPS QA 	<ul style="list-style-type: none"> • Image cataloging/manipulation (e.g., fusion/registration/segmentation) • Assist in IMRT/IGRT/equipment QA 	<ul style="list-style-type: none"> • Adequate instruction in anatomy • Proper utilization of emerging imaging/segmentation tools
Radiation Therapist	<ul style="list-style-type: none"> • Provide safe and effective delivery of radiation as prescribed • Daily equipment and new patient treatment QA 	<ul style="list-style-type: none"> • Assessment of 2-D/3-D images to make decisions concerning patient treatment/ motion/ alignment 	<ul style="list-style-type: none"> • Safe and proper use of additional imaging and treatment delivery systems
Nurse	<ul style="list-style-type: none"> • Assist with patient care/ education • Manage toxicity 	<ul style="list-style-type: none"> • Patient pain • Assist in multidisciplinary coordination 	<ul style="list-style-type: none"> • Adequate instruction in evolving technologies • Knowledge of evolving chemotherapy agents
Nonphysician Providers	<ul style="list-style-type: none"> • Assist physician with patient care 	<ul style="list-style-type: none"> • Coordination with multidisciplinary team 	<ul style="list-style-type: none"> • Legal or regulatory restrictions
Administrator	<ul style="list-style-type: none"> • Oversight of regulatory compliance 	<ul style="list-style-type: none"> • Support patient safety program 	<ul style="list-style-type: none"> • Resource allocation
IT Specialist	<ul style="list-style-type: none"> • Desktop support 	<ul style="list-style-type: none"> • Connectivity • Failure mode analysis • Data archiving/recovery 	<ul style="list-style-type: none"> • Resources • Space • Vendor interoperability
All Clinical Staff	<ul style="list-style-type: none"> • Proper patient identification • Peer review 	<ul style="list-style-type: none"> • QA/Quality Improvement (QI) • Increased documentation in EMR • Evolving peer review • Compliance with evolving regulatory requirements 	<ul style="list-style-type: none"> • Identification/discussion of near-misses • Continuous education • Increased reliance on EMR • Adequate instruction with software/technological advances • Dedicating time for safety initiatives • Minimizing distractions

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

3.4.6 Human Factors Engineering ^[5, 8]

Human-machine interactions are ubiquitous. Human factors engineering aims to define processes, interfaces and machinery that facilitate correct usage. 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 is 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 hundreds of human-machine interfaces that are navigated daily. These require increasing mental effort as they become more complicated or lack standardization. Many are well designed, 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.

3.4.7 Incorporating QA Tools/Functionality Into Software

Often, QA is not incorporated into the planning or record and verify delivery systems. For example, user-configurable checklists and time-outs are not an option. Although potentially valuable, such embedded checklists still require the user to verify that checklist items are appropriately addressed rather than being automatic. Some embedded automatic QA functions would be useful, such as:

- For a new plan, the system searches its directory archive for patients with the same name to identify inadvertent retreatment.
- For common diagnoses, the planning system 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 treatment planner, date, etc.
- Common nomenclature of target volumes, organs at risk and plans to facilitate review of plans and identification of outliers.

Some of these functions may already exist. At least one manufacturer is “training” their planning system to identify discrepancies between pending plans and their library of “similar plans” ^[9].

3.4.8 Peer and Interdisciplinary Review

Peer review is an essential part of the safe delivery of radiation. Prospective peer review is critical, especially for new technologies such as IMRT and IGRT ^[10, 11]. Once treatment has been initiated, the threshold for making a meaningful change in image segmentation or motion-management strategy is relatively high because it may result in time-consuming replanning and QA. Physician-to-physician peer review is useful, and review of target delineation and image segmentation prior to planning deserves more standardization. Peer review is also conducted as part of the chart rounds process. See Chapter 4, sections 4.1.5 and 4.1.6, in this document for the specifics regarding the components of this process.

Peer review is clearly important for other team members as well. As an example, medical dosimetrists can check each other’s work (e.g., choice of beam selection/weighting). A distinction is often made between quality assurance and peer review (*Table 3.2, see page 23*). Quality assurance is often taken to relate to objective/quantitative “right versus wrong” actions (e.g., was the correct plan sent from the planning system 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 (e.g., target definition or dose selection) that are perhaps less likely to lead to major clinical events, and not affect a large number of patients. These interactions traditionally occur roughly as physics-, planning- or therapy-based versus physician-based. However, this distinction can be readily blurred. For example, should there be a double check for things such as machine QA? (e.g., there may be two people to confirm the machine output). Similarly, a physician can make gross right or wrong type errors in target delineation (e.g., mislabeling the left atrium as a sub-carinal lymph node) or misinterpreting published data leading to systematic errors in treatment recommendation that could affect many patients.

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

	Peer Review	Quality Assurance
Physician	<ul style="list-style-type: none"> • Target definition 	<ul style="list-style-type: none"> • Verify appropriate nomenclature and documentation • Verify dose constraints are within policy • Review portal films
Medical Physicist	<ul style="list-style-type: none"> • Verify machine output 	<ul style="list-style-type: none"> • Verify the correct transfer of data from the planning system to the treatment machine
Medical Dosimetrist	<ul style="list-style-type: none"> • Assess selection of beam orientation and weighting • Evaluate plan for target coverage and normal tissue exposure 	<ul style="list-style-type: none"> • Verify that prescription matches the treatment plan
Radiation Therapist**	<ul style="list-style-type: none"> • Double check patient setup accuracy 	<ul style="list-style-type: none"> • Ensure patient-specific procedure time-out

* Examples shown are items that might be (somewhat arbitrarily) 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.⁽¹²⁾

There is additional utility to prospective multidisciplinary interactions (e.g., between physician, medical physicist, medical dosimetrist, nurse and radiation therapist). A dosimetrist might note inconsistencies in the segmentations and directives, and anticipate dosimetric challenges (e.g., “I cannot meet both the cord and the planning target volume [PTV] doses due to their proximity”) prior to initiating planning. Such a preplanning/treatment meeting facilitates a healthy interdisciplinary dialogue that can make the subsequent planning/treatment processes smoother, but may also require more time between simulation and treatment.

3.4.9 Daily Morning Meetings

Having all members of the team meet daily to review the upcoming clinical activities can be a useful exercise to preempt potential problems. 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. Medical 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 pre-RT films/imaging reviewed that day, the daily patient treatment census and potential challenges (e.g., anesthesiology cases). All members of the group are invited to raise concerns, make announcements, and so forth. The morning meeting 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 department together daily, fostering an environment of easy communication among all team members.

3.4.10 Safety Rounds

Safety rounds may be characterized by personal 15- to 20-minute interviews by the chairman (or members of the safety or quality committees) and members of the leadership team with staff members in groups of one to three people at their worksite, asking about near-misses or unsafe conditions causing potential or real harm to patients or employees.

3.4.11 Routine Public Announcements/Updates

Issues relating to safety/quality/efficiency should be routinely included in all departmental activities. For example, the morning meeting is a good opportunity for leadership to make announcements about ongoing initiatives.

Similarly, regular reports summarizing the outcomes of safety rounds can be provided to all department members and posted in prominent locations throughout the department. This demonstrates the responsiveness of leadership and reinforces leadership's 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.

3.4.12 Address Errors and Near-Misses

Employees should be encouraged to report both errors and near-misses (errors that almost happen). Experienced employees typically know how to rapidly work around challenges, and may not always recognize the potential problems that could arise, since they are so skilled at adapting to situations. The study of near-misses is powerful in identifying problems with work processes that can lead to an error. The reporting of near-misses should be met positively, and not with fear of punitive action. Near-misses should be addressed with a similar vigor as that applied to errors, and reported through the Quality Assurance Committee.

3.4.13 Quality Assurance Committee

A dedicated formal QA committee should consist of a multidisciplinary team (e.g., physicians, medical physicists, medical dosimetrists, nurses, radiation therapists and IT support) that meets regularly and serves as liaison with leadership and hospital-wide safety committees. This committee should develop initiatives related to patient safety (e.g., sections 4.1-4.12), which are feasible and work best for the individual institution. This committee should ensure that a mechanism for reporting and monitoring errors and near-misses is in place, that leadership is aware of trends, and that a process exists for implementing change when needed. Monitoring appropriate compliance with local, national and international safety, licensure and credentialing standards falls under this committee, as does developing mechanisms to investigate serious or potentially serious incidents in near real-time (e.g., less than 24 hours). Such mechanisms may include having a dedicated team on-call to meet with staff involved in an error or near-miss, to help in determining root causes of the incident, to provide input on the potential impact of the error or near-miss and on proposed solutions or recommended changes (if any). This committee also disseminates safety information through peer review meetings, the morning meeting and safety rounds, in addition to more formal safety, QA or possibly morbidity/mortality rounds.

Peer review meetings, QA Committee, morning meetings 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 punitive.

3.4.14 Credentialing and Training

Institutional policies must exist for appropriate training and credentialing of personnel. This could be challenging with new technologies where there are few training programs or the technology is rarely available. Nevertheless, centers must ensure that providers are qualified to deliver any care for which they are privileged.

3.5.0 INGRAINING SAFETY INTO EVERYDAY PRACTICE

Safety and quality initiatives are often viewed as separate from routine practice. For example, QA meetings are something that The Joint Commission (TJC) requires, where the leadership reacts to events in the clinic 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 our clinical operations, such that it is seen as a natural component of evolving clinical practice (*Figures 3.1A and B, see page 25*). This requires a persistent acknowledgement of safety concerns by the leadership to enable an increased mindfulness among the staff.

Figure 3.1A. Hierarchical Model

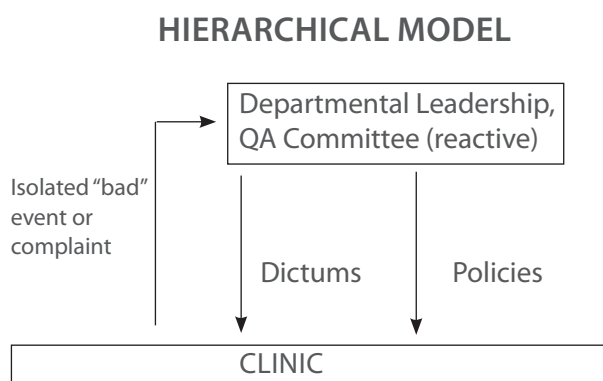


Figure 3.1B. Collaborative Model

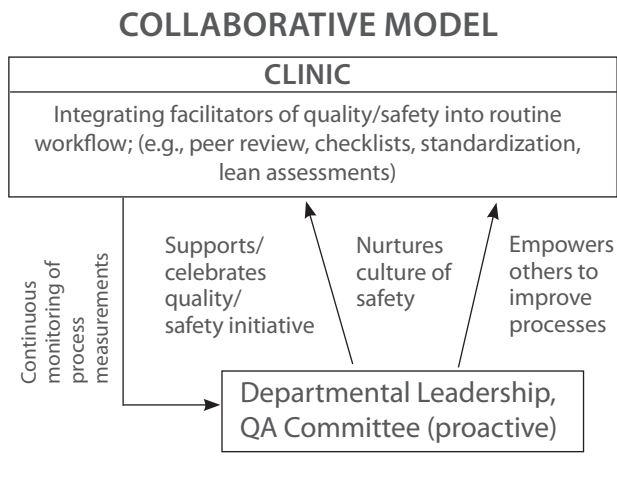
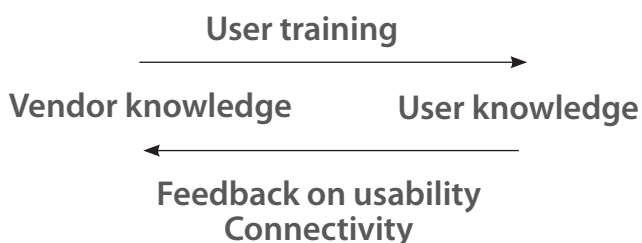


Figure 3.1. Panel A: Hierarchical model where departmental leadership and QA committee operate in a largely reactive mode where policies and dictums are “handed down” to the clinic, often in response to isolated events. Panel B: Collaborative Model where departmental leadership and QA committee proactively support and nurture a culture of safety. All staff are encouraged to become engaged in improving operations. Measures from the clinic are continually monitored to assess for opportunities for improvement.

3.6.0 COLLABORATION BETWEEN USERS AND VENDORS

The practice of modern radiation oncology requires the use of multiple commercial products. As safety becomes an increasing concern, our partnership with the vendors of these products must mature. An open exchange is needed where users and manufacturers work synergistically to maximize the likelihood of optimal outcomes (*Figure 3.2*). The responsibilities and opportunities are complementary.

Figure 3.2. User/Vendor Relationship



Users and vendors have a synergistic relationship that is critical for the healthy evolution of safe and useful products. 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 (*see section 3.4.6, Human Factors Engineering*). 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.

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 (e.g., the context) to enable the vendor to make a full assessment. Users should take the time to familiarize themselves with the functionality of new/evolving products prior to their clinical implementation and communicate with the vendors so that they can work together to seek needed improvements to products.

It is important that the team tasked with managing the needs of the radiation therapy department’s information technology reviews and approves any and all software or hardware that is involved in treatment planning and delivery. Vendor specifications and network connectivity requirements must be approved prior to the purchase of any new system (*see Chapter 4, section 1.6, Equipment and Devices*). There could be logistic challenges that limit the ability for vendors to rapidly alter products (e.g., Food and Drug Administration [FDA] regulatory review, and user acceptance of “short cycle” upgrades).

3.7.0 INVOLVING THOSE BEYOND RADIATION ONCOLOGY

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

Table 3.3. Multidisciplinary Approaches to Quality in Cancer Care Delivery

Radiation Oncology Initiative	Analogous Multidisciplinary Initiative
Pretreatment team discussion	Tumor board
Daily meeting	Regular multidisciplinary meetings to review patients under treatment
Determining unambiguous methods of communication between team members in the radiation oncology EMR	Determining unambiguous methods of communication between multidisciplinary care providers in an oncology-specific or hospital-wide EMR
Safety rounds within radiation oncology	Safety rounds within cancer center
Departmental safety culture	Cancer center or hospital-wide safety culture
Discipline-specific training	Team training

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Management and Assurance of Quality in Radiation Oncology

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4.1.0 QUALITY REQUIREMENTS FOR RADIATION ONCOLOGY PROGRAMS

The overall goal of the guidelines summarized in this chapter is the delivery of high quality radiation oncology treatment to all patients. Note that quality assurance is a shorthand term which is often used to describe some or all of the different aspects involved in quality management (QM) and a culture of safety.

4.1.1 Facilities

A radiation oncology facility must satisfy numerous requirements:

- General space requirements include providing adequate clinic space, exam rooms and equipment, patient waiting and changing space, convenient patient parking, treatment rooms, simulation/imaging room(s), brachytherapy source preparation and storage space (if service is offered), dosimetry and treatment planning rooms, office space for professional staff (physicians, medical physicists, nursing, etc.) and medical physics laboratory/equipment storage space. The extent of facilities should be appropriate for the volume of patients seen and treated, as well as the modalities offered.
- Treatment rooms for linear accelerators or other treatment machines (e.g., tomotherapy, cobalt, robotic accelerator systems, etc.) must be carefully designed for radiation shielding, environmental conditions, adequate storage space for spare parts, testing and dosimetry equipment, patient access and safety, while also allowing installation, testing and repair of the treatment system. Design must include video and audio patient monitoring systems, dosimetry monitors (when required), electronic cables for dosimetry, computers and other systems.
- Each department must have access to CT imaging for treatment planning. Radiation oncology CT-Simulator room designs must carefully protect staff from accidental radiation exposures, while allowing patient positioning, immobilization device implementation or fabrication. The same requirements apply to MR-Simulation rooms (when the modality is offered) with the additional requirements for the establishment of an MR safety zone.
- Rooms used for brachytherapy procedures require special attention to the specific radiation protection requirements associated with the particular brachytherapy modalities used. If the brachytherapy procedure load warrants it, a brachytherapy suite should be available, including patient waiting space, procedure rooms, recovery rooms (if necessary) and brachytherapy source preparation and storage areas, so that the entire brachytherapy process can be performed within a well-designed and controlled space, to ensure radiation protection and source control.
- Each department must have electronic access to the hospital, clinic or outside information system(s) and picture archiving and communication system (PACS), interaction with other medical specialties to insure

coordination of care as well as access to laboratory services, and other ancillary services such as social service, dentistry and nutrition for the benefit of patients during therapy.

4.1.2 Program Requirements

Each radiation oncology program must satisfy a number of general requirements.

4.1.2.1 Program Accreditation

Each radiation oncology program should become accredited by an established radiation oncology-specific accreditation program. This process will verify that crucial basic capabilities and procedures necessary for quality radiation therapy are performed, and will raise the general level of radiation oncology practice in the country.

4.1.2.2 Required Capabilities

The following specific capabilities and methods for various aspects of the radiation therapy process are essential:

- Calibration of treatment machines, CT and MR scanners, treatment planning systems and brachytherapy sources shall be carefully accomplished according to the appropriate protocols described by scientific/professional organizations.
- A safety program designed to improve patient safety, avoid radiation incidents and prevent errors in the treatment process shall be in place and periodically reviewed and enhanced.
- The system for documenting radiation therapy treatment, and other aspects of the patient's medical care ("charting") must be rigorous, periodically reviewed and enhanced, and available to all members of the radiation oncology team when needed.
- High quality and comprehensive treatment planning, using 3-D computerized treatment planning for dose calculations, imaging and other aspects of the planning process, is essential.
- A comprehensive quality management program, including quality assurance, quality control (QC) and other quality improvement tools shall be in place.
- Radiation monitoring of machinery, sources and patients (where necessary) and staff exposures are crucial.
- All radioactive sources shall be carefully controlled and monitored, as required by regulatory agencies
- A careful and pre-emptive program for maintenance and repair of equipment is essential.
- Staff training shall be comprehensive, ongoing and well documented.

- Each department shall have a well-developed strategy for peer review, for the entire department and its procedures, as well as for individual clinical care, physician and qualitative decisions made throughout the process (e.g., treatment plan quality, patient setup technique acceptability).
- Each department must have access to medical oncology, surgical oncology and other physicians involved in the multidisciplinary care of the patient, as well as access to dentistry, nutrition, laboratory testing and other supportive services necessary for patient care or handling of patient toxicity that arise during (or after) therapy.

4.1.2.3 Policies and Procedures

Each department shall develop and implement careful and well-described policies and procedures for each aspect of the process used for patient care, for QA of the patient care process, and for staff behavior, as well as those issues impacting safety for patients and/or staff. Each specific treatment (e.g., IMRT, IGRT and SBRT) should have detailed documentation of its treatment planning and delivery process, roles and responsibilities of each team member in that procedure, QA checklists and test procedures, and a plan for continuous quality improvement and safety.

4.1.3 Radiation Safety

Radiation safety, for patients and staff, is a crucial responsibility for all members of the radiation oncology department. This section documents, in brief, the technical requirements for facilities and machines that will facilitate safety.

4.1.3.1 Radioactive Source Procedures

AAPM Task Group Reports 56^[50], 59^[33], 138^[15] and 144^[72] outline safety and quality standards for the handling of radioactive sources such as those used in brachytherapy clinical procedures and QA. Safety considerations should be consistent with state and federal regulations. The radiation oncologist, medical physicist and radiation safety officer should define local radiation safety guidelines that are consistent with the ASTRO, ACR/ASTRO, American Brachytherapy Society (ABS) and regulatory brachytherapy guidelines.

4.1.3.2 Accelerator 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 ensure patients and staff members do not receive any

unwarranted radiation exposure. A monitoring program that updates and enhances the safety of this program must be a part of the departmental procedures.

4.1.3.3 Safety for Imaging Devices

Unlike the general situation with diagnostic imaging and image guided surgery, imaging in radiation therapy adds the imaging dose to an already high level of radiation therapy. There is a strong correlation between increased imaging and improved quality of delivery of the therapeutic dose; therefore, the emphasis in radiation therapy should be on optimizing rather than simply minimizing the imaging dose. AAPM Task Group 75^[38] provides guidance on optimal use of imaging and strategies for reducing imaging dose without sacrificing its clinical effectiveness.

4.1.4 Monitoring Safety, Errors and Medical Quality

One of the most crucial activities in a quality radiation oncology department 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 means from the leadership of the institution and of the radiation therapy department; on individual effort by every member of the department; and on organized support for quality and safety at every level in the institution. This section briefly describes a few of the organization- and department-level activities that can help to create the necessary culture and awareness.

4.1.4.1 Quality and Error Monitoring

Each department should have a department-wide review committee which monitors quality problems, near-misses and errors in treatment, diagnosis, patient care or other procedural problems that might lead to errors. This committee should organize the collection and analysis of such events, work to identify potential problems in devices or processes, and then try to mitigate these problems by modifying processes or adding new checks or actions to minimize the likelihood of further problems. It is important that these kinds of safety-related efforts, data and notes be identified as peer review protected and not subject to legal discovery. Further detail can be found in Chapter 3, Safety.

4.1.4.2 Safety, Morbidity and Mortality Rounds

Radiation oncology departments 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 to be reviewed

should include unusual or severe acute complications of treatment, unexpected deaths or unplanned treatment interruptions. At a minimum, participants included should represent all the team members, including radiation oncologists, nurses, medical physicists, medical dosimetrists, radiation therapists and administrators. Minutes of this review should be recorded.

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 institution should determine the appropriate process time allocated for each step in the process. **Table 4.1** (see page 32) is an example of such a record, listing basic steps in the process. It is the responsibility of each institution to develop its own guidelines for the amount of time allocated to each step in order to avoid inappropriate time pressures. The goal of this effort is to avoid safety issues caused by time pressures, while satisfying the responsibility of the radiation oncology team to set a course of action that will assure a timely, yet safe and accurate transition from patient clinical evaluation to treatment.

4.1.5 Monitoring Professional Performance

Over the past several years, there has been increasing interest on the part of public and government agencies in requirements for greater oversight for physicians and other healthcare providers. In response to the public’s concerns, the American Board of Medical Specialties (ABMS) decided that all medical specialties should develop MOC programs to replace current recertification initiatives. The ABMS has defined four components of MOC: professional standing, lifelong learning and self-assessment, cognitive expertise and practice quality improvement (PQI).

Many specialty societies offer opportunities for radiation oncologists and medical physicists to satisfy the requirements of MOC. For example, ASTRO has developed online courses with self-assessment modules (SAMs) to fulfill the lifelong learning requirements and a special program called the Performance Assessment for the Advancement of Radiation Oncology Treatment (PAAROT)^[76] to meet the PQI requirements. ACR has the R-O PEER program and the AAPM offers similar initiatives for medical physicists. Radiation oncologists and medical physicists should take advantage of these opportunities.

One important aspect of those programs is the use of peer review methods to help individuals learn from other practitioners in the field. Peer review is relevant in a number of different aspects of clinical practice: overall review

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

Individual institutions 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.

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	x days
Planning: 3-D IMRT, Volumetric Modulated Arc Therapy (VMAT)	x days
Planning: 3-D SBRT	x days
Planning: SRS	x hours
Plan evaluation and physician approval	x minutes (though xx hours must be allocated to schedule this time)
IMRT QA and analysis	To be completed x hours before treatment
Treatment preparation (transfer from treatment planning system to treatment management system before treatment start)	Allow x hours
Final checks before treatment	x minutes or hours
Treatment setup and delivery (based on complexity)	x minutes

of the behavior of the practice, review of individual skills and methods, as well as the common practice of reviews of physician clinical decisions which occur at a weekly “chart rounds” type review of ongoing patient treatments. Note that peer review is a quality improvement tool that has application throughout the process of radiation therapy (see, for example, the Safety White Paper on Peer Review^[77]).

4.1.5.1 Ongoing Monitoring/Evaluation of Staff Qualifications

It is equally important that the other members of the radiation oncology team have proper credentials and training in the simulation, treatment planning, treatment delivery and QA processes of each specialized treatment technique. The staff should also be appropriately trained to use each specific device.

Radiation oncology is a technologically demanding field which is dependent on well-trained and highly-skilled members of the radiation oncology team, as described earlier in this report. It is crucial that all members of the team

maintain the proper credentials, skills and training levels, satisfying clinical competencies annually. In some cases (for example, radiation therapists moving between different kinds of treatment machines), additional training or review sessions in the use of specific devices may be necessary more often than annually. Each facility should follow the ASTRO recommendations and ensure that the staff have opportunity to maintain continued competence in their job responsibilities. See, for example, the roles, responsibilities and training requirements for each staff member described in the recent Safety White Paper on IMRT^[37].

4.1.6 Equipment and Devices

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 quality assurance. Further patient- and process-oriented quality measures and QA are described later.

4.1.6.1 General Guidance

For any device, system or process to be integrated into the radiation oncology care process, many of the same general methods and issues must be addressed, as described here.

System Specification, Acceptance Testing, Clinical Commissioning and Clinical Release:

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

- **System Specification:** To prevent later safety or effectiveness problems, each system should be carefully specified before acquisition, purchase or development, including design, expectations, capabilities, tolerances, hazards, necessary training, usability and technical specifications.
- **System Connectivity:** To prevent data communication errors and clinical efficiency issues, each system must be interoperable and interconnectable with other systems in the clinic. Integrating Healthcare Enterprise-Radiation Oncology (IHE-RO) compliance can help ensure interoperability and interconnectivity of devices in the clinic.
- **Acceptance Testing:** To document that the new system satisfies the specifications, acceptance testing must be performed. Often, the acceptance criteria and/or testing methods should be documented as part of the specification for the system.
- **Clinical Commissioning:** All the activities that must be performed to understand, document, characterize and prove that a given system is ready to be used clinically are included in clinical commissioning. Determination of the limitations under which the system can be used safely is one of the important parts of the commissioning process. Such commissioning should be dependent on the clinical use(s) of the system, and typically is not a static thing that can be done only once, since clinical system use usually evolves and changes with time and clinical needs. Standard operating procedures, training and hazard analysis should be part of the commissioning process.
- **Clinical Release:** Each new system, device, capability and process must be formally released for clinical use after clinical commissioning has been completed.

Device, System or Process QA: Clinical use of a device, system or process must be included in the creation and application of a safety- and quality-oriented program which helps assure that the system is working appropriately and as desired. This kind of program has many aspects:

- **Quality Management:** QM, the overall program that aims to organize all the quality efforts appropriately to assure the quality and safety of the use of the system, must be established for each new system or process. The QM program should include hazard analysis, quality control, quality assurance, training and documentation, and ongoing quality improvement efforts.
- **Hazard analysis:** Hazard analysis, the active evaluation of the potential for failures that will cause incorrect results or harm to the patient, should be performed in some fashion for any new system, as it will help delineate issues which can benefit from QC, QA, training or other mitigation strategies. The methodologies, such as failure mode and effect analysis (FMEA), that are prevalent in the industrial world are being adapted for process and quality improvement in healthcare. The Joint Commission now requires every hospital to use FMEA as one means to improve its processes.
- **Quality Control:** QC includes activities that force 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 QC, QA or other methods depends on how to prevent errors most efficiently. Note that QA is the typical shorthand term used throughout the field to describe the entire QM program, not just the quality assurance aspect.
- **Training and Documentation:** Training of staff in goals, methods, results, operation and evaluation of the quality of output can be very important in proper use of any system. Documentation of appropriate operating procedures is also critical, so new staff can be trained. Both training and documentation should be updated often. In particular, it is often necessary to perform retraining of 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 QA/QC/QM program. Maintenance programs (below) are another important part of any QM program.

Maintenance: All systems, devices and processes require routine maintenance. While most people are familiar with the maintenance needs of mechanical devices, electronics and software, processes also need routine maintenance, though the specifics of the maintenance required are different:

- **Mechanical systems:** Routine mechanical and preventative maintenance programs are crucial to prevent major component failures, and are safety critical, as failures can lead to major potential safety problems.
- **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 behavior.
- **Software systems:** Since software is never completely bug-free, and the use of the system can evolve as experience is gained, maintenance in the software context often involves the installation of new versions of the software. 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) can contain significant new problems that can be unrecognized before the commercial release of the software, so these upgrades can 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:** All processes evolve as they are used clinically. This evolution therefore changes the potential failures that the process may be sensitive to, so the QM program associated with that progress must be modified (maintained) just as other systems require maintenance.

Adequate time, materials and resources must be allocated for the maintenance program of all systems and devices.

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 virtually all interconnected. The safety and quality of any therapy planned or performed with this

system of interconnected devices is crucially 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 will always occur given a specific set of circumstances. These errors can be nearly impossible to find without specific formal hazard analysis and directed testing.

A concerted program directed toward rigorous testing and documentation of the accuracy and correctness of computer system interconnections, interfaces and interoperability must be used for all systems involved in radiation therapy. The IHE-RO program is one effort to address this need, but each institution should evaluate and implement QM/QA/QC testing programs to confirm that interconnected systems used in their center are correct and safe. IHE-RO compliance should be part of this testing.

External Review: Single points of failure, or extremely unlikely combinations of errors, can happen to anyone or any institution. Independent review of crucial aspects of any quality program is an extremely effective way to avoid those highly unlikely or single point failures, and should be used wherever practical.

The intersociety group recommends the creation of mechanisms to support the following independent/external reviews:

- Basic treatment machine calibration should be confirmed before clinical use and annually thereafter by a nationally-available program (similar to the radiological physics center [RPC] remote monitoring program).
- Special treatment techniques (including IMRT, SBRT, SRS, IGRT, intraoperative radiation therapy [IORT] and others) should undergo external peer review initially and at regular intervals to maintain “competency” in that technology.
- Review of treatment planning system implementation and use should happen initially and at regular intervals. Comparisons can be detailed, as performed by the RPC, or more limited comparisons performed with the appropriately designed plan comparison strategies, including use of similar machine data and calculation methods.
- Treatment protocols and standard operating procedures should be peer reviewed by an external radiation oncologist every five years (as part of accreditation).
- Many more aspects of a radiation oncology program will benefit from similar review, including the device calibration and QA program, clinical protocols and nursing support.

Equipment Replacement, Upgrades and Additions:

Radiation therapy devices require replacement or upgrades when they become technologically obsolete or worn out. 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. On the other hand, treatment planning systems require replacement or upgrade when the hardware becomes obsolete or the software functionality limits its ability to satisfy the current standard of care.

Beyond its useful working life, a treatment planning and/or delivery system 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 departmental and institutional, not geographical or political, needs.

Furthermore, the need for additional equipment in a specific facility 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.

4.1.6.2 External Beam Treatment Machines

Minimum Device Requirements: State-of-the-art radiation oncology facilities require a standard treatment delivery platform to deliver 2-D and 3-D conformal external beam radiation therapy and IMRT. Standard features include one or more photon energies, multiple electron energies, multileaf collimator (MLC), electronic portal imager and a computerized treatment delivery and management system. The equipment capabilities should be sufficient to provide a continuum of care for patients.

As an example, it is unrealistic to assume that all patients needing electron beam therapy will be specifically referred to an “outside” facility for that purpose. However, there is also justification for the establishment of specialized care facilities for complex circumstances, like treatment of pediatric cases, radiosurgery and proton therapy. These types of centers can provide focused expertise in certain complex treatment delivery techniques that may require special considerations in terms of staffing and training. Professional and scientific organizations in the United States (AAPM, ACR, American College of Radiation Oncologists [ACRO] and ASTRO) have established practice guidelines/standards that outline accepted processes related to these complex techniques. Referral of patients to such facilities for specialty care should be supported and encouraged.

Minimum QA Requirements: The bulk of radiation therapy treatment is performed with external beam machines (linear accelerators, tomotherapy, robot accelerator systems, etc.). A complete quality management program is essential for each device, and should include routine quality assurance and quality control procedures, monthly and annual testing, as well as a hazard analysis of the treatment process used for that machine to identify procedural problems in addition to the technical or mechanical issues that the QA/QC checks address. Current quality expectations are described in detail by well-known guidance documents (**Table 4.2**). Modern techniques such as IMRT and IGRT have become the standard of care for the treatment of a wide variety of disease sites. The basic QA/QC and clinical practice guidelines for these procedures are also well documented (**Table 4.2**). Newer IMRT delivery techniques such as VMAT and Flattening Filter-Free (FFF) treatment delivery do not have published guidelines. Therefore, it is the responsibility of medical physicists (along with other members of the radiation oncology team) to evolve and modify existing QA programs to make them as effective as possible for the clinical treatments

Table 4.2. Basic External Beam QA Requirements

Name	Issue	Recent Summary	References
Linac + MLC	Linear Accelerator Use	TG 40 + TG 142. TG 148 (tomotherapy), TG 135 (robot accelerator)	[32], [31], [34], [16]
3-D CRT	3-D Conformal Therapy and Treatment Planning	ACR 3-D, TG 53	[1], [20]
IMRT	Intensity Modulated Radiation Therapy	IMRT Safety White Paper	[37] and references therein
IGRT	Image Guided Radiation Therapy	IGRT Safety White Paper	[30] and references therein

performed in that institution, as well as to deal with evolution of the technology and capabilities of the equipment.

4.1.6.3 Brachytherapy Devices

Minimum Device Requirements: Due to its century-long record of clinical implementation, the field of brachytherapy has grown into a subspecialty, having devices developed specifically for each disease site. Still, there are frequent advances that move the field forward and permit improved local control rates and/or minimized healthy tissue toxicities. It is not feasible to outline the minimum standards for devices used for every current disease site. However, the expected minimum standard is to provide at least the same current level of safety and capability as existing devices. New capabilities that supersede existing capabilities are required for new brachytherapy devices.

Minimum QA Requirements: The AAPM and other radiation therapy professional societies have prepared reports issuing quality standards for the sources and devices used for brachytherapy. **Table 4.3** indicates the associated reports providing guidance for these sources and devices.

4.1.6.4 Imaging Devices

Minimum QA Requirements: Numerous imaging devices are crucial to the radiation therapy process, including diagnostic systems used for development of the

treatment approach and plan (e.g., CT, MR, PET), as well as systems used during treatment for patient setup, positioning, alignment, motion assessment and IGRT (e.g., megavoltage portal imaging, kilovoltage imaging, cone beam CT [CBCT] and numerous alternate technologies). Finally, the advent of adaptive and individualized approaches to the treatment course, based on serial CT and/or MR imaging, as well as functional MR, PET and Single Photon Emission Computed Tomography (SPECT) images, has led to new QA requirements for the use of these systems within the radiation therapy treatment course.

- Diagnostic systems used in radiation therapy (CT, MR, PET) must satisfy the usual diagnostic QA requirement^[85, 84], but must also satisfy the more stringent geometric requirements forced by the use of the images for patient and beam geometry. Additional testing for this issue is recommended.
- QA for the kV and MV imaging systems which are used for patient localization, setup and motion assessment is well described by recent reports^[86-91], as well as the recent ASTRO IGRT Safety White Paper^[30] and the ACR/ASTRO IGRT Standard of Practice^[2]. It is essential that the recommendations of these reports be used, but they should be modified to appropriately handle the specific requirements of the IGRT or other positioning techniques used in each institution, paying close attention to the tolerances which the entire process allows.

Table 4.3. Brachytherapy Devices

Brachytherapy sources or devices	References
Radiation sources	
General	[48], [32], [49]
HDR and pulsed-dose-rate remote (PDR) afterloaders	[50], [70], [15], [23]
LDR sources	[33], [51]
⁹⁰ Y unsealed sources	[72]
Electronic brachytherapy sources	[74], [53]
Liquid radioactive sources (Iotrex)	[73]
Intravascular brachytherapy (IVBT) sources	[52], [13]
Applicators	[50], [73]
Hardware	[50]
Imaging devices	[50]
Treatment planning systems and dose calculation processes	[48], [32], [49], [20], [50]
Survey instruments, badges, radiation safety	[48], [32], [50]

- The use of functional and metabolic imaging as part of the adaptive treatment process is a technique which is just developing now, so many changes are expected. 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.

4.1.6.5 Treatment Planning Systems

Minimum Device Requirements: 3-D computerized treatment planning based on CT data is the minimum state-of-the-art for modern radiation therapy. Safe and effective use of planning requires direct input of CT, MR and other imaging information; the capability 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; dose-volume histograms (DVHs) and other plan evaluation metrics; and electronic downloading of treatment plan information to the treatment management system. Many special treatment techniques require specific and sophisticated use of additional planning capabilities, as described in **Table 4.4** (see page 38).

Minimum QA Requirements: Computerized treatment planning is an essential requirement of virtually every radiation therapy treatment, so the quality assurance of the planning system and of the process in which it is used is crucial. AAPM TG 53^[20] provides a general guidance to all the issues which must be addressed in order to use 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 4.4**. Specific discussion of dose calculation algorithm issues is described by a number of reports, including the recent TG 105 on Monte Carlo treatment planning issues^[92].

4.1.6.6 Treatment Management Systems (TMS)

Minimum Device Requirements: State of the art radiation therapy involves the use of a computerized treatment management system (TMS) which manages treatment delivery and/or all the treatment preparation and planning steps involved before treatment. These systems, evolved from record and verify systems which were used to check manually set treatment parameters on “analog” treatment machines, now involve 1) an information system piece (sometimes called an “RT-EMR”) 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 treatment delivery system that directly manages the flow of activities during treatment delivery, as well as patient setup, imaging and IGRT, treatment verification and other activities that happen during each fraction of a patient’s treatment. The TMS communicates with the departmental network, hospital EMR, other ancillary treatment setup, verification, dosimetry and scheduling systems.

Minimum QA Requirements: The TMS is one of the newest and most quickly evolving systems involved in radiation therapy. As such, the quality management program, which should be associated with safe use of the system, is less well-described and understood than almost any other system. A few of the crucial QA issues for TMS that have been published are listed in **Table 4.5** (see page 39), however, new efforts to develop improved guidance in this area are needed.

4.1.6.7 Particle Therapy

Minimum Device Requirements: Particle therapy is another contemporary form of radiation therapy that has its own unique challenges. 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 intrafractional patient and organ motion, physiological changes and treatment delivery. Furthermore, the locations, shapes and sizes of diseased tissue can change significantly because of daily positioning uncertainties and anatomical changes during the course of radiation treatments. To ensure safe and accurate treatment planning and delivery of particle therapy, minimum device requirements include on-line 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.

Minimum QA Requirements: Particle therapy does not currently have QA guidelines published by our national scientific organizations, though there are AAPM task groups at work on aspects of proton therapy QA. Therefore, it is the responsibility of medical physicists (along with other members of the RT team) to evolve and modify existing QA programs to make them as effective as possible for the clinical treatments performed with a particle therapy system, as well as to deal with evolution of the technology and capabilities of the equipment.

Table 4.4. Additional Treatment Planning Requirements

Technique	Requirement	References
IMRT	Automated optimization, cost function creation, MLC sequencing (or equivalent delivery script creation)	[19], [37], [25]
SBRT	Preparation of IGRT reference data (annotated digitally restored radio-graphics [DRRs], or reference data for CBCT comparisons)	[64], [10], [6], [58]
SRS	Integrated use of stereotactic frame coordinate systems, integrated use of specialized radiosurgery applicators and arc delivery	[5]
VMAT	Field and MLC optimization capabilities for specialized IMRT arc therapy delivery, including delivery constraints	[69]
Use of MRI, PET, etc.	Requires image dataset registration and fusion of imaging information	[20], [71]
NTCP and Biological Modeling Features	Clinical use of normal tissue complication probability or other biological modeling information requires appropriate algorithms and especially the relevant clinical data. Specifically note the recent Quantitative Analysis of Normal Tissue Effects in Clinic (QUANTEC) project publications ^[80] .	[80], [36]

4.1.6.8 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 radiation therapy techniques and devices. Robotic radiation delivery systems, SRS, SBRT, IORT, electronic brachytherapy, motion and setup management devices and unsealed radiopharmaceutical sources are some of the examples of such specialized techniques and devices. Each of these techniques and devices have unique performance and QA requirements that should be critically evaluated before they are introduced in the clinic. Issues that should be considered include: reason(s) for device/technique introduction and use; minimum requirements to use device safely (including an adequate team both for the planning and delivery process, *see section 4.2.2.2*); description of how device is to be introduced; necessary training; and need to compare results with current clinical standard with respect to clinical objectives for use and outcomes.

Often, but not always, the introduction of specialized techniques and devices prompts professional organizations such as ASTRO, AAPM and ACR to develop clinical/QA guidelines. For example, ACR and ASTRO already have practice guidelines for the performance of IMRT, IGRT, SRS, SBRT, total body irradiation (TBI), electronic brachytherapy and therapy with unsealed radiopharma-

ceutical sources. AAPM also has QA task group reports on most of these specialized techniques and some devices. However, the development of these guidelines and recommendation usually lag behind their clinical implementation. Therefore, it is incumbent upon the early adopters of emerging technologies and techniques (radiation oncologists and medical 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.

4.2.0 PATIENT-RELATED QUALITY MANAGEMENT

Concentration of QA efforts and scrutiny of the devices and processes involved in radiation therapy address only one aspect of the overall problem. Within the complex and many-step process with which radiation therapy patients are treated, patient-specific issues must be carefully and comprehensively analyzed, documented and verified.

Table 4.5. Treatment Management and Delivery System Issues

Safety/Quality Issue	Recommendations	Reference
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	[59]
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.	[59]
System interconnectivity	IHE-RO protocols	[81]

4.2.1 General Guidelines

4.2.1.1 General Medical Issues

Each radiation oncology facility, regardless of its location, size or complexity, must appropriately manage and adhere to high quality standards of practice for general medical issues, including:

- Drug allergies
- Do-not-resuscitate codes
- Cleanliness and efforts to reduce infection
- Patient confidentiality and security of protected health information

4.2.1.2 Multidisciplinary Physician Conferences and Multidisciplinary Clinics

Modern oncology patient care very often involves multiple modalities and requires the review and discussion of experts in various oncology-related disciplines. It is critical that many types of cancer, and most complex cases, are addressed by the appropriate mix of disciplines. Regular presentation of these cases to multidisciplinary physician conferences (conventional tumor boards or prospective disease-site treatment planning conferences) is one standard of care, and should be performed for most cancer cases 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 clinics by various specialists (surgeon, radiation oncologist, medical oncologist) in concurrent or sequential fashion (see The Advisory Board Oncology Roundtable, 2008 on Multidisciplinary Cancer Clinics).

4.2.1.3 Quality and Safety in Patient Care Process

The process of patient care in radiation oncology departments varies between institutions, and depends on the specific organization and details of each department. However, maintenance of the safety and quality of the radiation therapy process for most patients requires that a number of procedures must be performed adequately. Guidelines regarding many common radiation oncology procedures are addressed in the ACR Practice Guideline for Radiation Oncology^[94]. These SOPs include:

- **History and Physical (H/P):** It is essential for the radiation oncologist to obtain a clear, accurate and detailed description of the patient’s history, current status and medical issues so that appropriate radiation therapy decisions are made. The H/P information must be available to others who interact with the patient so they can make informed and appropriate decisions.

- **New patient conference:** In most departments, a brief presentation of the details of each patient's H/P, disease status and plan for therapy to the other physicians and staff involved in patient care is used as early peer review for the basic treatment decisions and plan.
- **Multidisciplinary physician conferences (tumor board/prospective disease-site treatment planning conferences) or multidisciplinary disease-site clinics:** As previously mentioned, discussion in a multidisciplinary physician conference or evaluation in concurrent or sequential multidisciplinary clinics is essential for many patients' cases.
- **CT-Simulation:** Virtually all patients who receive non-superficial radiation therapy should receive a CT-based simulation.
- **Contouring/contour review:** After the physician defines target volumes and normal organs/tissues, this anatomical description of the patient should be reviewed and confirmed (by physician, with peer review if possible) before treatment planning begins.
- **Plan evaluation and approval:** After treatment planning, the physician and members of the planning team must review the plan, verify that it satisfies the clinical requirements and prescription(s) from the physician, and that it can be carried out accurately.
- **On-treatment visits:** For most patient care, on-treatment visits of the patient to the physician are essential for continuity of care and monitoring of patient response and toxicity. Typically, this happens approximately every five fractions at a minimum, but clinical circumstance may require more frequent visits.
- **Patient chart rounds:** Traditionally, chart rounds is an important peer review procedure used throughout radiation oncology, involving weekly review of patients under treatment by the radiation therapy team, including multiple physicians, radiation therapists, nurses, medical dosimetrists and medical physicists. The ongoing review of patients under treatment is crucial, and many institutions are attempting to develop improved methods for both peer review and technical quality assurance techniques. See, for example, the ASTRO Safety White Paper on Peer Review^[77]. Note that for small or remote centers, electronic peer review or other collaborative method from other locations may be necessary.
- **Follow-up visits:** Patient follow-up visits are crucial to clinical patient management and to gather treatment outcome information. Newer processes, including patient-reported outcome reporting, are in development. The frequency and method of follow-up are specific to each type of cancer, stage and clinical status

of the patient. Patients would preferably have a component of their follow-up performed in the office(s) of the treating radiation oncologist by either the radiation oncologist or a nonphysician provider so that the most accurate information is obtained with regard to both treatment tolerance and disease status (free of disease; local, regional or distant relapse).

4.2.1.4 Charting and Documentation

In a highly technical field like radiation oncology, documentation of all the relevant details of the overall plan for patient care, including the technical details of all procedures as well as the clinical trade-off decisions and compromises that led to decisions about the treatment course, are crucial. Maintenance and improvement of the quality and accessibility of the documentation of patient's treatment strategy and delivery is a high priority.

Radiation oncology is currently involved in the transition from paper charts to EMRs and a paperless environment, so many of the old standards of care are being revised or completely changed to handle the new EMR environment. Radiation oncology departments, practices, vendors and everyone else in the field must continue to improve the design, implementation and effectiveness of electronic documentation for radiation oncology care, changing processes and quality management strategies to address the fundamental change and the kinds of errors or misunderstandings that may commonly occur with electronic systems.

Currently, there is significant emphasis on behalf of governmental bodies and regulations attempting to push the health enterprise toward improved use of EMR technology. The radiation oncology team should make use of EMR technology to enhance patient care coordination, as required by the recent HITECH ACT^[78].

4.2.1.5 Outcome Assessment

Performance status and organ function prior to treatment should be assessed in many clinical circumstances to determine baseline status. Thereafter, routine and consistent assessment of patient outcomes and toxicity should occur both during and after treatment. This is a crucial aspect of quality radiation therapy treatment, and must be performed in a systematic way, preferably in the treating physician's office, as noted in section 4.2.1.3. 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 overall quality management system for the institution. Standard toxicity scoring schemes (e.g., RTOG, European Organisation for Research and

Treatment Center [EORTC] or similar) should always be employed when applicable. Departments should consider the collection of “Patient Reported Outcomes” as another aspect of outcomes assessment since these valid instruments have come into common use. These results can also be linked with physician quality reporting systems (PQRS) as they become available.

4.2.1.6 Outcomes Registry

In addition to the assessment of outcomes by each individual institution for their local QA, reporting clinical patient outcomes, such as treatment-related toxicity and control rates, to a shared registry serves an important role in the development of the “Rapid Learning Health System”^[93]. Registries also serve to identify variations in technique, physician methods, process of care, patient selection and various other confounding variables that will allow for improvement in radiation oncology treatment. Outcomes data will be most accurate if obtained in the treating physician’s office (radiation oncologist, NP or PA), as noted in section 4.2.1.3.

4.2.2 External Beam Quality Assurance (QA)

4.2.2.1 General Guidelines

QA for the Standard External Beam Process: Nearly all external beam treatment processes involve 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-Simulation); creation of the anatomical model (contouring); specification of the treatment intent; creation of the planning directive and treatment prescription by the physician; computerized treatment planning and dose calculation; monitor unity (MU) calculation and/or IMRT leaf sequencing; plan and electronic chart preparation; plan evaluation; download to TMS; patient-specific QA typically performed for IMRT, SRS and SBRT; patient setup and delivery; plan verification checks; plan adaptation and modifications; chart checks; and more. See for example^[1, 3, 25, 37] and many other references. **Table 4.6** (see page 42) describes a standard set of quality assurance process steps commonly used to help prevent errors or loss of quality in most standard external beam treatment processes. The sequence of these steps may vary depending on clinical presentation and circumstance.

Commissioning and QA of the Treatment Planning and Delivery Process: Commissioning and quality assurance of the process used for planning and delivery of treatment to each patient is just as crucial as the commissioning and QA for the systems used as part of that process. 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. Commissioning of a clinical process typically should include the following:

- Commissioning and testing of each individual component of the process
- Evaluation of the potential failure modes of the process using a hazard analysis or similar technique to look for potential weak points in the process
- Directed testing of the interfaces between systems (for example, testing the download connection from treatment planning to the treatment management and delivery system)
- 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
- Review and identification of QA tests or other process changes which can prevent or mitigate the most likely failure modes of the process
- 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

4.2.2.2 Technique-Specific Issues

There are a variety of specialized techniques in radiation oncology that are used in appropriate clinical situations (3-D CRT, IGRT, IMRT, SRS, SBRT, TBI, partial breast irradiation [PBI], IORT). Details regarding recommended clinical practices and quality assurance parameters, developed by expert panels, are covered in documents from ASTRO, ACR and other professional organizations. The reader may consult these documents for more comprehensive information (**Table 4.7, see page 43**).

3-D Conformal Radiation Therapy: Clinical requirements for appropriate use of 3-D CRT include:

- Experience with dual photon energy linear accelerators with electron beams, radiographic imaging and megavoltage imaging devices
- Clinical experience with use of CT scanner equipped with CT-Simulation software and laser alignment devices
- Knowledge and experience with 3-D treatment planning software, including the ability to contour target(s) and adjacent critical structures and ability to perform volumetric dosimetric analysis with DVHs
- Experience with design and use of beam shaping devices (including cerrobend blocks or MLCs)
- A radiation oncology team (physician, medical dosime-

Table 4.6. General Clinical QA Guidelines

This table describes optimal quality assurance process checks which are commonly used during routine radiation therapy. There are a wide variety of times when these checks are performed. This table describes the timing that is likely the most efficient.

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, Medical Dosimetrist, Medical Physicist	Describe plan intent, target volumes, dose expectations, normal tissue limits, other treatment constraints or goals; peer review of goals and limits is important.	Before planning process
Approval of volumes	Radiation Oncologist, Medical Dosimetrist, Medical Physicist	Verify accuracy and appropriateness of target volumes (including GTVs, CTVs, PTVs, ITVs (per ICRU-50 [52], ICRU-62 [53], and ICRU-70 [54]) and critical normal tissues; peer review of target volumes and decisions is important.	Initial step of planning process
Treatment prescription accuracy	Radiation Oncologist, Medical Dosimetrist, Medical Physicist	Define dose fractionation techniques and dosimetric constraints	Before final plan checks
Treatment plan quality	Medical Dosimetrist, Medical 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	Medical Physicist	Verify accuracy and appropriateness of MU calculation.	After plan approval; before plan download to TMS
Patient-specific QA checks	Medical Physicist	Dosimetric (for example, IMRT) or geometric patient-specific checks of plan data, delivery accuracy, etc.	Typically, day before treatment starts
Preparation and download of electronic plan	Medical Physicist	Verify plan information has been prepared correctly and downloaded accurately from treatment planning into TMS.	Recommended at least 1 hour before treatment, as last minute difficulties are a potentially serious problem
Day 1 Treatment verification	Radiation Oncologist, Medical Physicist, Radiation Therapist	Specific Day 1 verification methods, including portal imaging, patient SSD measurements, etc.	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	Medical Physicist	Formal procedure for chart check, including dose tracking, prescription, plan parameters, etc.	At least every 5 fractions (standard fractionation), as often as daily for few fraction SBRT
Final check	Radiation Oncologist, Medical Physicist, Medical Dosimetrist	Verify accuracy and completeness of the record of the patient’s treatment course, including the physician’s summary	For each patient

trist, medical physicist) with anatomic knowledge and the ability to contour structures correctly, as well as to interpret DVHs and other plan evaluation metrics

- Appropriate use of patient positioning and immobilization devices (mask, alpha cradle, etc.) to allow reproducible patient positioning
- Planning system dose calculations accurately reproduce beam characteristics and include sophisticated heterogeneity corrections
- Physician must have appropriate knowledge of normal tissue tolerances in order to make good plan optimization choices
- If MR, PET or other imaging is used for planning, software and clinical knowledge, combined with experience with image dataset registration and information fusion, is essential.

Intensity Modulated Radiation Therapy: IMRT is a highly technological method that can be used to deliver highly conformal therapy. In addition to the requirements (above) for 3-D conformal therapy, IMRT also requires the following:

- The machine must be equipped with IMRT capability, including segmental MLC or dynamic MLC delivery of modulated beam intensity (compensators are also possible).
- The IMRT planning and delivery system must be carefully characterized and clinically commissioned, and techniques for routine patient-specific IMRT QA must be implemented, tested and characterized so that accuracy of individual patient IMRT plans is confirmed.

- The treatment delivery system must be used with computer-controlled delivery and verification of the IMRT plan for each treatment fraction.
- The radiation oncologist and planning team must have extensive knowledge of anatomy for structure delineation and normal tissue tolerance, as well as detailed experience creating optimized IMRT treatment plans.
- IMRT QA and QC program and devices are crucial, as well as direct oversight of the QA processes by the physics staff.

Image Guided Radiation Therapy: IGRT has become an important part of modern radiation oncology, and its utilization is growing each year. The ACR guideline on IGRT^[57] and the recent IGRT Safety White Paper^[30] summarizes all the recent safety and quality guidance on the use of IGRT processes in the clinic.

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy: SRS and SBRT are techniques that deliver high radiation doses in a small number of treatment fractions (typically 1-5). While single fraction SRS is typically confined to the brain and spine, clinical data on the use of few fraction SBRT to sites in the body has been growing. Both SRS and SBRT use multiple photon beams, carefully shaped to the target and delivered with high precision, often with high precision IGRT guidance (SBRT). Practice guidelines from the ACR and ASTRO^[5, 6, 58] have been published, and guidance on technical aspects of the treatment process have been described in AAPM reports including TG 101^[10]. The recent Safety White Paper on

Table 4.7. General Procedure Guidelines

Specialized Technique/Modality	Organization	Reference #
3-D External Beam and Conformal Radiation Therapy (EBRT, CRT)	ACR/ASTRO	[1]
Image Guided Radiation Therapy (IGRT)	ACR/ASTRO ASTRO	[2], [57] [30]
Intensity Modulated Radiation Therapy (IMRT)	ACR/ASTRO ASTRO	[3], [25] [37]
Stereotactic Radiosurgery (SRS)	ACR/ASTRO ASTRO	[5] [63]
Stereotactic Body Radiation Therapy (SBRT)	ACR/ASTRO ASTRO	[6], [58] [78]
Total Body Irradiation (TBI)	ACR/ASTRO	[7]
Partial Breast Irradiation (PBI)	ASTRO	[63]

SBRT summarizes much of the recent guidance on quality and safety for these techniques^[64]. For patients treated with curative intent SRS or SBRT, a qualified radiation oncologist and medical physicist should be present for the treatment.

Photon Total Body Irradiation: TBI is a treatment modality mainly to support stem cell graft-host success in the practice of bone marrow transplantation. The ACR and ASTRO have issued practice guidelines on this modality^[7] and the AAPM has issued quality assurance standards for oversight of safe treatment delivery^[75].

Intraoperative Radiation Therapy: IORT is most commonly given as a single boost dose of 10-20 Gy with electrons or HDR brachytherapy, combined with 45-54 Gy of fractionated EBRT in standard 1.8-2 Gy fractions, for patients treated with curative intent. Occasionally IORT is given as the only component of irradiation (primarily early breast cancer). In view of the large single fraction size, a qualified radiation oncologist and physicist should be present for the treatment.

4.2.3 Brachytherapy QA

The QA process for brachytherapy, similar to that of external beam, involves several components that must be carefully confirmed as part of the patient-specific QA management: treatment planning; treatment delivery systems; applicator commissioning; applicator periodic checks; imaging (i.e., CT-Simulation or plain film) checks; specification of the treatment intent; planning directive; treatment prescription by the physician; plan and chart preparation; plan evaluation; download toTMS; plan verification checks; plan modifications; and chart checks. Some aspects of quality assurance directed at preventing errors in treatment planning and delivery specific to brachytherapy are summarized in the following references:

- ACR: Technical Standard for the Performance of Brachytherapy Physics: Remotely Loaded HDR Source Res. 18^[4]. This document is a general description of HDR brachytherapy physics.
- ESTRO Booklet 8^[18] is a full-length book detailing quality procedures for brachytherapy, including HDR brachytherapy. While some of the procedures, such

as calibration of an HDR brachytherapy unit in air, are considered outdated because of the uncertainties involved, most of the material remains current.

- IAEA TECDOC – 1257^[29] is simply an overview for hospital administrators in developing countries.

4.2.3.1 Qualification of Brachytherapy Personnel

To administer brachytherapy, a qualified physician and medical physicist must be present for the initiation of treatment. Board certification or eligibility is required by the radiation oncologist and the medical physicist with other staff requiring registration for all cases. A specific “Focused Practice” certification in brachytherapy through the ABR is now available for brachytherapy practice, signaling the specialty’s recognition of the increased complexity of many procedures and the need for enhanced expertise for all but the most routine brachytherapy cases.

4.2.3.2 Brachytherapy Treatment Recommendations

The use of brachytherapy, particularly HDR brachytherapy, has increased significantly and adherence to recommended standards is important in the process of patient care. Trained personnel must be appropriately informed and work together to ensure accurate and safe treatment of a variety of well-defined procedures. Several organizations have generated guidelines and recommendations that review details of the processes required for proper patient care, including the American Brachytherapy Society (ABS), ASTRO, the Groupe Européen de Curiethérapie-European Society for Therapeutic Radiology and Oncology (GEC-ESTRO), the ACR and the AAPM. For patients treated with HDR brachytherapy, a qualified radiation oncologist and medical physicist must be present in the control room. **Table 4.8** (see page 45) outlines the various topics covered by these organizations with respect to specific clinical sites.

Table 4.8. General Brachytherapy Guidance for Specific Clinical Sites

Site	Issue	Organization	Online	Reference #
General Principles	General guidelines	ACR/ASTRO	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Radiation_Oncology.pdf	
	HDR	ACR/ASTRO	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/High_Dose_Rate_Brachy.pdf	[17]
		ASTRO	White Paper	[65]
	LDR	ACR/ASTRO	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Low_Dose_Rate_Brachytherapy.pdf	
Gynecology Cervical Cancer	General principles	ABS	http://www.americanbrachytherapy.org/guidelines/index.cfm	[66]
	Equivalent dose worksheets	ABS		
	HDR			
	LDR/PDR	ABS		[67], [41]
	MR-based contouring	ABS		[35], [43]
	Dose-volume parameter reporting	GEC-ESTRO		[24] [55]
	Postoperative cylinder	ABS		[39], [61]
	Vaginal cancer interstitial	ABS		[11]
Prostate	LDR	ACR/ASTRO	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Brachy_Prostate_Cancer.pdf	[60], [21]
	LDR	ABS		[42], [12], [40], [14]
	HDR	ABS		[68]
Breast		ASTRO		[62]
		GEC-ESTRO		[54]
		ABS		[8], [9]
Esophageal	Endoluminal	ABS		[22]
Microspheres		ACR	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/RMBD.pdf	[82], [83]
Vascular		ABS		[44]
		GEC-ESTRO		[56]
		ACR	http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Coronary_Vascular_Brachy.pdf	
Sarcoma		ABS		[45]
Head and Neck		ABS		[46]
Uveal Melanoma		ABS		[47]

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APPENDIX I:

Acronym Glossary

A

AAMD = American Association of Medical Dosimetrists
AANP = American Academy of Nurse Practitioners
AAPA = American Association of Physician Assistants
AAPM = American Association of Physicists in Medicine
ABMP = American Board of Medical Physics
ABMS = American Board of Medical Specialties
ABR = American Board of Radiology
ABS = American Brachytherapy Society
ACR = American College of Radiology
ACRO = American College of Radiation Oncology
AFROC = Association of Freestanding Radiation Oncology Centers
ANCC = American Nurses Credentialing Center
ARRT = American Registry of Radiologic Technologists
ASRT = American Society of Radiologic Technologists
ASTRO = American Society for Radiation Oncology

B

C

CBCT = cone beam computed tomography
CCPM = Canadian College of Physicists in Medicine
CME = continuing medical education
CT = computed tomography

D

DRR = digitally restored radiographs
DVH = dose-volume histogram

E

EBRT = external beam radiation therapy
EMR = electronic medical record
EORTC = European Organisation for Research and Treatment Center
EPID = electronic portal imaging device

F

FDA = Food and Drug Administration
FFF = flattening filter-free
FMEA = failure mode and effect analysis
FTE = full-time employee

G

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

H

H/P = history/physical
HDR = high-dose-rate

I

IGRT = image guided radiation therapy
IHE-RO = Integrating the Healthcare Enterprise-Radiation Oncology
IMPT = intensity modulated proton therapy
IMRT = intensity modulated radiation therapy
IORT = intraoperative radiation therapy
IVBT = intravascular brachytherapy

J

K

L

LDR = low-dose-rate

M

MDCB = Medical Dosimetrist Certification Board
MLC = multileaf collimator
MOC = maintenance of certification
MR = magnetic resonance (imaging)
MU = monitor unity

N

NACNS = National Association of Clinical Nursing Specialists
NCCPA = National Commission for the Certification of
Physician Assistants
NP = nurse practitioner
NTCP = normal tissue complication probability

O

OAR = organs at risk

P

PA = physician assistant
PAAROT = Performance Assessment for the Advancement of
Radiation Oncology Treatment
PACS = picture archiving and communication system
PBI = partial breast irradiation
PDR = pulsed-dose-rate
PET = positron emission tomography
PQI = practice quality improvement
PQRS = physician quality reporting systems
PTV = planning target volume

Q

QA = quality assurance
QC = quality control
QI = quality improvement
QM = quality management
QUANTEC = Quantitative Analysis of Normal Tissue Effects in
Clinic

R

RPC = radiological physics center
RT = radiation therapy
RTOG = Radiation Therapy Oncology Group

S

SAM = self-assessment module
SBRT = stereotactic body radiation therapy
SCAROP = Society of Chairmen of Academic Radiation
Oncology Programs
SOP = standard operating procedure
SPECT = Single Photon Emission Computed Tomography
SROA = Society for Radiation Oncology Administrators
SRS = stereotactic radiosurgery

T

TBI = total body irradiation
TG = task group
TJC = The Joint Commission
TMS = treatment management system
TPS = treatment planning system

U

V

VMAT = volumetric modulated arc therapy

W

X

Y

Z

0-9

2-D CRT = two-dimensional conformal radiation therapy
3-D CRT = three-dimensional conformal radiation therapy
4-D = four-dimensional



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American College of Radiation Oncology (ACRO)
American Radium Society (ARS)
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TARGETING CANCER CARE